

# CERTIFICATE

## *EC Declaration of Conformity*

Manufacturer:  
CITEST DIAGNOSTICS INC.  
170-422 Richards Street, Vancouver BC V6B 2Z4 Canada  
Single Registration Number: CA-MF-000022516

European Representative:  
VIDAQUICK BIOTECH S.L.  
No.132, Rosello Street, Barcelona, Barcelona Province, 08036, Spain  
Single Registration Number: ES-AR-000048138

Herewith declare that the products described below:

**Product name: Refer to Attachment I**  
**Cat No: Refer to Attachment I**  
**Classification: Self-declaration of IVDD 98/79/EC**  
**Conformity Assessment Route: IVDD 98/79/EC Annex III (excluding section 6)**

meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

General applicable directives:

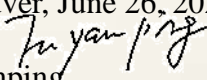
DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices

Standard Applied: EN ISO 13485:2016, EN ISO 14971:2019, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, ISO 20916:2019, EN ISO 23640:2015, EN 13641:2002, EN ISO 15223-1:2021, EN 62366-1:2015

These products are covered by the declaration of conformity signed on 25/05/2022. This has had to be amended only as far as change of EC REP is concerned.

As the Manufacturer we declare that:

- The products continue to comply with the provisions of Directive 98/79/EC;
- There are no significant changes in the design or intended purpose;
- The products do not present a risk to the health or safety of the patient, users or other persons or to other aspects of public health protection.

Place, Date: Vancouver, June 26, 2025  
Signature:   
Name: Fu Yanping  
Title: General Manager

CITEST DIAGNOSTICS INC



**Attachment I Product List- Drug of Abuse**

| <b>Cat.no.</b>     | <b>Product Name</b>                                                         | <b>Certificate No.</b> | <b>Classification under IVDD</b> |
|--------------------|-----------------------------------------------------------------------------|------------------------|----------------------------------|
| DABP-102/114/101   | AB-PINACA (ABP) Rapid Test (Urine)                                          | RPS/1188/2025          | Self-declaration Others          |
| DAC-102/114/101    | Acetaminophen (ACE) Rapid Test (Urine)                                      | RPS/1188/2025          | Self-declaration Others          |
| DACL-102/114/101   | 7-Aminoclonazepam (7-ACL) Rapid Test (Urine)                                | RPS/1188/2025          | Self-declaration Others          |
| DAL-102/114/101    | Alcohol (ALC) Rapid Test (Urine)                                            | RPS/1188/2025          | Self-declaration Others          |
| DAL-801/802/803    | Alcohol Rapid Test (Oral Fluid)                                             | RPS/1190/2025          | Self-declaration Others          |
| DAL-902            | Breath Alcohol Test With/Without blow bag (Breath)                          | RPS/1190/2025          | Self-declaration Others          |
| DALP-102/114/101   | Alprazolam(ALP) Rapid Test (Urine)                                          | RPS/1190/2025          | Self-declaration Others          |
| DAM-102/114/101    | Amphetamine (AMP) Rapid Test (Urine)                                        | RPS/1188/2025          | Self-declaration Others          |
| DAM-402            | AMP Rapid Test (WB/S/P)                                                     | RPS/1215/2025          | Self-declaration Others          |
| DAM-802/803        | Amphetamine (AMP) Rapid Test (Oral Fluid)                                   | RPS/1215/2025          | Self-declaration Others          |
| DAM-H902           | Amphetamine (AMP) Rapid Test (Hair)                                         | RPS/1222/2025          | Self-declaration Others          |
| DAP-102/114/101    | alpha-Pyrrolidinovalerophenone (alpha-PVP) Rapid Test (Urine)               | RPS/1189/2025          | Self-declaration Others          |
| DAP-802/803        | $\alpha$ -Pyrrolidinovalerophenone ( $\alpha$ -PVP) Rapid Test (Oral Fluid) | RPS/1215/2025          | Self-declaration Others          |
| DAT-111            | Adulteration Test(Urine)                                                    | RPS/1190/2025          | Self-declaration Others          |
| DBA-102/114/101    | Barbiturate (BAR) Rapid Test (Urine)                                        | RPS/1189/2025          | Self-declaration Others          |
| DBA-402            | BAR Rapid Test (WB/S/P)                                                     | RPS/1215/2025          | Self-declaration Others          |
| DBA-802/803        | Barbiturates (BAR) Rapid Test (Oral Fluid)                                  | RPS/1215/2025          | Self-declaration Others          |
| DBA-H902           | Barbiturate (BAR) Rapid Test (Hair)                                         | RPS/1222/2025          | Self-declaration Others          |
| DBU-102/114/101    | Buprenorphine (BUP) Rapid Test (Urine)                                      | RPS/1189/2025          | Self-declaration Others          |
| DBU-402            | BUP Rapid Test (WB/S/P)                                                     | RPS/1215/2025          | Self-declaration Others          |
| DBU-802/803        | Buprenorphine (BUP) Rapid Test (Oral Fluid)                                 | RPS/1215/2025          | Self-declaration Others          |
| DBU-H902           | Buprenorphine (BUP) Rapid Test (Hair)                                       | RPS/1222/2025          | Self-declaration Others          |
| DBZ-102/114/101    | Benzodiazepines (BZO) Rapid Test (Urine)                                    | RPS/1189/2025          | Self-declaration Others          |
| DBZ-402            | BZO Rapid Test (WB/S/P)                                                     | RPS/1215/2025          | Self-declaration Others          |
| DBZ-802/803        | Benzodiazepines (BZO) Rapid Test (Oral Fluid)                               | RPS/1215/2025          | Self-declaration Others          |
| DBZ-H902           | Benzodiazepines (BZO) Rapid Test (Hair)                                     | RPS/1222/2025          | Self-declaration Others          |
| DCA-102/114/101    | Cathine (CAT) Rapid Test (Urine)                                            | RPS/1189/2025          | Self-declaration Others          |
| DCAF-102/114/101   | Caffeine (CAF) Rapid Test (Urine)                                           | RPS/1189/2025          | Self-declaration Others          |
| DCAR-102/114/101   | Carisoprodol(CAR) Rapid Test (Urine)                                        | RPS/1189/2025          | Self-declaration Others          |
| DCCHOCI            | Cholesterol Test Strip (3 in 1 test)                                        | RPS/1174/2025          | Self-declaration Others          |
| DCFY-102/114/101   | Carfentanyl(CFYL) Rapid Test (Urine)                                        | RPS/1189/2025          | Self-declaration Others          |
| DCFY-802/803       | Carfentanyl(CFYL) Rapid Test (Oral Fluid)                                   | RPS/1215/2025          | Self-declaration Others          |
| DCIT-CT102/114/101 | Citalopram (CIT) Rapid Test (Urine)                                         | RPS/1222/2025          | Self-declaration Others          |
| DCL-102/114/101    | Clonazepam (CLO) Rapid Test (Urine)                                         | RPS/1189/2025          | Self-declaration Others          |
| DCNB-102/114/101   | Cannabinol (CNB) Rapid Test (Urine)                                         | RPS/1189/2025          | Self-declaration Others          |
| DCO-102/114/101    | COCAINE (COC) Rapid Test (Urine)                                            | RPS/1189/2025          | Self-declaration Others          |
| DCO-402            | COC Rapid Test (WB/S/P)                                                     | RPS/1215/2025          | Self-declaration Others          |
| DCO-802/803        | COCAINE (COC) Rapid Test (Oral Fluid)                                       | RPS/1215/2025          | Self-declaration Others          |
| DCO-H902           | Cocaine (COC) Rapid Test(Hair)                                              | RPS/1220/2025          | Self-declaration Others          |
| DCT-102/114/101    | Cotinine (COT) Rapid Test (Urine)                                           | RPS/1189/2025          | Self-declaration Others          |
| DCT-402            | COT Rapid Test (WB/S/P)                                                     | RPS/1215/2025          | Self-declaration Others          |
| DCT-802/803        | Cotinine (COT) Rapid Test (Oral Fluid)                                      | RPS/1215/2025          | Self-declaration Others          |
| DCT-H902           | Cotinine (COT) Rapid Test (Hair)                                            | RPS/1220/2025          | Self-declaration Others          |
| DDI-102/114/101    | Diazepam (DIA) Rapid Test (Urine)                                           | RPS/1189/2025          | Self-declaration Others          |

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|----------------------|-------------------------------------------------------------------|---------------|-------------------------|
| DED-102/114/101      | Ethylenediamine-dimethylphosphinic acid (EDDP) Rapid Test (Urine) | RPS/1189/2025 | Self-declaration Others |
| DED-402              | EDDP Rapid Test (WB/S/P)                                          | RPS/1215/2025 | Self-declaration Others |
| DET-102/114/101      | Ethyl Glucuronide (ETG) Rapid Test (Urine)                        | RPS/1189/2025 | Self-declaration Others |
| DET-402              | ETG Rapid Test (WB/S/P)                                           | RPS/1220/2025 | Self-declaration Others |
| DETO-CT102/114/101   | Etomidate (ETO) Rapid Test (Urine)                                | RPS/1159/2025 | Self-declaration Others |
| DFKE-CT102/114/101   | Fluoketamine (FKET) Rapid Test (Urine)                            | RPS/1222/2025 | Self-declaration Others |
| DFLX-102/114/101     | Fluoxetine (FLX) Rapid Test (Urine)                               | RPS/1189/2025 | Self-declaration Others |
| DFY-102/114/101      | Fentanyl (FYL) Rapid Test (Urine)                                 | RPS/1189/2025 | Self-declaration Others |
| DFY-402              | FYL Rapid Test (WB/S/P)                                           | RPS/1220/2025 | Self-declaration Others |
| DFY-802/803          | Fentanyl (FYL) Rapid Test (Oral Fluid)                            | RPS/1215/2025 | Self-declaration Others |
| DGAB-102/114/101     | Gabapentin(GAB) Rapid Test (Urine)                                | RPS/1189/2025 | Self-declaration Others |
| DGHB-102/CT114/CT101 | gamma-Hydroxybutyric acid (GHB) Rapid Test (Urine)                | RPS/1189/2025 | Self-declaration Others |
| DGHB-CT114/101       | γ-Hydroxybutyric acid (GHB) Rapid Test                            | RPS/1166/2025 | Self-declaration Others |
| DKE-102/114/101      | Ketamine (KET)Rapid Test (Urine)                                  | RPS/1189/2025 | Self-declaration Others |
| DKE-402              | KET Rapid Test (WB/S/P)                                           | RPS/1220/2025 | Self-declaration Others |
| DKE-802/803          | Ketamine(KET) Rapid Test (Oral Fluid)                             | RPS/1215/2025 | Self-declaration Others |
| DKE-H902             | Ketamine (KET) Rapid Test (Hair)                                  | RPS/1222/2025 | Self-declaration Others |
| DKRA-102/114/101     | Kratom(KRA) Rapid Test (Urine)                                    | RPS/1189/2025 | Self-declaration Others |
| DLS-102/114/101      | Lysergic Acid Diethylamide (LSD) Rapid Test (Urine)               | RPS/1190/2025 | Self-declaration Others |
| DLS-402              | LSD Rapid Test (WB/S/P)                                           | RPS/1220/2025 | Self-declaration Others |
| DMA-102/114/101      | 6-Monoacetylmorphine (6-MAM) Rapid Test (Urine)                   | RPS/1189/2025 | Self-declaration Others |
| DMA-802/803          | 6-Monoacetylmorphine (6-MAM) Rapid Test (Oral Fluid)              | RPS/1215/2025 | Self-declaration Others |
| DMA-H902             | 6-Monoacetylmorphine (6-MAM) Rapid Test (Hair)                    | RPS/1222/2025 | Self-declaration Others |
| DMCA-102/114/101     | Methcathinone(MCAT) Rapid Test (Urine)                            | RPS/1189/2025 | Self-declaration Others |
| DMD-102/114/101      | Ecstasy (MDMA) Rapid Test (Urine)                                 | RPS/1189/2025 | Self-declaration Others |
| DMD-402              | MDMA Rapid Test (WB/S/P)                                          | RPS/1220/2025 | Self-declaration Others |
| DMD-802/803          | Ecstasy (MDMA) Rapid Test (Oral Fluid)                            | RPS/1215/2025 | Self-declaration Others |
| DMDA-102/114/101     | Tenamfetamine (MDA) Rapid Test (Urine)                            | RPS/1189/2025 | Self-declaration Others |
| DMDA-402             | MDA Rapid Test (WB/S/P)                                           | RPS/1220/2025 | Self-declaration Others |
| DMD-H902             | Ecstasy (MDMA) Rapid Test (Hair)                                  | RPS/1222/2025 | Self-declaration Others |
| DMDP-102/114/101     | Methylenedioxypropylvalerone (MDPV) Rapid Test (Urine)            | RPS/1189/2025 | Self-declaration Others |
| DMDP-402             | MDPV Rapid Test (WB/S/P)                                          | RPS/1220/2025 | Self-declaration Others |
| DMDP-802/803         | Methylenedioxypropylvalerone (MDPV) Rapid Test (Oral Fluid)       | RPS/1215/2025 | Self-declaration Others |
| DME-102/114/101      | Methamphetamine (MET) Rapid Test (Urine)                          | RPS/1189/2025 | Self-declaration Others |
| DME-402              | MET Rapid Test (WB/S/P)                                           | RPS/1220/2025 | Self-declaration Others |
| DME-802/803          | Methamphetamine (MET) Rapid Test (Oral Fluid)                     | RPS/1215/2025 | Self-declaration Others |
| DME-H902             | Methamphetamine (MET) Rapid Test (Hair)                           | RPS/1220/2025 | Self-declaration Others |
| DMEP-102/114/101     | Mephedrone HCl (MEP) Rapid Test (Urine)                           | RPS/1189/2025 | Self-declaration Others |
| DMES-102/114/101     | Mescaline (MES) Rapid Test (Urine)                                | RPS/1190/2025 | Self-declaration Others |
| DMO-102/114/101      | Morphine (MOP) Rapid Test (Urine)                                 | RPS/1190/2025 | Self-declaration Others |
| DMO-402              | MOP Rapid Test (WB/S/P)                                           | RPS/1220/2025 | Self-declaration Others |
| DMO-H902             | Morphine (MOP) Rapid Test (Hair)                                  | RPS/1220/2025 | Self-declaration Others |
| DMP-102/114/101      | Methylphenidate(MPD) Rapid Test (Urine)                           | RPS/1189/2025 | Self-declaration Others |
| DMPR-102/114/101     | Meperidine (MPRD) Rapid Test (Urine)                              | RPS/1189/2025 | Self-declaration Others |
| DMQ-102/114/101      | Methaqualone (MQL) Rapid Test (Urine)                             | RPS/1190/2025 | Self-declaration Others |
| DMT-102/114/101      | Methodone (MTD) Rapid Test (Urine)                                | RPS/1190/2025 | Self-declaration Others |

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|----------------------------------|-------------------------------------------------------------------|---------------|-------------------------|
| DMT-402                          | MTD Rapid Test (WB/S/P)                                           | RPS/1220/2025 | Self-declaration Others |
| DMT-802/803                      | Methadone (MTD) Rapid Test (Oral Fluid)                           | RPS/1215/2025 | Self-declaration Others |
| DMT-CTH902                       | MTD Rapid Test Cassette (Hair)                                    | RPS/1584/2025 | Self-declaration Others |
| DMTZ-CT102/114/101               | Desmethyilmirtazapine(MTZ) Rapid Test (Urine)                     | RPS/1223/2025 | Self-declaration Others |
| DNND-CT102/114/101               | N,N-Dimethyltryptamine(NND) Rapid Test (Urine)                    | RPS/1223/2025 | Self-declaration Others |
| DNTZ-CT101/CT111/<br>CT102/CT114 | Nitazene (NTZ) Rapid Test(Urine)                                  | RPS/1780/2025 | Self-declaration Others |
| DOA-125~1175/<br>DUA-125-1175    | Multi-Drug X Drugs Rapid Test with/Without<br>Adulteration(Urine) | RPS/1190/2025 | Self-declaration Others |
| DOA-124~1204/<br>DUA-124~1204    |                                                                   |               |                         |
| DOA-127~1227/<br>DUA-127~1227    |                                                                   |               |                         |
| DOA-425~4175                     | Multi-drug Rapid Test (WB/S/P)                                    | RPS/1220/2025 | Self-declaration Others |
| DOA-H925~H9135                   | Multi-drug Rapid Test Cassette (Hair)                             | RPS/1220/2025 | Self-declaration Others |
| DOP-102/114/101                  | Opiates (OPI) Rapid Test (Urine)                                  | RPS/1190/2025 | Self-declaration Others |
| DOP-802/803                      | Opiates (OPI) Rapid Test (Oral Fluid)                             | RPS/1215/2025 | Self-declaration Others |
| DOX-102/114/101                  | Oxycodone (OXY) Rapid Test (Urine)                                | RPS/1190/2025 | Self-declaration Others |
| DOX-402                          | OXY Rapid Test (WB/S/P)                                           | RPS/1220/2025 | Self-declaration Others |
| DOX-802/803                      | Oxycodone (OXY) Rapid Test (Oral Fluid)                           | RPS/1215/2025 | Self-declaration Others |
| DOX-H902                         | Oxycodone (OXY) Rapid Test (Hair)                                 | RPS/1222/2025 | Self-declaration Others |
| DOZP-102/114/101                 | Olanzapine (OZP) Rapid Test Cassette (Urine)                      | RPS/1190/2025 | Self-declaration Others |
| DPAP-102/114/101                 | Papaverine (PAP) Rapid Test (Urine)                               | RPS/1190/2025 | Self-declaration Others |
| DPC-102/114/101                  | Phencyclidine (PCP) Rapid Test (Urine)                            | RPS/1190/2025 | Self-declaration Others |
| DPC-402                          | PCP Rapid Test (WB/S/P)                                           | RPS/1220/2025 | Self-declaration Others |
| DPC-802/803                      | Phencyclidine (PCP) Rapid Test (Oral Fluid)                       | RPS/1215/2025 | Self-declaration Others |
| DPC-H902                         | Phencyclidine (PCP) Rapid Test (Hair)                             | RPS/1222/2025 | Self-declaration Others |
| DPG-102/114/101                  | Pregabalin (PGB) Rapid Test (Urine)                               | RPS/1190/2025 | Self-declaration Others |
| DPG-CT802/803                    | Pregabalin (PGB) Rapid Test (Oral Fluid)                          | RPS/1159/2025 | Self-declaration Others |
| DPP-102/114/101                  | Propoxyphene (PPX) Rapid Test (Urine)                             | RPS/1190/2025 | Self-declaration Others |
| DPP-402                          | PPX Rapid Test (WB/S/P)                                           | RPS/1220/2025 | Self-declaration Others |
| DPRT-CT101/CT111/<br>CT102/CT114 | Paroxetine (PRT) Rapid Test (Urine)                               | RPS/1780/2025 | Self-declaration Others |
| DPY-CT102/114/101                | Psilocybin (PY) Rapid Test (Urine)                                | RPS/1159/2025 | Self-declaration Others |
| DQTP-102/114/101                 | Quetiapine(QTP) Rapid Test (Urine)                                | RPS/1190/2025 | Self-declaration Others |
| DRPD-CT102/114/101               | Risperidone(RPD) Rapid Test (Urine)                               | RPS/1190/2025 | Self-declaration Others |
| DSC-CT102/114/101                | Scopolamine (SCOP) Rapid Test (Urine)                             | RPS/1223/2025 | Self-declaration Others |
| DSD-823~8123                     | Multi-Drug Rapid Test(Oral Fluid)                                 | RPS/1215/2025 | Self-declaration Others |
| DSD-825~895                      |                                                                   |               |                         |
| DSD-827~8167                     |                                                                   |               |                         |
| DSM-102/114/101                  | Synthetic Marijuana (K2) Rapid Test (Urine)                       | RPS/1190/2025 | Self-declaration Others |
| DSM-402                          | K2 Rapid Test (WB/S/P)                                            | RPS/1220/2025 | Self-declaration Others |
| DSM-802/803                      | Synthetic Marijuana (K2) Rapid Test (Oral Fluid)                  | RPS/1215/2025 | Self-declaration Others |
| DTAP-CT102/114/101               | Tapentadol (TAP) Rapid Test (Urine)                               | RPS/1223/2025 | Self-declaration Others |
| DTC-102/114/101                  | Tricyclic Antidepressants (TCA) Rapid Test (Urine)                | RPS/1190/2025 | Self-declaration Others |
| DTC-402                          | TCA Rapid Test (WB/S/P)                                           | RPS/1220/2025 | Self-declaration Others |
| DTH-102/114/101                  | Marijuana (THC) Rapid Test (Urine)                                | RPS/1190/2025 | Self-declaration Others |
| DTH-402                          | THC Rapid Test (WB/S/P)                                           | RPS/1220/2025 | Self-declaration Others |
| DTH-P802/803                     | Marijuana (THC) Rapid Test (Oral Fluid)                           | RPS/1215/2025 | Self-declaration Others |
| DTLD-102/114/101                 | Tilidine (TLD) Rapid Test (Urine)                                 | RPS/1190/2025 | Self-declaration Others |
| DTH-CTH902                       | THC Rapid Test Cassette (Hair)                                    | RPS/1584/2025 | Self-declaration Others |
| DTH-CTP802H                      | THC Rapid Test Cassette (Oral Fluid)                              | RPS/1780/2025 | Self-declaration Others |

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| DTM-102/114/101               | Tramadol (TML) Rapid Test (Urine)                       | RPS/1190/2025 | Self-declaration Others |
| DTM-402                       | TML Rapid Test (WB/S/P)                                 | RPS/1220/2025 | Self-declaration Others |
| DTM-802/803                   | Tramadol(TML) Rapid Test (Oral Fluid)                   | RPS/1215/2025 | Self-declaration Others |
| DTRO-102/114/101              | Tropicamide(TRO)Rapid Test (Urine)                      | RPS/1190/2025 | Self-declaration Others |
| DTZD-102/114/101              | Trazodone(TZD) Rapid Test (Urine)                       | RPS/1190/2025 | Self-declaration Others |
| DUR-102/114/101               | UR-144 Rapid Test (Urine)                               | RPS/1190/2025 | Self-declaration Others |
| DXYL-CT102/114/101            | Xylazine(XYL) Rapid Test (Urine)                        | RPS/1159/2025 | Self-declaration Others |
| DZAL-102/114/101              | Zaleplon(ZAL) Rapid Test (Urine)                        | RPS/1190/2025 | Self-declaration Others |
| DZO-102/114/101               | Zolpidem(ZOL) Rapid Test (Urine)                        | RPS/1190/2025 | Self-declaration Others |
| DZOP-102/114/101              | Zopiclone(ZOP) Rapid Test (Urine)                       | RPS/1190/2025 | Self-declaration Others |
| RTARPCI/RTARPACI<br>RTARPBCI  | Aripiprazole (ARP) Rapid Test (Urine)                   | RPS/2711/2025 | Self-declaration Others |
| RTDIPCI/RTDIPACI/<br>RTDIPBCI | Diphenoxylate (DIP) Rapid Test (Urine)                  | RPS/2711/2025 | Self-declaration Others |
| RTDXMCI/RTDXMA<br>CI/RTDXMBCI | Dextromethorphan (DXM) Rapid Test (Urine)               | RPS/2711/2025 | Self-declaration Others |
| RTNTZCI/RTNTZACI<br>/RTNTZBCI | Nitazene (NTZ) Rapid Test (Urine)                       | RPS/2711/2025 | Self-declaration Others |
| RTCODBCI                      | Codeine (COD) Rapid Test (Urine)                        | RPS/2880/2025 | Self-declaration Others |
| RTMAMGCI                      | 6-MAM Rapid Test Cassette (Whole<br>Blood/Serum/Plasma) | RPS/2880/2025 | Self-declaration Others |





# CERTIFICATE

This is to certify that the Quality management system for medical devices of the company

**CiTEST DIAGNOSTICS INC.**  
**170-422, RICHARDS ST, VANCOUVER, BC V6B 2Z4, CANADA**

has been found in compliance with requirements of the standard

**ISO 13485: 2016 /**  
**EN ISO 13485: 2016 + A11: 2021**



for the following scope:

**Design and Development, Production and Distribution of In Vitro Diagnostic Reagents, Control Material and Instruments for Clinical Chemistry, Immunochemistry (Immunology), Haemostasis, Infectious Diseases and Immunohaematology, including Professional Laboratory Use, Near Patient and Self Testing**

**Certificate no.:** QMS-13-001-2022/A  
**Initial certificate issue:** 12/04/2022

**Date of issue:** 07/04/2025  
**Valid from:** 12/04/2025

*On condition that the organisation will maintain an effective quality management system for medical devices, this certificate remains valid until **11/04/2028**.*

Ľubica Škrovanová  
Head of Certification Body



### Instruction Sheet for testing of any combination of the following drugs:

ACE/AMP/BAR/BZO/BUP/COC/THC/MTD/MET/MDMA/MOP/MQL/OPI/PCP/PPX/TCA/TML/KET/OXY/COT/EDDP/FYL/K2/6-MAM/MDA/ETG/CLO/LSD/MPD/ZOL/MEP/MDPV/DIA/ZOP/MCAT/7-ACL/CAF/CFYL/CAT/TRO/ALP/PGB/ZAL/MPR/MPRD/CNB/GAB/TZD/CAR/ABP(K3)/QTP/FLX/UR-144(K4)/KRA/TLD/ $\alpha$ -PVP/MES/PAP/CIT/FKET/OZP/RPD/TAP/NND/SCOP/MTZ/HMO/ALC

### Including Specimen Validity Tests (S.V.T): for:

Oxidants/PCC, Specific Gravity, pH, Nitrite, Glutaraldehyde, Creatinine and Bleach

A rapid test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in human urine. For healthcare professionals including professionals at point of care sites. Immunoassay for *in vitro* diagnostic use only.

### INTENDED USE

The Multi-Drug Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations:

| Test                                                     | Calibrator                                        | Cut-off (ng/mL)             |
|----------------------------------------------------------|---------------------------------------------------|-----------------------------|
| Acetaminophen (ACE)                                      | Acetaminophen                                     | 5,000                       |
| Amphetamine (AMP)                                        | d-Amphetamine                                     | 1,000/500/300               |
| Barbiturates (BAR)                                       | Secobarbital                                      | 300/200                     |
| Benzodiazepines (BZO)                                    | Oxazepam                                          | 500/300/200/100             |
| Buprenorphine (BUP)                                      | Buprenorphine                                     | 10/5                        |
| Cocaine (COC)                                            | Benzoylcegonine                                   | 1,500/300/200/150/100       |
| Marijuana (THC)                                          | 11-nor- $\Delta^9$ -THC-9 COOH                    | 600/300/200/150/50/30/25/20 |
| Methadone (MTD)                                          | Methadone                                         | 300/200                     |
| Methamphetamine (MET)                                    | d-Methamphetamine                                 | 1,000/500/300/200           |
| Methylenedioxy-methamphetamine(MDMA)                     | d,l-Methylenedioxy-methamphetamine                | 1,000/500/300               |
| Morphine/Opiate (MOP/OPI)                                | Morphine                                          | 300/200/100                 |
| Methaqualone (MQL)                                       | Methaqualone                                      | 300                         |
| Meperidine (MPRD)                                        | Normeperidine                                     | 100                         |
| Opiate (OPI)                                             | Morphine                                          | 2,000/1,000                 |
| Phencyclidine (PCP)                                      | Phencyclidine                                     | 50/25                       |
| Propoxyphene (PPX)                                       | Propoxyphene                                      | 300                         |
| Tricyclic Antidepressants (TCA)                          | Nortriptyline                                     | 1,000/500/300               |
| Tramadol (TML)                                           | Cis-Tramadol                                      | 500/300/200/100             |
| Ketamine (KET)                                           | Ketamine                                          | 1,000/500/300/100           |
| Oxycodone (OXY)                                          | Oxycodone                                         | 300/100                     |
| Cotinine (COT)                                           | Cotinine                                          | 500/300/200/100/50/10       |
| 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP) | 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine | 300/100                     |
| Fentanyl (FYL)                                           | Norfentanyl                                       | 20/10                       |
| Fentanyl (FYL)                                           | Fentanyl                                          | 300/200/100                 |
| Synthetic Marijuana (K2)                                 | JWH-018, JWH-073                                  | 50/30/25                    |
| 6-Monoacetylmorphine (6-MAM)                             | 6-MAM                                             | 10                          |
| ( $\pm$ ) 3,4-Methylenedioxy-Amphetamine (MDA)           | ( $\pm$ ) 3,4-Methylenedioxy-Amphetamine          | 500                         |
| Ethyl- $\beta$ -D-Glucuronide (ETG)                      | Ethyl- $\beta$ -D-Glucuronide                     | 1,500/1,000/500/300         |
| Clonazepam (CLO)                                         | Clonazepam                                        | 400/150                     |
| Lysergic Acid Diethylamide (LSD)                         | Lysergic Acid Diethylamide                        | 50/20/10                    |
| Methylphenidate (MPD)                                    | Methylphenidate                                   | 300/150                     |
| Methylphenidate (MPD)                                    | Ritalin acid                                      | 1,000                       |
| Zolpidem (ZOL)                                           | Zolpidem                                          | 50                          |
| Mephedrone (MEP)                                         | Mephedrone                                        | 500/100                     |
| 3, 4-methylenedioxy-pyrovaleone (MDPV)                   | 3, 4-methylenedioxy-pyrovaleone                   | 1,000/500/300               |
| Diazepam (DIA)                                           | Diazepam                                          | 300/200                     |
| Zopiclone (ZOP)                                          | Zopiclone                                         | 300/50                      |
| Methcathinone (MCAT)                                     | S(-)-Methcathinone                                | 500                         |
| 7-Aminoclonazepam (7-ACL)                                | 7-Aminoclonazepam                                 | 300/200/100                 |
| Carfentanyl (CFYL)                                       | Carfentanyl                                       | 500/250                     |
| Cannabinol (CNB)                                         | Cannabinol                                        | 500                         |
| Caffeine (CAF)                                           | Caffeine                                          | 1,000                       |
| Cathine (CAT)                                            | (+)-Norpseudoephedrine                            | 150                         |
| Tropicamide (TRO)                                        | Tropicamide                                       | 350                         |
| Alprazolam (ALP)                                         | Alprazolam                                        | 100                         |
| Pregabalin (PGB)                                         | Pregabalin                                        | 50,000/500                  |
| Gabapentin (GAB)                                         | Gabapentin                                        | 2,000                       |
| Zaleplon (ZAL)                                           | Zaleplon                                          | 100                         |
| Carisoprodol (CAR)                                       | Carisoprodol                                      | 2,000/1,000/500             |
| AB-PINACA (ABP/K3)                                       | AB-PINACA                                         | 10                          |
| Quetiapine (QTP)                                         | Quetiapine                                        | 1,000                       |
| Fluoxetine (FLX)                                         | Fluoxetine                                        | 500                         |
| UR-144/K4                                                | UR-144 5-Pentanoic acid                           | 25                          |
| Kratom (KRA)                                             | Mitragynine                                       | 300                         |
| Tilidine (TLD)                                           | Nortilidine                                       | 50                          |
| Trazodone (TZD)                                          | Trazodone                                         | 200                         |
| Alpha-Pyrrolidinovalerophenone ( $\alpha$ -PVP)          | Alpha-Pyrrolidinovalerophenone                    | 2,000/1,000/500/300         |
| Mescaline (MES)                                          | Mescaline                                         | 300/100                     |
| Papaverine (PAP)                                         | Papaverine                                        | 500                         |
| Citalopram (CIT)                                         | Citalopram                                        | 500                         |
| Fluoketamine (FKET)                                      | Fluoketamine                                      | 1,000                       |
| Olanzapine (OZP)                                         | Olanzapine                                        | 1,000                       |
| Risperidone (RPD)                                        | Risperidone                                       | 150                         |
| Tapentadol (TAP)                                         | Tapentadol                                        | 1,000                       |
| N,N-Dimethyltryptamine (NND)                             | N,N-Dimethyltryptamine                            | 1,000                       |
| Scopolamine (SCOP)                                       | Scopolamine                                       | 500                         |

|                     |                      |             |
|---------------------|----------------------|-------------|
| Mirtazapine (MTZ)   | Desmethylmirtazapine | 500         |
| Hydromorphone (HMO) | Hydromorphone        | 500/300/250 |

| Test         | Calibrator | Cut-off |
|--------------|------------|---------|
| Alcohol(ALC) | Alcohol    | 0.02%   |

Configurations of the Multi-Drug Rapid Test Cassette come with any combination of the above listed drug analytes with or without S.V.T. This assay provides only a preliminary test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

### SUMMARY OF ADULTERATION

Adulteration is the tampering of a urine specimen with the intention of altering the test results. The use of adulterants can cause false negative results in drug tests by either interfering with the screening test and/or destroying the drugs present in the urine. Dilution may also be employed in an attempt to produce false negative drug test results.

One of the best ways to test for adulteration or dilution is to determine certain urinary characteristics such as pH, specific gravity and creatinine and to detect the presence of oxidants/PCC, nitrites or glutaraldehyde in urine.

### PRINCIPLE (FOR DOA TESTS EXCLUDING ALCOHOL)

During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test region of the specific drug dipstick. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test region.

A drug-positive urine specimen will not generate a colored line in the specific test region of the dipstick because of drug competition, while a drug-negative urine specimen will generate a line in the test region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

### PRINCIPLE OF ADULTERATION

**Oxidants/PCC (Pyridiniumchlorochromate)** tests for the presence of oxidizing agents such as bleach and hydrogen peroxide. Pyridiniumchlorochromate (sold under the brand name Urine Luck) is a commonly used adulterant.<sup>2</sup> Normal human urine should not contain oxidants of PCC.

**Specific gravity** tests for sample dilution. The normal range is from 1.003 to 1.030. Values outside this range may be the result of specimen dilution or adulteration.

**pH** tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in the range of 4.0 to 9.0. Values outside of this range may indicate the sample has been altered.

**Nitrite** tests for commonly used commercial adulterants such as Klear and Whizzies. They work by oxidizing the major cannabinoid metabolite THC-COOH.<sup>3</sup> Normal urine should contain no trace of nitrite. Positive results generally indicate the presence of an adulterant.

**Glutaraldehyde** tests for the presence of an aldehyde. Adulterants such as Urin Aid and Clear Choice contain glutaraldehyde which may cause false negative results by disrupting the enzyme used in some immunoassay tests.<sup>3</sup> Glutaraldehyde is not normally found in urine; therefore, detection of glutaraldehyde in a urine specimen is generally an indicator of adulteration.

**Creatinine** is a waste product of creatine; an amino-acid contained in muscle tissue and found in urine.<sup>1</sup> A person may attempt to foil a test by drinking excessive amounts of water or diuretics such as herbal teas to “flush” the system. Creatinine and specific gravity are two ways to check for dilution and flushing, which are the most common mechanisms used in an attempt to circumvent drug testing. Low Creatinine and specific gravity levels may indicate dilute urine. The absence of Creatinine (<5 mg/dL) is indicative of a specimen not consistent with human urine.

**Bleach** tests for the presence of bleach. Bleach refers to a number of chemicals which remove color, whiten or disinfect, often by oxidation. Bleaches are used as household chemicals to whiten clothes and remove stains and as disinfectants. Normal human urine should not contain bleach.

### PRINCIPLE (FOR ALCOHOL)

The urine Alcohol Rapid Test Cassette consists of a plastic strip with a reaction pad attached at the tip. On contact with alcohol, the reaction pad will change colors depending on the concentration of alcohol present. This is based on the high specificity of alcohol oxidase for ethyl alcohol in the presence of peroxidase and enzyme substrate such as TMB.

### REAGENTS(FOR DOA TESTS EXCLUDING ALCOHOL)

Each test line contains anti-drug mouse monoclonal antibody and corresponding drug-protein conjugates. The control line contains goat anti-rabbit IgG polyclonal antibodies and rabbit IgG.

### REAGENTS (FOR ALCOHOL)

Tetramethylbenzidine, Alcohol Oxidase, Peroxidase

### S.V.T REAGENTS

| Adulteration Pad | Reactive indicator | Buffers and non-reactive ingredients |
|------------------|--------------------|--------------------------------------|
| Creatinine       | 0.04%              | 99.96%                               |
| Nitrite          | 0.07%              | 99.93%                               |
| Bleach           | 0.39%              | 99.61%                               |
| Glutaraldehyde   | 0.02%              | 99.98%                               |
| pH               | 0.06%              | 99.94%                               |
| Specific Gravity | 0.25%              | 99.75%                               |
| Oxidants / PCC   | 0.36%              | 99.64%                               |

### PRECAUTIONS

- For healthcare professionals including professionals at point of care sites.
- Immunoassay for *in vitro* diagnostic use only. The Test should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test should be discarded according to local regulations.

### STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30 °C. The test is stable through the expiration date printed on the sealed pouch. The Test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

### SPECIMEN COLLECTION AND PREPARATION

#### Urine Assay

The urine specimen should be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

#### Specimen Storage

Urine specimens may be stored at 2-8 °C for up to 48 hours prior to testing. For prolonged storage, specimens

may be frozen and stored below -20 °C. Frozen specimens should be thawed and mixed well before testing. When testing cards with S.V.T. or Alcohol storage of urine specimens should not exceed 2 hours at room temperature or 4 hours refrigerated prior to testing.

### MATERIALS

#### Materials Provided

- Test Cassettes
- Droppers
- Package Insert
- Adulteration Color Chart (when applicable)

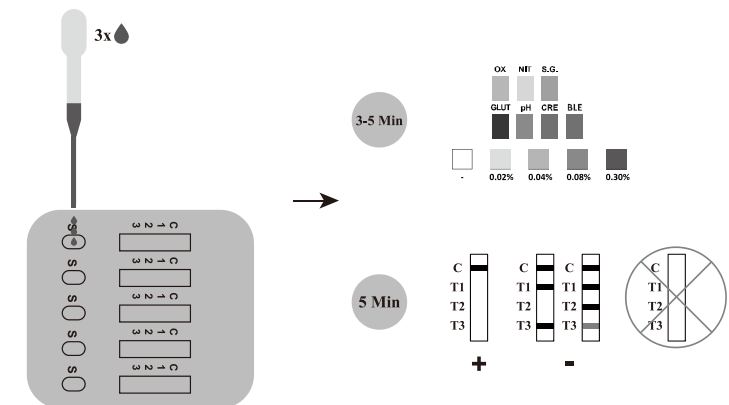
#### Materials Required But Not Provided

- Timer

### DIRECTIONS FOR USE

#### Allow the test, urine specimen and/or controls to reach room temperature (15-30 °C) prior to testing.

- Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within one hour.
- Place the test cassette on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine to the specimen well (S) of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
- Read the adulteration strips and alcohol strip between **3-5 minutes** according to color chart provided separately/on foil pouch. Refer to your Drug Free Policy for guidelines on adulterated specimens. We recommend not to interpret the drug test results and either retest the urine or collect another specimen in case of any positive result for any adulteration test.
- The drug strip result should be read at **5 minutes**. Do not interpret the result after 10 minutes.



### INTERPRETATION OF RESULTS

(Please refer to the illustration above)

**NEGATIVE:** \* A colored line appears in the control region (C) and colored line appears in the test region (T). This negative result means that the concentrations in the urine sample are below the designated cut-off levels for a particular drug tested.

\*NOTE: The shade of the colored lines(s) in the test region (T) may vary. The result should be considered negative whenever there is even a faint line.

**POSITIVE:** A colored line appears in the control region (C) and no line appears in the test region (T). The positive result means that the drug concentration in the urine sample is greater than the designated cut-off for a specific drug.

**INVALID:** No line appears in the control region (C). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Read the directions again and repeat the test with a new test. If the result is still invalid, contact your manufacturer.

### INTERPRETATION OF RESULTS (S.V.T/ ADULTERATION)

(Please refer to the color chart)

Semi-Quantitative results are obtained by visually comparing the reacted color blocks on the strip to the printed color blocks on the color chart. No instrumentation is required.

### INTERPRETATION OF RESULTS (ALCOHOL STRIP)

**Negative:** Almost no color change by comparing with the background. The negative result indicates that the urine alcohol level is less than 0.02%.

**Positive:** A distinct color developed all over the pad. The positive result indicates that the urine alcohol concentration is 0.02% or higher.

**Invalid:** The test should be considered invalid if only the edge of the reactive pad turned color that might be ascribed to insufficient sampling. The subject should be re-tested. Besides, if the color pad has a blue color before applying urine sample, do not use the test.

### QUALITY CONTROL

A procedural control is included in the test. A line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

### LIMITATIONS

- The Multi-Drug Rapid Test Cassette provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas Chromatography /Mass Spectrometry (GC/MS) is the preferred confirmatory method.<sup>4,5</sup>
- There is a possibility that technical or procedural errors, as well as interfering substances in the urine specimen may cause erroneous results.
- Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
- A positive result does not indicate level or intoxication, administration route or concentration in urine.
- A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
- This test does not distinguish between drugs of abuse and certain medications.
- A positive test result may be obtained from certain foods or food supplements.

### S.V.T/ ADULTERATION LIMITATIONS

- The adulteration tests included with the product are meant to aid in the determination of abnormal specimens. While comprehensive, these tests are not meant to be an “all-inclusive” representation of possible adulterants.
- Oxidants/PCC:** Normal human urine should not contain oxidants or PCC. The presence of high levels of antioxidants in the specimen, such as ascorbic acid, may result in false negative results for the oxidants/PCC pad.

- Specific Gravity:** Elevated levels of protein in urine may cause abnormally high specific gravity values.
- Nitrite:** Nitrite is not a normal component of human urine. However, nitrite found in urine may indicate urinary tract infections or bacterial infections. Nitrite levels of >20 mg/dL may produce false positive glutaraldehyde results.
- Glutaraldehyde:** is not normally found in urine. However certain metabolic abnormalities such as ketoacidosis (fasting, uncontrolled diabetes or high protein diets) may interfere with the test results.
- Creatinine:** Normal Creatinine levels are between 20 and 350 mg/dL. Under rare conditions, certain kidney diseases may show dilute urine.
- Bleach:** Normal human urine should not contain bleach. The presence of high levels of bleach in the specimen may result in false negative results for the bleach pad.
- pH:** Normal PH levels are between 4.0 and 9.0.

### PERFORMANCE CHARACTERISTICS

#### Accuracy

#### % Agreement with GC/MS

|                    | ACE   | AMP   | AMP   | AMP   | BAR   | BAR   | BZO   | BZO   | BZO   | BZO   | BUP    |
|--------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|--------|
|                    | 5,000 | 1,000 | 500   | 300   | 300   | 200   | 500   | 300   | 200   | 100   | 10     |
| Positive Agreement | 93.5% | 98.1% | 99.1% | 99.1% | 96.1% | 95.3% | 98.2% | 98.4% | 99.2% | 99.2% | 99.1%  |
| Negative Agreement | 98.6% | 97.9% | 98.6% | 98.5% | 98.6% | 97.9% | 97.8% | 99.2% | 98.4% | 97.5% | >99.9% |
| Total Results      | 97.0% | 98.0% | 98.8% | 98.8% | 97.6% | 96.8% | 98.0% | 98.8% | 98.8% | 98.4% | 99.6%  |

|                    | BUP    | COC   | COC    | COC   | COC   | THC   | THC   | THC   | THC   | THC   | MTD   |
|--------------------|--------|-------|--------|-------|-------|-------|-------|-------|-------|-------|-------|
|                    | 5      | 300   | 200    | 150   | 100   | 300   | 150   | 50    | 25    | 20    | 300   |
| Positive Agreement | 99.1%  | 98.2% | >99.9% | 98.3% | 99.2% | 95.5% | 94.5% | 97.9% | 96.9% | 94.8% | 98.9% |
| Negative Agreement | >99.9% | 97.8% | >99.9% | 97.0% | 97.0% | 98.1% | 97.5% | 98.1% | 97.4% | 99.3% | 98.8% |
| Total Results      | 99.6%  | 98.0% | 100.0% | 97.6% | 98.0% | 97.2% | 96.4% | 98.0% | 97.2% | 97.6% | 98.8% |

|                    | MTD   | MET   | MET   | MET   | MDMA  | MDMA  | MDMA  | MOP/OPI | MOP/OPI | MQL   | OPI   |
|--------------------|-------|-------|-------|-------|-------|-------|-------|---------|---------|-------|-------|
|                    | 200   | 1,000 | 500   | 300   | 1,000 | 500   | 300   | 300     | 300     | 300   | 2,000 |
| Positive Agreement | 98.9% | 96.2% | 97.6% | 97.8% | 98.0% | 98.1% | 98.1% | 95.0%   | 97.0%   | 89.8% | 96.7% |
| Negative Agreement | 98.7% | 97.1% | 97.0% | 97.5% | 99.3% | 99.3% | 99.3% | 95.3%   | 96.6%   | 93.2% | 93.8% |
| Total Results      | 98.8% | 96.8% | 97.2% | 97.6% | 98.8% | 98.8% | 98.8% | 95.2%   | 96.8%   | 92.0% | 95.2% |

|                    | PCP   | PPX   | TCA   | TCA   | TML   | TML   | TML   | KET   | KET   | KET   | KET   |
|--------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
|                    | 25    | 300   | 1,000 | 500   | 200   | 300   | 1,000 | 500   | 300   | 300   | 100   |
| Positive Agreement | 92.4% | 96.0% | 94.8% | 94.9% | 88.2% | 88.2% | 88.0% | 97.5% | 97.6% | 96.7% | 96.0% |
| Negative Agreement | 96.8% | 94.0% | 91.6% | 92.1% | 92.4% | 96.2% | 96.2% | 98.2% | 98.2% | 97.5% | 97.3% |
| Total Results      | 95.2% | 94.8% | 92.8% | 93.2% | 90.8% | 93.2% | 93.2% | 98.0% | 98.0% | 97.2% | 96.8% |

|  | OXY | OXY | COT | COT | COT | COT | COT | EDDP | EDDP | FYL | FYL |
|--|-----|-----|-----|-----|-----|-----|-----|------|------|-----|-----|
|  | 100 | 300 | 500 | 200 | 100 | 50  | 10  |      |      |     |     |



|                                   |         |                                  |         |
|-----------------------------------|---------|----------------------------------|---------|
| Clobazam                          | 200     | Nitrazepam                       | 200     |
| Clonazepam                        | 500     | Norchlordiazepoxide              | 100     |
| Clorazepatedipotassium            | 500     | Nordiazepam                      | 900     |
| Delorazepam                       | 900     | Oxazepam                         | 300     |
| Desalkylflurazepam                | 200     | Temazepam                        | 100     |
| Flunitrazepam                     | 200     | Diazepam                         | 300     |
| (±) Lorazepam                     | 3,000   | Estazolam                        | 6,000   |
| RS-Lorazepamglucuronide           | 200     | Triazolam                        | 3,000   |
| Midazolam                         | 6,000   |                                  |         |
| <b>BENZODIAZEPINES (BZO 200)</b>  |         |                                  |         |
| Alprazolam                        | 70      | Bromazepam                       | 600     |
| a-hydroxylprazolam                | 1,000   | Chlordiazepoxide                 | 600     |
| Clobazam                          | 120     | Nitrazepam                       | 120     |
| Clonazepam                        | 300     | Norchlordiazepoxide              | 70      |
| Clorazepatedipotassium            | 300     | Nordiazepam                      | 600     |
| Delorazepam                       | 600     | Oxazepam                         | 200     |
| Desalkylflurazepam                | 120     | Temazepam                        | 70      |
| Flunitrazepam                     | 120     | Diazepam                         | 200     |
| (±) Lorazepam                     | 2,000   | Estazolam                        | 4,000   |
| RS-Lorazepamglucuronide           | 120     | Triazolam                        | 2,000   |
| Midazolam                         | 4,000   |                                  |         |
| <b>BENZODIAZEPINES (BZO 100)</b>  |         |                                  |         |
| Alprazolam                        | 40      | Bromazepam                       | 300     |
| a-hydroxylprazolam                | 500     | Chlordiazepoxide                 | 300     |
| Clobazam                          | 60      | Nitrazepam                       | 60      |
| Clonazepam                        | 150     | Norchlordiazepoxide              | 40      |
| Clorazepatedipotassium            | 150     | Nordiazepam                      | 300     |
| Delorazepam                       | 300     | Oxazepam                         | 100     |
| Desalkylflurazepam                | 60      | Temazepam                        | 40      |
| Flunitrazepam                     | 60      | Diazepam                         | 100     |
| (±) Lorazepam                     | 1,000   | Estazolam                        | 2,000   |
| RS-Lorazepamglucuronide           | 60      | Triazolam                        | 1,000   |
| Midazolam                         | 2,000   |                                  |         |
| <b>BUPRENORPHINE (BUP 10)</b>     |         |                                  |         |
| Buprenorphine                     | 10      | Norbuprenorphine                 | 50      |
| Buprenorphine 3-D-Glucuronide     | 50      | Norbuprenorphine 3-D-Glucuronide | 100     |
| <b>BUPRENORPHINE (BUP 5)</b>      |         |                                  |         |
| Buprenorphine                     | 5       | Norbuprenorphine                 | 25      |
| Buprenorphine 3-D-Glucuronide     | 25      | Norbuprenorphine 3-D-Glucuronide | 50      |
| <b>COCAINE (COC 1,500)</b>        |         |                                  |         |
| Benzoylcegonine                   | 1,500   | Cocaethylene                     | 100,000 |
| Cocaine HCl                       | 1200    | Ecgonine                         | 150,000 |
| <b>COCAINE (COC 300)</b>          |         |                                  |         |
| Benzoylcegonine                   | 300     | Cocaethylene                     | 20,000  |
| Cocaine HCl                       | 200     | Ecgonine                         | 30,000  |
| <b>COCAINE (COC 200)</b>          |         |                                  |         |
| Benzoylcegonine                   | 200     | Cocaethylene                     | 13,500  |
| Cocaine HCl                       | 135     | Ecgonine                         | 20,000  |
| <b>COCAINE (COC 150)</b>          |         |                                  |         |
| Benzoylcegonine                   | 150     | Cocaethylene                     | 10,000  |
| Cocaine HCl                       | 120     | Ecgonine                         | 15,000  |
| <b>COCAINE (COC 100)</b>          |         |                                  |         |
| Benzoylcegonine                   | 100     | Cocaethylene                     | 7,000   |
| Cocaine HCl                       | 80      | Ecgonine                         | 10,000  |
| <b>MARIJUANA (THC 600)</b>        |         |                                  |         |
| Cannabinol                        | 400,000 | Δ <sup>8</sup> -THC              | 300,000 |
| 11-nor-Δ <sup>8</sup> -THC-9 COOH | 400     | Δ <sup>9</sup> -THC              | 300,000 |
| 11-nor-Δ <sup>9</sup> -THC-9 COOH | 600     |                                  |         |
| <b>MARIJUANA (THC 300)</b>        |         |                                  |         |
| Cannabinol                        | 200,000 | Δ <sup>8</sup> -THC              | 100,000 |
| 11-nor-Δ <sup>8</sup> -THC-9 COOH | 200     | Δ <sup>9</sup> -THC              | 100,000 |
| 11-nor-Δ <sup>9</sup> -THC-9 COOH | 300     |                                  |         |
| <b>MARIJUANA (THC 200)</b>        |         |                                  |         |
| Cannabinol                        | 140,000 | Δ <sup>8</sup> -THC              | 68,000  |
| 11-nor-Δ <sup>8</sup> -THC-9 COOH | 120     | Δ <sup>9</sup> -THC              | 68,000  |
| 11-nor-Δ <sup>9</sup> -THC-9 COOH | 200     |                                  |         |
| <b>MARIJUANA (THC 150)</b>        |         |                                  |         |
| Cannabinol                        | 100,000 | Δ <sup>8</sup> -THC              | 50,000  |
| 11-nor-Δ <sup>8</sup> -THC-9 COOH | 100     | Δ <sup>9</sup> -THC              | 50,000  |
| 11-nor-Δ <sup>9</sup> -THC-9 COOH | 150     |                                  |         |
| <b>MARIJUANA (THC 50)</b>         |         |                                  |         |
| Cannabinol                        | 35,000  | Δ <sup>8</sup> -THC              | 17,000  |
| 11-nor-Δ <sup>8</sup> -THC-9 COOH | 30      | Δ <sup>9</sup> -THC              | 17,000  |
| 11-nor-Δ <sup>9</sup> -THC-9 COOH | 50      |                                  |         |
| <b>MARIJUANA (THC 30)</b>         |         |                                  |         |
| Cannabinol                        | 20,000  | Δ <sup>8</sup> -THC              | 10,000  |
| 11-nor-Δ <sup>8</sup> -THC-9 COOH | 20      | Δ <sup>9</sup> -THC              | 10,000  |
| 11-nor-Δ <sup>9</sup> -THC-9 COOH | 30      |                                  |         |
| <b>MARIJUANA (THC 25)</b>         |         |                                  |         |
| Cannabinol                        | 17,500  | Δ <sup>8</sup> -THC              | 8,500   |
| 11-nor-Δ <sup>8</sup> -THC-9 COOH | 15      | Δ <sup>9</sup> -THC              | 8,500   |
| 11-nor-Δ <sup>9</sup> -THC-9 COOH | 25      |                                  |         |
| <b>MARIJUANA (THC 20)</b>         |         |                                  |         |
| Cannabinol                        | 14,000  | Δ <sup>8</sup> -THC              | 6,800   |
| 11-nor-Δ <sup>8</sup> -THC-9 COOH | 12      | Δ <sup>9</sup> -THC              | 6,800   |

|                                                           |        |                                        |         |
|-----------------------------------------------------------|--------|----------------------------------------|---------|
| 11-nor-Δ <sup>9</sup> -THC-9 COOH                         | 20     |                                        |         |
| <b>METHADONE (MTD 300)</b>                                |        |                                        |         |
| Methadone                                                 | 300    | Doxylamine                             | 100,000 |
| <b>METHADONE (MTD 200)</b>                                |        |                                        |         |
| Methadone                                                 | 200    | Doxylamine                             | 65,000  |
| <b>METHAMPHETAMINE (MET 1,000)</b>                        |        |                                        |         |
| p-Hydroxymethamphetamine                                  | 25,000 | (±)-3,4-Methylenedioxy-methamphetamine | 12,500  |
| D-Methamphetamine                                         | 1,000  | Mephentermine                          | 50,000  |
| L-Methamphetamine                                         | 20,000 | Mephentermine                          | 50,000  |
| <b>METHAMPHETAMINE (MET 500)</b>                          |        |                                        |         |
| p-Hydroxymethamphetamine                                  | 12,500 | (±)-3,4-Methylenedioxy-methamphetamine | 6,250   |
| D-Methamphetamine                                         | 500    | Mephentermine                          | 25,000  |
| L-Methamphetamine                                         | 10,000 | Mephentermine                          | 25,000  |
| <b>METHAMPHETAMINE (MET 300)</b>                          |        |                                        |         |
| p-Hydroxymethamphetamine                                  | 7,500  | (±)-3,4-Methylenedioxy-methamphetamine | 3,750   |
| D-Methamphetamine                                         | 300    | Mephentermine                          | 15,000  |
| L-Methamphetamine                                         | 6,000  | Mephentermine                          | 15,000  |
| <b>METHAMPHETAMINE (MET 200)</b>                          |        |                                        |         |
| p-Hydroxymethamphetamine                                  | 5,000  | (±)-3,4-Methylenedioxy-methamphetamine | 2,500   |
| D-Methamphetamine                                         | 200    | Mephentermine                          | 10,000  |
| L-Methamphetamine                                         | 4,000  | Mephentermine                          | 10,000  |
| <b>METHYLENEDIOXYMETHAMPHETAMINE (MDMA 1,000) Ecstasy</b> |        |                                        |         |
| (±) 3,4-Methylenedioxy-methamphetamine HCl                | 1,000  | 3,4-Methylenedioxyethylamphetamine     | 600     |
| (±) 3,4-Methylenedioxyamphetamine HCl                     | 6,000  |                                        |         |
| <b>METHYLENEDIOXYMETHAMPHETAMINE (MDMA 500) Ecstasy</b>   |        |                                        |         |
| (±) 3,4-Methylenedioxy-methamphetamine HCl                | 500    | 3,4-Methylenedioxyethylamphetamine     | 300     |
| (±) 3,4-Methylenedioxyamphetamine HCl                     | 3,000  |                                        |         |
| <b>METHYLENEDIOXYMETHAMPHETAMINE (MDMA 300) Ecstasy</b>   |        |                                        |         |
| (±) 3,4-Methylenedioxy-methamphetamine HCl                | 300    | 3,4-Methylenedioxyethylamphetamine     | 180     |
| (±) 3,4-Methylenedioxyamphetamine HCl                     | 1,800  |                                        |         |
| <b>MORPHINE (MOP/OPI 300)</b>                             |        |                                        |         |
| Codeine                                                   | 200    | Norcodeine                             | 6,000   |
| Levorphanol                                               | 1,500  | Normorphone                            | 50,000  |
| Morphine-3-β-D-Glucuronide                                | 800    | Oxycodone                              | 30,000  |
| Ethylmorphine                                             | 6,000  | Oxymorphone                            | 50,000  |
| Hydrocodone                                               | 50,000 | Procaine                               | 15,000  |
| Hydromorphone                                             | 3,000  | Thebaine                               | 6,000   |
| 6-Monoacetylmorphine                                      | 300    | Morphine                               | 300     |
| <b>MORPHINE (MOP/OPI 200)</b>                             |        |                                        |         |
| Codeine                                                   | 160    | Norcodeine                             | 4,000   |
| Levorphanol                                               | 1,000  | Normorphone                            | 40,000  |
| Morphine-3-β-D-Glucuronide                                | 600    | Oxycodone                              | 20,000  |
| Ethylmorphine                                             | 4,000  | Oxymorphone                            | 40,000  |
| Hydrocodone                                               | 40,000 | Procaine                               | 10,000  |
| Hydromorphone                                             | 2,000  | Thebaine                               | 4,000   |
| 6-Monoacetylmorphine                                      | 200    | Morphine                               | 200     |
| <b>MORPHINE (MOP/OPI 100)</b>                             |        |                                        |         |
| Codeine                                                   | 80     | Norcodeine                             | 2,000   |
| Levorphanol                                               | 500    | Normorphone                            | 20,000  |
| Morphine-3-β-D-Glucuronide                                | 300    | Oxycodone                              | 10,000  |
| Ethylmorphine                                             | 2,000  | Oxymorphone                            | 20,000  |
| Hydrocodone                                               | 20,000 | Procaine                               | 5,000   |
| Hydromorphone                                             | 1,000  | Thebaine                               | 2,000   |
| 6-Monoacetylmorphine                                      | 200    | Morphine                               | 100     |
| <b>METHAQUALONE (MQL 300)</b>                             |        |                                        |         |
| Methaqualone                                              | 300    |                                        |         |
| <b>MORPHINE/OPIATE (OPI 2,000)</b>                        |        |                                        |         |
| Codeine                                                   | 2,000  | Morphine                               | 2,000   |
| Ethylmorphine                                             | 3,000  | Norcodeine                             | 25,000  |
| Hydrocodone                                               | 50,000 | Normorphone                            | 50,000  |
| Hydromorphone                                             | 15,000 | Oxycodone                              | 25,000  |
| Levorphanol                                               | 25,000 | Oxymorphone                            | 25,000  |
| 6-Monoacetylmorphine                                      | 3,000  | Procaine                               | 50,000  |
| Morphine 3-β-D-glucuronide                                | 2,000  | Thebaine                               | 25,000  |
| <b>MORPHINE/OPIATE (OPI 1,000)</b>                        |        |                                        |         |
| Codeine                                                   | 1,000  | Morphine                               | 1,000   |
| Ethylmorphine                                             | 1,500  | Norcodeine                             | 12,500  |
| Hydrocodone                                               | 25,000 | Normorphone                            | 25,000  |
| Hydromorphone                                             | 7,500  | Oxycodone                              | 12,500  |
| Levorphanol                                               | 12,500 | Oxymorphone                            | 12,500  |
| 6-Monoacetylmorphine                                      | 1,500  | Procaine                               | 25,000  |
| Morphine 3-β-D-glucuronide                                | 1,000  | Thebaine                               | 12,500  |
| <b>MEPERIDINE (MPRD 100)</b>                              |        |                                        |         |
| Normeperidine                                             | 100    | Meperidine                             | 100     |
| <b>PHENCYCLIDINE (PCP 50)</b>                             |        |                                        |         |
| Phencyclidine                                             | 50     | 4-Hydroxyphencyclidine                 | 25,000  |
| <b>PHENCYCLIDINE (PCP 25)</b>                             |        |                                        |         |
| Phencyclidine                                             | 25     | 4-Hydroxyphencyclidine                 | 12,500  |
| <b>PROPOXYPHENE (PPX 300)</b>                             |        |                                        |         |
| D-Propoxyphene                                            | 300    | D-Norpropoxyphene                      | 300     |
| <b>TRICYCLIC ANTIDEPRESSANTS (TCA 1,000)</b>              |        |                                        |         |
| Nortriptyline                                             | 1,000  | Imipramine                             | 400     |
| Nordoxepine                                               | 500    | Clomipramine                           | 50,000  |

|                                            |         |                                           |         |
|--------------------------------------------|---------|-------------------------------------------|---------|
| Trimipramine                               | 3,000   | Doxepine                                  | 2,000   |
| Amitriptyline                              | 1,500   | Maprotiline                               | 2,000   |
| Promazine                                  | 3,000   | Promethazine                              | 50,000  |
| Desipramine                                | 200     | Perphenazine                              | 50,000  |
| Cyclobenzaprine                            | 2,000   | Dithiaden                                 | 10,000  |
| <b>TRICYCLIC ANTIDEPRESSANTS (TCA 500)</b> |         |                                           |         |
| Nortriptyline                              | 500     | Imipramine                                | 200     |
| Nordoxepine                                | 250     | Clomipramine                              | 25,000  |
| Trimipramine                               | 1,500   | Doxepine                                  | 1,000   |
| Amitriptyline                              | 750     | Maprotiline                               | 1,000   |
| Promazine                                  | 1,500   | Promethazine                              | 25,000  |
| Desipramine                                | 100     | Perphenazine                              | 25,000  |
| Cyclobenzaprine                            | 1,000   | Dithiaden                                 | 5,000   |
| <b>TRICYCLIC ANTIDEPRESSANTS (TCA 300)</b> |         |                                           |         |
| Nortriptyline                              | 300     | Imipramine                                | 120     |
| Nordoxepine                                | 150     | Clomipramine                              | 15,000  |
| Trimipramine                               | 900     | Doxepine                                  | 600     |
| Amitriptyline                              | 450     | Maprotiline                               | 600     |
| Promazine                                  | 900     | Promethazine                              | 15,000  |
| Desipramine                                | 60      | Perphenazine                              | 15,000  |
| Cyclobenzaprine                            | 600     | Dithiaden                                 | 3,000   |
| <b>TRAMADOL (TML 100)</b>                  |         |                                           |         |
| n-Desmethyl-cis-tramadol                   | 200     | o-Desmethyl-cis-tramadol                  | 10,000  |
| Cis-tramadol                               | 100     | Phencyclidine                             | 100,000 |
| Procyclidine                               | 100,000 | d,l-O-Desmethyl venlafaxine               | 50,000  |
| <b>TRAMADOL (TML 200)</b>                  |         |                                           |         |
| n-Desmethyl-cis-tramadol                   | 400     | o-Desmethyl-cis-tramadol                  | 20,000  |
| Cis-tramadol                               | 200     | Phencyclidine                             | 200,000 |
| Procyclidine                               | 200,000 | d,l-O-Desmethyl venlafaxine               | 100,000 |
| <b>TRAMADOL (TML 300)</b>                  |         |                                           |         |
| n-Desmethyl-cis-tramadol                   | 600     | o-Desmethyl-cis-tramadol                  | 30,000  |
| Cis-tramadol                               | 300     | Phencyclidine                             | 300,000 |
| Procyclidine                               | 300,000 | d,l-O-Desmethyl venlafaxine               | 150,000 |
| <b>TRAMADOL (TML 500)</b>                  |         |                                           |         |
| n-Desmethyl-cis-tramadol                   | 1,000   | o-Desmethyl-cis-tramadol                  | 50,000  |
| Cis-tramadol                               | 500     | Phencyclidine                             | 500,000 |
| Procyclidine                               | 500,000 | d,l-O-Desmethyl venlafaxine               | 250,000 |
| <b>KETAMINE (KET 1,000)</b>                |         |                                           |         |
| Ketamine                                   | 1,000   | Benzphetamine                             | 25,000  |
| Dextromethorphan                           | 2,000   | (+) Chlorpheniramine                      | 25,000  |
| Methoxyphenamine                           | 25,000  | Clonidine                                 | 100,000 |
| d-Norpropoxyphene                          | 25,000  | EDDP                                      | 50,000  |
| Promazine                                  | 25,000  | 4-Hydroxyphencyclidine                    | 50,000  |
| Promethazine                               | 25,000  | Levorphanol                               | 50,000  |
| Pentazocine                                | 25,000  | MDE                                       | 50,000  |
| Phencyclidine                              | 25,000  | Meperidine                                | 25,000  |
| Tetrahydrozoline                           | 500     | 4-Methamphetamine                         | 50,000  |
| Mephentermine                              | 25,000  | 4-Methamphetamine                         | 50,000  |
| (1R, 2S) - (-)-Ephedrine                   | 100,000 | 3,4-Methylenedioxy-methamphetamine (MDMA) | 100,000 |
| Disopyramide                               | 25,000  | Thioridazine                              | 50,000  |
| <b>KETAMINE (KET 500)</b>                  |         |                                           |         |
| Ketamine                                   | 500     | Benzphetamine                             | 12,500  |
| Dextromethorphan                           | 1,000   | (+) Chlorpheniramine                      | 12,500  |
| Methoxyphenamine                           | 12,500  | Clonidine                                 | 50,000  |
| d-Norpropoxyphene                          | 12,500  | EDDP                                      | 25,000  |
| Promazine                                  | 12,500  | 4-Hydroxyphencyclidine                    | 25,000  |
| Promethazine                               | 12,500  | Levorphanol                               | 25,000  |
| Pentazocine                                | 12,500  | MDE                                       | 25,000  |
| Phencyclidine                              | 12,500  | Meperidine                                | 12,500  |
| Tetrahydrozoline                           | 250     | 4-Methamphetamine                         | 25,000  |
| Mephentermine                              | 12,500  | 4-Methamphetamine                         | 25,000  |
| (1R, 2S) - (-)-Ephedrine                   | 50,000  | 3,4-Methylenedioxy-methamphetamine (MDMA) | 50,000  |
| Disopyramide                               | 12,500  | Thioridazine                              | 25,000  |
| <b>KETAMINE (KET 300)</b>                  |         |                                           |         |
| Ketamine                                   | 300     | Benzphetamine                             | 6,250   |
| Dextromethorphan                           | 600     | (+) Chlorpheniramine                      | 6,250   |
| Methoxyphenamine                           | 6,250   | Clonidine                                 | 30,000  |
| d-Norpropoxyphene                          | 6,250   | EDDP                                      | 15,000  |
| Promazine                                  | 6,250   | 4-Hydroxyphencyclidine                    | 15,000  |
| Promethazine                               | 6,250   | Levorphanol                               | 15,000  |
| Pentazocine                                | 6,250   | MDE                                       | 15,000  |
| Phencyclidine                              | 6,250   | Meperidine                                | 6,250   |
| Tetrahydrozoline                           | 150     | 4-Methamphetamine                         | 15,000  |
| Mephentermine                              | 6,250   | 4-Methamphetamine                         | 15,000  |
| (1R, 2S) - (-)-Ephedrine                   | 30,000  | 3,4-Methylenedioxy-methamphetamine (MDMA) | 30,000  |
| Disopyramide                               | 6,250   | Thioridazine                              | 15,000  |
| <b>KETAMINE (KET 100)</b>                  |         |                                           |         |
| Ketamine                                   | 100     | Benzphetamine                             | 2,000   |
| Dextromethorphan                           | 200     | (+) Chlorpheniramine                      | 2,000   |
| Methoxyphenamine                           | 2,000   | Clonidine                                 | 10,000  |
| d-Norpropoxyphene                          | 2,000   | EDDP                                      | 5,000   |
| Promazine                                  | 2,000   | 4-Hydroxyphencyclidine                    | 5,000   |
| Promethazine                               | 2,000   | Levorphanol                               | 5,000   |
| Pentazocine                                | 2,000   | MDE                                       | 5,000   |

|                                                                     |          |                                           |         |
|---------------------------------------------------------------------|----------|-------------------------------------------|---------|
| Phencyclidine                                                       | 2,000    | Meperidine                                | 2,000   |
| Tetrahydrozoline                                                    | 50       | 4-Methamphetamine                         | 5,000   |
| Mephentermine                                                       | 2,000    | 4-Methamphetamine                         | 5,000   |
| (1R, 2S) - (-)-Ephedrine                                            | 10,000   | Thioridazine                              | 5,000   |
| Disopyramide                                                        | 2,000    | 3,4-Methylenedioxy-methamphetamine (MDMA) | 10,000  |
| <b>OXYCODONE (OXY 300)</b>                                          |          |                                           |         |
| Oxycodone                                                           | 300      | Hydromorphone                             | 150,000 |
| Oxymorphone                                                         | 900      | Naloxone                                  | 75,000  |
| Levorphanol                                                         | 15,000   | Naltrexone                                | 75,000  |
| Hydrocodone                                                         | 75,000   |                                           |         |
| <b>OXYCODONE (OXY 100)</b>                                          |          |                                           |         |
| Oxycodone                                                           | 100      | Hydromorphone                             | 50,000  |
| Oxymorphone                                                         | 300      | Naloxone                                  | 25,000  |
| Levorphanol                                                         | 50,000   | Naltrexone                                | 25,000  |
| Hydrocodone                                                         | 25,000   |                                           |         |
| <b>COTININE (COT 300)</b>                                           |          |                                           |         |
| (-) Cotinine                                                        | 300      | (-) Nicotine                              | 7,500   |
| <b>COTININE (COT 200)</b>                                           |          |                                           |         |
| (-) Cotinine                                                        | 200      | (-) Nicotine                              | 5,000   |
| <b>COTININE (COT 100)</b>                                           |          |                                           |         |
| (-) Cotinine                                                        | 100      | (-) Nicotine                              | 2,500   |
| <b>COTININE (COT 500)</b>                                           |          |                                           |         |
| (-) Cotinine                                                        | 500      | (-) Nicotine                              | 12,500  |
| <b>COTININE (COT 50)</b>                                            |          |                                           |         |
| (-) Cotinine                                                        | 50       | (-) Nicotine                              | 1,250   |
| <b>COTININE (COT 10)</b>                                            |          |                                           |         |
| (-) Cotinine                                                        | 10       | (-) Nicotine                              | 250     |
| <b>2-ETHYLIDENE-1,5-DIMETHYL-3,3-DIPHENYLPYRROLIDINE (EDDP 300)</b> |          |                                           |         |
| 2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)            |          |                                           | 300     |
| <b>2-ETHYLIDENE-1,5-DIMETHYL-3,3-DIPHENYLPYRROLIDINE (EDDP 100)</b> |          |                                           |         |
| 2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)            |          |                                           | 100     |
| <b>FENTANYL (FYL 300)</b>                                           |          |                                           |         |
| Alfentanyl                                                          | >600,000 | Buspirone                                 | 80,000  |
| Norf                                                                |          |                                           |         |

|                                                     |          |                           |          |
|-----------------------------------------------------|----------|---------------------------|----------|
| Glucuronic Acid                                     | >100,000 | Ethanol                   | >100,000 |
| Methanol                                            | >100,000 |                           |          |
| <b>ETHYL-β-D-GLUCURONIDE (ETG 1,500)</b>            |          |                           |          |
| Ethyl-β-D-Glucuronide                               | 1,500    | Propyl β-D-glucuronide    | 150,000  |
| Morphine 3β-glucuronide                             | >100,000 | Morphine 6β-glucuronide   | >100,000 |
| Glucuronic Acid                                     | >100,000 | Ethanol                   | >100,000 |
| Methanol                                            | >100,000 |                           |          |
| <b>CLONAZEPAM (CLO 400)</b>                         |          |                           |          |
| Clonazepam                                          | 400      | Flunitrazepam             | 300      |
| Alprazolam                                          | 200      | (±) Lorazepam             | 1,250    |
| 4-hydroxylprazolam                                  | 2,000    | RS-Lorazepamglucuronide   | 250      |
| Bromazepam                                          | 1,000    | Midazolam                 | 5,000    |
| Chlordiazepoxide                                    | 1,000    | Nitrazepam                | 200      |
| Clobazam                                            | 250      | Norchlordiazepoxide       | 200      |
| Clorazepatedipotassium                              | 600      | Nordiazepam               | 1,000    |
| Delorazepam                                         | 1,000    | Oxazepam                  | 350      |
| Desalkylflurazepam                                  | 250      | Temazepam                 | 150      |
| Diazepam                                            | 300      | Triazolam                 | 5,000    |
| Estazolam                                           | 1,250    |                           |          |
| <b>CLONAZEPAM (CLO 150)</b>                         |          |                           |          |
| Clonazepam                                          | 150      | Flunitrazepam             | 120      |
| Alprazolam                                          | 75       | (±) Lorazepam             | 500      |
| 4-hydroxylprazolam                                  | 750      | RS-Lorazepamglucuronide   | 100      |
| Bromazepam                                          | 400      | Midazolam                 | 2,000    |
| Chlordiazepoxide                                    | 400      | Nitrazepam                | 75       |
| Clobazam                                            | 100      | Norchlordiazepoxide       | 75       |
| Clorazepatedipotassium                              | 250      | Nordiazepam               | 400      |
| Delorazepam                                         | 400      | Oxazepam                  | 130      |
| Desalkylflurazepam                                  | 100      | Temazepam                 | 60       |
| Diazepam                                            | 120      | Triazolam                 | 2,000    |
| Estazolam                                           | 500      |                           |          |
| <b>LYSERGIC ACID DIETHYLAMIDE (LSD 10)</b>          |          |                           |          |
| Lysergic Acid Diethylamide                          | 10       |                           |          |
| <b>LYSERGIC ACID DIETHYLAMIDE (LSD 20)</b>          |          |                           |          |
| Lysergic Acid Diethylamide                          | 20       |                           |          |
| <b>LYSERGIC ACID DIETHYLAMIDE (LSD 50)</b>          |          |                           |          |
| Lysergic Acid Diethylamide                          | 50       |                           |          |
| <b>METHYLPHENIDATE (MPD 300)</b>                    |          |                           |          |
| Methylphenidate (Ritalin)                           | 300      | Ritalinic Acid            | 1,000    |
| <b>METHYLPHENIDATE (MPD 150)</b>                    |          |                           |          |
| Methylphenidate (Ritalin)                           | 150      | Ritalinic Acid            | 500      |
| <b>METHYLPHENIDATE (MPD 1,000)</b>                  |          |                           |          |
| Methylphenidate (Ritalin)                           | 350      | Ritalinic Acid            | 1,000    |
| <b>ZOLPIDEM (ZOL 50)</b>                            |          |                           |          |
| Zolpidem                                            | 50       |                           |          |
| <b>MEPHEDRONE (MEP 500)</b>                         |          |                           |          |
| Mephedrone HCl                                      | 500      | R(+)-Methcathinone HCl    | 7,500    |
| S(-)-Methcathinone HCl                              | 2,500    | 3-Fluoromethcathinone HCl | 7,500    |
| 4-Fluoromethcathinone HCl                           | 1,500    | Methoxyphenamine          | 100,000  |
| <b>MEPHEDRONE (MEP 100)</b>                         |          |                           |          |
| Mephedrone HCl                                      | 100      | R(+)-Methcathinone HCl    | 1,500    |
| S(-)-Methcathinone HCl                              | 500      | 3-Fluoromethcathinone HCl | 1,500    |
| 4-Fluoromethcathinone HCl                           | 300      | Methoxyphenamine          | 100,000  |
| <b>3, 4-METHYLENEDIOXYPYROVALERONE (MDPV 1,000)</b> |          |                           |          |
| 3, 4- methylenedioxy-pyrovalerone                   | 1,000    |                           |          |
| <b>3, 4-METHYLENEDIOXYPYROVALERONE (MDPV 500)</b>   |          |                           |          |
| 3, 4- methylenedioxy-pyrovalerone                   | 500      |                           |          |
| <b>3, 4-METHYLENEDIOXYPYROVALERONE (MDPV 300)</b>   |          |                           |          |
| 3, 4- methylenedioxy-pyrovalerone                   | 300      |                           |          |
| <b>DIAZEPAM (DIA 300)</b>                           |          |                           |          |
| Diazepam                                            | 300      | Midazolam                 | 6,000    |
| Clobazam                                            | 200      | Nitrazepam                | 200      |
| Clonazepam                                          | 500      | Norchlordiazepoxide       | 100      |
| Clorazepate dipotassium                             | 500      | Nordiazepam               | 900      |
| Alprazolam                                          | 100      | Flunitrazepam             | 200      |
| 4-hydroxylprazolam                                  | 1,500    | (±) Lorazepam             | 3,000    |
| Bromazepam                                          | 900      | RS-Lorazepam glucuronide  | 200      |
| Chlordiazepoxide                                    | 900      | Triazolam                 | 3,000    |
| Estazolam                                           | 6,000    | Temazepam                 | 100      |
| Delorazepam                                         | 900      | Oxazepam                  | 300      |
| Desalkylflurazepam                                  | 200      |                           |          |
| <b>DIAZEPAM (DIA 200)</b>                           |          |                           |          |
| Diazepam                                            | 200      | Midazolam                 | 4,000    |
| Clobazam                                            | 120      | Nitrazepam                | 120      |
| Clonazepam                                          | 300      | Norchlordiazepoxide       | 70       |
| Clorazepate dipotassium                             | 300      | Nordiazepam               | 600      |
| Alprazolam                                          | 70       | Flunitrazepam             | 120      |
| 4-hydroxylprazolam                                  | 1,000    | (±) Lorazepam             | 2,000    |
| Bromazepam                                          | 600      | RS-Lorazepam glucuronide  | 120      |
| Chlordiazepoxide                                    | 600      | Triazolam                 | 2,000    |
| Estazolam                                           | 4,000    | Temazepam                 | 70       |
| Delorazepam                                         | 600      | Oxazepam                  | 200      |
| Desalkylflurazepam                                  | 120      |                           |          |
| <b>ZOPICLONE (ZOP 300)</b>                          |          |                           |          |

|                                      |         |                                             |        |
|--------------------------------------|---------|---------------------------------------------|--------|
| Zopiclone-x-oxide                    | 300     | Zopiclone                                   | 300    |
| <b>ZOPICLONE (ZOP 50)</b>            |         |                                             |        |
| Zopiclone-x-oxide                    | 50      | Zopiclone                                   | 50     |
| <b>METHCATHINONE (MCAT 500)</b>      |         |                                             |        |
| S(-)-Methcathinone HCl               | 500     | R(+)-Methcathinone HCl                      | 1,500  |
| Methoxyphenamine                     | 100,000 | 3-Fluoromethcathinone HCl                   | 1,500  |
| <b>7-AMINOCLONAZEPAM (7-ACL 300)</b> |         |                                             |        |
| 4-hydroxylprazolam                   | 6,000   | Flunitrazepam                               | 3,000  |
| Bromazepam                           | 6,000   | RS-Lorazepam glucuronide                    | 2,700  |
| Chlordiazepoxide                     | 6,000   | Norchlordiazepoxide                         | 4,500  |
| Clobazam                             | 9,000   | Nordiazepam                                 | 15,000 |
| Clonazepam                           | 2,400   | Temazepam                                   | 9,000  |
| Delorazepam                          | 6,000   | 7-Aminoclonazepam                           | 300    |
| Desalkylflurazepam                   | 6,000   |                                             |        |
| <b>7-AMINOCLONAZEPAM (7-ACL 200)</b> |         |                                             |        |
| 4-hydroxylprazolam                   | 4,000   | Flunitrazepam                               | 2,000  |
| Bromazepam                           | 4,000   | RS-Lorazepam glucuronide                    | 1,800  |
| Chlordiazepoxide                     | 4,000   | Norchlordiazepoxide                         | 3,000  |
| Clobazam                             | 6,000   | Nordiazepam                                 | 10,000 |
| Clonazepam                           | 1,600   | Temazepam                                   | 6,000  |
| Delorazepam                          | 4,000   | 7-Aminoclonazepam                           | 200    |
| Desalkylflurazepam                   | 4,000   |                                             |        |
| <b>7-AMINOCLONAZEPAM (7-ACL 100)</b> |         |                                             |        |
| 4-hydroxylprazolam                   | 2,000   | Flunitrazepam                               | 1,000  |
| Bromazepam                           | 2,000   | RS-Lorazepam glucuronide                    | 900    |
| Chlordiazepoxide                     | 2,000   | Norchlordiazepoxide                         | 1,500  |
| Clobazam                             | 3,000   | Nordiazepam                                 | 5,000  |
| Clonazepam                           | 800     | Temazepam                                   | 3,000  |
| Delorazepam                          | 2,000   | 7-Aminoclonazepam                           | 100    |
| Desalkylflurazepam                   | 2,000   |                                             |        |
| <b>CARFENTANYL (CFYL 500)</b>        |         |                                             |        |
| Carfentanyl                          | 500     | Fentanyl                                    | 100    |
| Sufentanil                           | 50,000  | Ramifentanil                                | 10,000 |
| (±)cis-3-Menthylfentanyl             | 20,000  | Butyl fentanyl                              | 150    |
| <b>CARFENTANYL (CFYL 250)</b>        |         |                                             |        |
| Carfentanyl                          | 250     | Fentanyl                                    | 50     |
| Sufentanil                           | 25,000  | Ramifentanil                                | 5,000  |
| (±)cis-3-Menthylfentanyl             | 10,000  | Butyl fentanyl                              | 75     |
| <b>CAFFEINE (CAF 1,000)</b>          |         |                                             |        |
| Caffeine                             | 1,000   |                                             |        |
| <b>CATHINE (CAT 150)</b>             |         |                                             |        |
| (+)-Norpseudoephedrine HCl (Cathine) | 150     | (+)-3,4-Methylenedioxyamphetami<br>ne (MDA) | 100    |
| d/l-Amphetamine                      | 100     | p-Hydroxyamphetamine                        | 100    |
| Tryptamine                           | 12,500  | Methoxyphenamine                            | 12,500 |
| <b>TROPICAMIDE (TRO 350)</b>         |         |                                             |        |
| Tropicamide                          | 350     |                                             |        |
| <b>ALPRAZOLAM (ALP 100)</b>          |         |                                             |        |
| Benzodiazepines                      | 300     | Flunitrazepam                               | 200    |
| 4-hydroxylprazolam                   | 1,500   | (±) Lorazepam                               | 3,000  |
| Bromazepam                           | 900     | RS-Lorazepamglucuronide                     | 200    |
| Chlordiazepoxide                     | 900     | Midazolam                                   | 6,000  |
| Clobazam                             | 200     | Nitrazepam                                  | 200    |
| Clonazepam                           | 500     | Norchlordiazepoxide                         | 100    |
| Clorazepatedipotassium               | 500     | Nordiazepam                                 | 900    |
| Delorazepam                          | 900     | Oxazepam                                    | 300    |
| Desalkylflurazepam                   | 200     | Temazepam                                   | 100    |
| Diazepam                             | 300     | Triazolam                                   | 3,000  |
| Estazolam                            | 6,000   | Alprazolam                                  | 100    |
| <b>PREGABALIN (PGB 50,000)</b>       |         |                                             |        |
| Pregabalin                           | 50,000  |                                             |        |
| <b>PREGABALIN (PGB 500)</b>          |         |                                             |        |
| Pregabalin                           | 500     |                                             |        |
| <b>ZALEPLON (ZAL 100)</b>            |         |                                             |        |
| Zaleplon                             | 100     |                                             |        |
| <b>CANNABINOL(CNB 500)</b>           |         |                                             |        |
| cannabinol                           | 500     | Δ <sup>9</sup> -THC                         | 10,000 |
| 11-nor-Δ <sup>9</sup> -THC-9 COOH    | 300     |                                             |        |
| <b>GABAPENTIN (GAB 2,000)</b>        |         |                                             |        |
| Gabapentin                           | 2,000   |                                             |        |
| <b>TRAZODONE (TZD 200)</b>           |         |                                             |        |
| Trazodone                            | 200     |                                             |        |
| <b>CARISOPRODOL (CAR 2,000)</b>      |         |                                             |        |
| Carisoprodol                         | 2,000   |                                             |        |
| <b>CARISOPRODOL (CAR 1,000)</b>      |         |                                             |        |
| Carisoprodol                         | 1,000   |                                             |        |
| <b>CARISOPRODOL (CAR 500)</b>        |         |                                             |        |
| Carisoprodol                         | 500     |                                             |        |
| <b>AB-PINACA (ABP/K3 10)</b>         |         |                                             |        |
| AB-PINACA                            | 10      | AB-PINACA 5-Pentanoic                       | 10     |
| AB-PINACA 5-hydroxypentyl            | 10      | AB-FUBINACA                                 | 10     |
| AB-PINACA 4-hydroxypentyl            | 10,000  | UR-144 5-Pentanoic                          | 5,000  |
| UR-144 5-hydroxypentyl               | 10,000  | UR-144 4-hydroxypentyl                      | 10,000 |
| APINACA 5-hydroxypentyl              | 10,000  | ADB-PINACA Pentanoic Acid                   | 10     |
| ADB-PINACA N-(5-hydroxypentyl)       | 30      | 5-fluoro AB-PINACA<br>N-(4-hydroxypentyl)   | 30     |
| 5-fluoro AB-PINACA                   | 25      |                                             |        |

|                                                                                                                                                                                                                                                                                                                                                                                            |         |                               |           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|-------------------------------|-----------|
| <b>UR-144/K4 (25)</b>                                                                                                                                                                                                                                                                                                                                                                      |         |                               |           |
| UR-144 5-Pentanoic acid                                                                                                                                                                                                                                                                                                                                                                    | 25      | UR-144 4-hydroxypentyl        | 10,000    |
| UR-144 5-hydroxypentyl                                                                                                                                                                                                                                                                                                                                                                     | 5000    | XLR-11 4-hydroxypentyl        | 2,000     |
| 5-fluoro<br>AB-Pinaca N-(4-hydroxypentyl)                                                                                                                                                                                                                                                                                                                                                  | 10,000  | ADB-PINAC N-(4-hydroxypentyl) | >10,000   |
| AB-PINACA 4-hydroxypentyl                                                                                                                                                                                                                                                                                                                                                                  | >10,000 |                               |           |
| <b>QUETIAPINE (QTP 1,000)</b>                                                                                                                                                                                                                                                                                                                                                              |         |                               |           |
| Quetiapine                                                                                                                                                                                                                                                                                                                                                                                 | 1,000   | Norquetiapine                 | 10,000    |
| <b>FLUOXETINE (FLX 500)</b>                                                                                                                                                                                                                                                                                                                                                                |         |                               |           |
| Fluoxetine                                                                                                                                                                                                                                                                                                                                                                                 | 500     |                               |           |
| <b>KRATOM (KRA 300)</b>                                                                                                                                                                                                                                                                                                                                                                    |         |                               |           |
| Mitragynine                                                                                                                                                                                                                                                                                                                                                                                | 300     | 7-hydroxymitragynine          | >50,000   |
| <b>TILDINE (TLD 50)</b>                                                                                                                                                                                                                                                                                                                                                                    |         |                               |           |
| Northilidine                                                                                                                                                                                                                                                                                                                                                                               | 50      | Tildine                       | 100       |
| <b>ALPHA-PYRROLIDINOVALEROPHENONE (α-PVP 2,000)</b>                                                                                                                                                                                                                                                                                                                                        |         |                               |           |
| Alpha-Pyrrolidinovalerophenone                                                                                                                                                                                                                                                                                                                                                             | 2,000   |                               |           |
| <b>ALPHA-PYRROLIDINOVALEROPHENONE (α-PVP 1,000)</b>                                                                                                                                                                                                                                                                                                                                        |         |                               |           |
| Alpha-Pyrrolidinovalerophenone                                                                                                                                                                                                                                                                                                                                                             | 1,000   |                               |           |
| <b>ALPHA-PYRROLIDINOVALEROPHENONE (α-PVP 500)</b>                                                                                                                                                                                                                                                                                                                                          |         |                               |           |
| Alpha-Pyrrolidinovalerophenone                                                                                                                                                                                                                                                                                                                                                             | 500     |                               |           |
| <b>ALPHA-PYRROLIDINOVALEROPHENONE (α-PVP 300)</b>                                                                                                                                                                                                                                                                                                                                          |         |                               |           |
| Alpha-Pyrrolidinovalerophenone                                                                                                                                                                                                                                                                                                                                                             | 300     |                               |           |
| <b>MESCALINE (MES 100)</b>                                                                                                                                                                                                                                                                                                                                                                 |         |                               |           |
| Mescaline                                                                                                                                                                                                                                                                                                                                                                                  | 100     |                               |           |
| <b>MESCALINE (MES 300)</b>                                                                                                                                                                                                                                                                                                                                                                 |         |                               |           |
| Mescaline                                                                                                                                                                                                                                                                                                                                                                                  | 300     |                               |           |
| <b>PAPAVERINE (PAP 500)</b>                                                                                                                                                                                                                                                                                                                                                                |         |                               |           |
| Papaverine                                                                                                                                                                                                                                                                                                                                                                                 | 500     | Diflunisal                    | 1,000,000 |
| Methortrexate                                                                                                                                                                                                                                                                                                                                                                              | 65,000  | Methedrone                    | 500,000   |
| Pragablin                                                                                                                                                                                                                                                                                                                                                                                  | 500,000 | Phenelzine                    | 8,000     |
| Quinine                                                                                                                                                                                                                                                                                                                                                                                    | 4,000   |                               |           |
| <b>TAPENTADOL (TAP 1,000)</b>                                                                                                                                                                                                                                                                                                                                                              |         |                               |           |
| 3-((1R,2R)-3-(dimethylamino)-1-ethyl-2-methylp<br>ropyl)phenol                                                                                                                                                                                                                                                                                                                             | 1,000   |                               |           |
| <b>CITALOPRAM (CIT 500)</b>                                                                                                                                                                                                                                                                                                                                                                |         |                               |           |
| Desmethylcitalopram                                                                                                                                                                                                                                                                                                                                                                        | 500     |                               |           |
| <b>F-KETAMINE (FKET 1,000)</b>                                                                                                                                                                                                                                                                                                                                                             |         |                               |           |
| 2-(2-fluorophenyl)-2-methylamino-cyclohexanone                                                                                                                                                                                                                                                                                                                                             | 1,000   |                               |           |
| <b>RISPERIDONE (RPD 150)</b>                                                                                                                                                                                                                                                                                                                                                               |         |                               |           |
| Risperidone                                                                                                                                                                                                                                                                                                                                                                                | 150     |                               |           |
| <b>SCOPOLAMINE (SCOP 500)</b>                                                                                                                                                                                                                                                                                                                                                              |         |                               |           |
| Scopolamine                                                                                                                                                                                                                                                                                                                                                                                | 500     | atropine                      | 3,000     |
| <b>N, N-DIMETHYLTRYPTAMINE (NND 1,000)</b>                                                                                                                                                                                                                                                                                                                                                 |         |                               |           |
| N, N-Dimethyltryptamine                                                                                                                                                                                                                                                                                                                                                                    | 1,000   |                               |           |
| <b>MIRTAZAPINE (MTZ 500)</b>                                                                                                                                                                                                                                                                                                                                                               |         |                               |           |
| N-Desmethyilmirtazapine                                                                                                                                                                                                                                                                                                                                                                    | 500     | Mirtazapine                   | 500       |
| <b>OLANZAPINE (OZP 1,000)</b>                                                                                                                                                                                                                                                                                                                                                              |         |                               |           |
| Olanzapine                                                                                                                                                                                                                                                                                                                                                                                 | 1,000   |                               |           |
| <b>HYDROMORPHONE (HMO 500)</b>                                                                                                                                                                                                                                                                                                                                                             |         |                               |           |
| Hydromorphone                                                                                                                                                                                                                                                                                                                                                                              | 500     | Morphine                      | 200       |
| Codeine                                                                                                                                                                                                                                                                                                                                                                                    | 120     | Ethylmorphine                 | 120       |
| Hydrocodone                                                                                                                                                                                                                                                                                                                                                                                | 500     | Morphine<br>3-β-D-Glucuronide | 250       |
| Levorphanol                                                                                                                                                                                                                                                                                                                                                                                | 2,000   | Oxycodone                     | 125000    |
| Normorphine                                                                                                                                                                                                                                                                                                                                                                                | 125000  | Norcodeine                    | 31200     |
| Oxymorphone                                                                                                                                                                                                                                                                                                                                                                                | 125000  | Nalorphine                    | 50000     |
| Thebaine                                                                                                                                                                                                                                                                                                                                                                                   | 10000   | Diacetylmorphine (Heroin)     | 250       |
| 6-Monoacetylmorphine                                                                                                                                                                                                                                                                                                                                                                       | 120     |                               |           |
| <b>HYDROMORPHONE (HMO 300)</b>                                                                                                                                                                                                                                                                                                                                                             |         |                               |           |
| Hydromorphone                                                                                                                                                                                                                                                                                                                                                                              | 300     | Morphine                      | 120       |
| Codeine                                                                                                                                                                                                                                                                                                                                                                                    | 75      | Ethylmorphine                 | 75        |
| Hydrocodone                                                                                                                                                                                                                                                                                                                                                                                | 300     | Morphine<br>3-β-D-Glucuronide | 150       |
| Levorphanol                                                                                                                                                                                                                                                                                                                                                                                | 1,200   | Oxycodone                     | 75,000    |
| Normorphine                                                                                                                                                                                                                                                                                                                                                                                | 75,000  | Norcodeine                    | 18,700    |
| Oxymorphone                                                                                                                                                                                                                                                                                                                                                                                | 75,000  | Nalorphine                    | 30,000    |
| Thebaine                                                                                                                                                                                                                                                                                                                                                                                   | 6,000   | Diacetylmorphine (Heroin)     | 150       |
| 6-Monoacetylmorphine                                                                                                                                                                                                                                                                                                                                                                       | 75      |                               |           |
| <b>HYDROMORPHONE (HMO 250)</b>                                                                                                                                                                                                                                                                                                                                                             |         |                               |           |
| Hydromorphone                                                                                                                                                                                                                                                                                                                                                                              | 250     | Morphine                      | 100       |
| Codeine                                                                                                                                                                                                                                                                                                                                                                                    | 60      | Ethylmorphine                 | 60        |
| Hydrocodone                                                                                                                                                                                                                                                                                                                                                                                | 250     | Morphine<br>3-β-D-Glucuronide | 125       |
| Levorphanol                                                                                                                                                                                                                                                                                                                                                                                | 1,000   | Oxycodone                     | 62,500    |
| Normorphine                                                                                                                                                                                                                                                                                                                                                                                | 62,500  | Norcodeine                    | 15,600    |
| Oxymorphone                                                                                                                                                                                                                                                                                                                                                                                | 62,500  | Nalorphine                    | 25,000    |
| Thebaine                                                                                                                                                                                                                                                                                                                                                                                   | 5,000   | Diacetylmorphine (Heroin)     | 125       |
| 6-Monoacetylmorphine                                                                                                                                                                                                                                                                                                                                                                       | 60      |                               |           |
| <b>Effect of Urinary Specific Gravity</b>                                                                                                                                                                                                                                                                                                                                                  |         |                               |           |
| Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.005-1.045) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The Multi-Drug Rapid Test was tested in duplicate using fifteen drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results. |         |                               |           |
| <b>Effect of Urinary pH</b>                                                                                                                                                                                                                                                                                                                                                                |         |                               |           |
| The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with the Multi-Drug Rapid Test. The results demonstrate that varying ranges of pH do not interfere with the                                                              |         |                               |           |

performance of the test.

**Cross-Reactivity**

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or drug positive urine containing above related calibrator substances. The following compounds show no cross-reactivity when tested with the Multi-Drug Rapid Test at a concentration of 100 µg/mL.

**Non Cross-Reacting Compounds**

|                      |                        |                 |                                   |
|----------------------|------------------------|-----------------|-----------------------------------|
| Acetophenetidin      | Cortisone              | Zomepirac       | Quinidine                         |
| N-Acetylprocainamide | Creatinine             | Ketoprofen      | Quinine                           |
| Acetylsalicylic acid | Deoxycorticosterone    | Labelalol       | Salicylic acid                    |
| Aminopyrine          | Dextromethorphan       | Loperamide      | Serotonin                         |
| Amoxicillin          | Diclofenac             | Meprobamate     | Sulfamethazine                    |
| Ampicillin           | Diflunisal             | Isoxsuprine     | Sulindac                          |
| l-Ascorbic acid      | Digoxin                | d,l-Propranolol | Tetracycline                      |
| Apomorphine          | Diphenhydramine        | Nalidixic acid  | Tetrahydrocortisone,<br>3-acetate |
| Aspartame            | Ethyl-p-aminobenzoate  | Naproxen        | Tetrahydrocortisone               |
| Atropine             | β-Estradiol            | Niacinamide     | Tetrahydrozoline                  |
| Benzilic acid        | Estrone-3-sulfate      | Nifedipine      | Thiamine                          |
| Benzoic acid         | Erythromycin           | Norethindrone   | Thioridazine                      |
| Bilirubin            | Fenpropfen             | Noscapine       | Tributamide                       |
| d,l-Brompheniramine  | Furosemide             | d,l-Octopamine  | d,l-Tyrosine                      |
| Cannabidiol          | Gentisic acid          | Oxalic acid     | Tramadol                          |
| Chloral hydrate      | Hemoglobin             | Oxolinic acid   | Tributamide                       |
| Chloramphenicol      | Hydralazine            | Oxymetazoline   | Trifluoperazine                   |
| Chlorothiazide       | Hydrochlorothiazide    | Papaverine      | Trimethoprim                      |
| d,l-Chlorpheniramine | Hydrocortisone         | Penicillin-G    | d,l-Tryptophan                    |
| Chlorpromazine       | o-Hydroxyhippuric acid | Perphenazine    | Uric acid                         |
| Cholesterol          | 3-Hydroxytyramine      | Phenelzine      | Verapamil                         |
| Clonidine            | d,l-Isoproterenol      | Prednisone      |                                   |

**ALCOHOL PERFORMANCE CHARACTERISTICS**

The detection limit on the **Urine Alcohol Rapid Test** is from 0.02% to 0.30% for approximate relative blood alcohol level. The cutoff level of the **Urine Alcohol Rapid Test** can vary based on local regulations and laws. Test results can be compared to reference levels with color chart on the foil package.

**ALCOHOL ASSAY SPECIFICITY**

The **Urine Alcohol Rapid Test** will react with methyl, ethyl and allyl alcohols.

**ALCOHOL INTERFERING SUBSTANCES**

The following substances may interfere with the **Urine Alcohol Rapid Test** when using samples other than urine. The named substances do not normally appear in sufficient quantity in urine to interfere with the test.

- A. Agents which enhance color development
- Peroxidases
  - Strong oxidizers
- B. Agents which inhibit color development
- Reducing agents: Ascorbic acid, Tannic acid, Pyrogallol, Mercaptans and tosylates, Oxalic acid, Uric Acid
  - Bilirubin
  - L-dopa
  - L-methylidopa
  - Methampyrone

**BIBLIOGRAPHY**

1. Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company, 1986; 1735.
2. B. Cody, J.T., "Specimen Adulteration in drug urinalysis. Forensic Sci. Rev., 1990, 2:63.
3. C. Tsai, S.C. et.al., J. Anal. Toxicol. 1998; 22 (6): 474
4. Hawks RL, CN Chiang. *Urine Testing for Drugs of Abuse*. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.
5. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 6th Ed. Biomedical Publ., Foster City, CA 2002.

**INDEX OF SYMBOLS**

|  |                                    |
|--|------------------------------------|
|  | In vitro diagnostic medical device |
|  | Temperature limit                  |
|  |                                    |

**Instruction Sheet for testing of any combination of the following drugs:**

**AMP/BAR/BZO/BUP/COC/THC/MTD/MET/MDMA/MOP/OPI/PPX/TCA/OXY/EDDP/COT/TML/FYL/MDPV/K2/PCP/KET/LS/MDMA**

*A rapid test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in human whole blood or serum or plasma, For healthcare professionals including professionals at point of care sites. Immunoassay for in vitro diagnostic use only.*

**INTENDED USE**

The Multi-Drug Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in whole blood or serum or plasma at the following cut-off concentrations:

| Test                                                     | Calibrator                                        | Cut-off (ng/mL) |
|----------------------------------------------------------|---------------------------------------------------|-----------------|
| Amphetamine (AMP)                                        | d-Amphetamine                                     | 80/50           |
| Barbiturates (BAR)                                       | Secobarbital                                      | 100             |
| Benzodiazepines (BZO)                                    | Oxazepam                                          | 100             |
| Buprenorphine (BUP)                                      | Buprenorphine                                     | 5/10            |
| Cocaine (COC)                                            | Benzoylcegonine                                   | 50              |
| Marijuana (THC)                                          | 11-nor-Δ9-THC-9 COOH                              | 35/12           |
| Methadone (MTD)                                          | Methadone                                         | 40              |
| Methamphetamine (MET)                                    | d-Methamphetamine                                 | 70              |
| Methylenedioxyamphetamine (MDMA)                         | d,l-Methylenedioxyamphetamine                     | 50              |
| Morphine (MOP/OPI)                                       | Morphine                                          | 40              |
| Propoxyphene (PPX)                                       | Propoxyphene                                      | 100             |
| Tricyclic Antidepressants (TCA)                          | Nortriptyline                                     | 300             |
| Oxycodone (OXY)                                          | Oxycodone                                         | 20              |
| 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP) | 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine | 50              |
| Cotinine(COT10)                                          | Cotinine                                          | 10              |
| Cotinine(COT100)                                         | Cotinine                                          | 100             |
| Tramadol(TML50)                                          | Cis-Tramadol                                      | 50              |
| Fentanyl(FYL)                                            | Norfentanyl                                       | 15              |
| 3,4-methylenedioxypropylvalerone(MDPV)                   | 3,4-methylenedioxypropylvalerone                  | 300             |
| Synthetic Marijuana(K2)                                  | JWH-018,JWH-073                                   | 100             |
| Phencyclidine(PCP)                                       | Phencyclidine                                     | 20              |
| Ketamine(KET)                                            | Ketamine                                          | 200             |
| Lysergic acid diethylamide (LSD)                         | Lysergic Acid Diethylamide                        | 20              |
| 3,4-Methylenedioxyamphetamine (MDA)                      | 3,4-Methylenedioxyamphetamine                     | 80              |

Configurations of the Multi-Drug Rapid Test Cassette come with any combination of the above listed drug analytes. This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

The test results can be used to provide evidence and basis for therapy and treatment plans of drug dependence and toxic psychosis. For laboratory professional in vitro diagnostic use only. The Multi-Drug Rapid Test Cassette (Whole Blood/Serum/Plasma) should only be performed by health professionals in a clinical/hospital setting to aid in screening of drug of abuse to determine the follow-up treatment measures in combination of clinical symptoms.

**SUMMARY**

The Multi-Drug Rapid Test Cassette is a rapid test in whole blood or serum or plasma screening test that can be performed without the use of an instrument.<sup>1</sup> The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in whole blood or serum or plasma.

**Amphetamine (AMP)**  
Amphetamine is a Schedule II controlled substance available by prescription (Dexedrine®) and is also available on the illicit market. Amphetamines are a class of potent sympathomimetic agents with therapeutic applications. They are chemically related to the human body's natural catecholamines: epinephrine and norepinephrine. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Amphetamines include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, and psychotic behavior. The effects of Amphetamines generally last 2-4 hours following use, and the drug has a half-life of 4-24 hours in the body. About 30% of Amphetamines are excreted in the whole blood or serum or plasma in unchanged form, with the remainder as hydroxylated and deaminated derivatives. The Multi-Drug Rapid Test Cassette yields a positive result when the concentration of amphetamines in whole blood/serum/plasma exceeds 80ng/mL.

**Barbiturates (BAR)**  
Barbiturates are CNS depressants. They are used therapeutically as sedatives, hypnotics, and anticonvulsants barbiturates are almost always taken orally as capsules or tablets. The effects resemble those of intoxication with alcohol. Chronic use of barbiturates leads to tolerance and physical dependence.

Short-acting barbiturates taken at 400mg/day for 2-3 months can produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death.

Only a small amount (less than 5%) of most barbiturates are excreted unaltered in the whole blood or serum or plasma.

The approximate detection time limits for barbiturates are:  
Short acting (e.g. Secobarbital) 100 mg PO (oral) 4.5 days  
Long acting (e.g. Phenobarbital) 400 mg PO (oral) 7 days<sup>2</sup>  
The Multi-Drug Rapid Test Cassette yields a positive result when the concentration of barbiturates in whole blood/serum/plasma exceeds 100ng/mL.

**Benzodiazepines (BZO)**  
Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors involving a neurochemical called gamma aminobutyric acid (GABA). Because they are safer and more effective, benzodiazepines have replaced barbiturates in the treatment of both anxiety and insomnia. Benzodiazepines are also used as sedatives before some surgical and medical procedures, and for the treatment of seizure disorders and alcohol withdrawal. Risk of physical dependence increases if benzodiazepines are taken regularly (e.g. daily) for more than a few months, especially at higher than normal doses. Stopping abruptly can bring on such symptoms as trouble sleeping, gastrointestinal upset, feeling unwell, loss of appetite, sweating, trembling, weakness, anxiety and changes in perception.

Only trace amounts (less than 1%) of most benzodiazepines are excreted unaltered in the whole blood or serum or plasma; most of the concentration in whole blood/serum/plasma is conjugated drug. The detection period for benzodiazepines in whole blood/serum/plasma is 3-7 days. The Multi-Drug Rapid Test Cassette yields a positive result when the concentration of benzodiazepines in whole blood/serum/plasma exceeds 100ng/mL.

**Buprenorphine (BUP)**  
Buprenorphine is a potent analgesic often used in the treatment of opioid addiction. The drug is sold under the trade names Subutex™, Buprenex™, Temgesic™ and Suboxone™, which contain Buprenorphine HCl alone or in combination with Naloxone HCl. Therapeutically, Buprenorphine is used as a substitution treatment for opioid addicts. Substitution treatment is a form of medical care offered to opiate addicts (primarily heroin addicts) based on a similar or identical substance to the drug normally used. In substitution therapy, Buprenorphine is as effective as Methadone but demonstrates a lower level of physical dependence. Concentrations of free Buprenorphine and Norbuprenorphine in

whole blood or serum or plasma may be less than 1 ng/mL after therapeutic administration, but can range up to 20 ng/mL in abuse situations. The plasma half life of Buprenorphine is 2-4 hours.<sup>3</sup> While complete elimination of a single dose of the drug can take as long as 6 days, the window of detection for the parent drug in whole blood/serum/plasma is thought to be approximately 3 days.

Substantial abuse of Buprenorphine has also been reported in many countries where various forms of the drug are available. The drug has been diverted from legitimate channels through theft, doctor shopping, and fraudulent prescriptions, and been abused via intravenous, sublingual, intranasal and inhalation routes.

The Multi-Drug Rapid Test Cassette yields a positive result when the Buprenorphine in whole blood/serum/plasma exceeds 5ng/mL.

**Cocaine (COC)**  
Cocaine is a potent central nervous system stimulant and a local anesthetic. Initially, it brings about extreme energy and restlessness while gradually resulting in tremors, over-sensitivity and spasms. In large amounts, cocaine causes fever, unresponsiveness, difficulty in breathing and unconsciousness. Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. It is excreted in the whole blood/serum/plasma in a short time primarily as benzoylecgonine.<sup>4,5</sup> Benzoylecgonine, a major metabolite of cocaine, has a longer biological half-life (5-8 hours) than cocaine (0.5-1.5 hours), and can generally be detected for 24-48 hours after cocaine exposure.<sup>5</sup> The Multi-Drug Rapid Test Cassette yields a positive result when the concentration of benzoylecgonine in whole blood/serum/plasma exceeds 50 ng/mL.

**Marijuana (THC)**  
THC (Δ9-tetrahydrocannabinol) is the primary active ingredient in cannabis (marijuana). When smoked or orally administered, THC produces euphoric effects. Users have impaired short-term memory and slowed learning. They may also experience transient episodes of confusion and anxiety. Long-term, relatively heavy use may be associated with behavioral disorders. The peak effect of marijuana administered by smoking occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette. Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 3-10 days after smoking. The main metabolite excreted in the whole blood/serum/plasma is 11-nor-Δ9-tetrahydrocannabinol-9-carboxylic acid. The Multi-Drug Rapid Test Cassette yields a positive result when the concentration of THC-COOH in whole blood/serum/plasma exceeds 35ng/mL.

**Methadone (MTD)**  
Methadone is a narcotic analgesic prescribed for the management of moderate to severe pain and for the treatment of opiate dependence (heroin, Vicodin, Percocet, morphine). The pharmacology of oral methadone is very different from IV methadone. Oral methadone is partially stored in the liver for later use. IV methadone acts more like heroin. In most states you must go to a pain clinic or a methadone maintenance clinic to beprescribed methadone. Methadone is a long acting pain reliever producing effects that last from twelve to forty-eight hours. Ideally, methadone frees the client from the pressures of obtaining illegal heroin, from the dangers of injection, and from the emotional roller coaster that most opiates produce. Methadone, if taken for long periods and at large doses, can lead to a very long withdrawal period. The withdrawals from methadone are more prolonged and troublesome than those provoked by heroin cessation, yet the substitution and phased removal of methadone is an acceptable method of detoxification for patients and therapists.<sup>6</sup>

The Multi-Drug Rapid Test Cassette yields a positive result when the concentration of methadone in whole blood/serum/plasma exceeds 40ng/mL.

**Methamphetamine (MET)**  
Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to Amphetamine, but the central nervous system effects of Methamphetamine are greater. Methamphetamine is made in illegal laboratories and has a high potential for abuse and dependence. The drug can be taken orally, injected, or inhaled. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Methamphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, psychotic behavior, and eventually, depression and exhaustion.

The effects of Methamphetamine generally last 2-4 hours and the drug have a half-life of 9-24 hours in the body. Methamphetamine is excreted in the whole blood/serum/plasma primarily as Amphetamine, and oxidized and deaminated derivatives. However, 10-20% of Methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the whole blood/serum/plasma indicates Methamphetamine use. Methamphetamine is generally detectable in the whole blood/serum/plasma for 3-5 days, depending on whole blood/serum/plasma pH level.

The Multi-Drug Rapid Test Cassette yields a positive result when the Methamphetamine in whole blood/serum/plasma exceeds 70ng/mL.

**Methylenedioxyamphetamine (MDMA)**  
Methylenedioxyamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity.<sup>7</sup> Those who take the drug frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly a stimulant, although it has, in common with amphetamine drugs, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of increased sensitivity to light, difficulty in focusing, and blurred vision in some users. Its mechanism of action is thought to be via release of the neurotransmitter serotonin. MDMA may also release dopamine, although the general opinion is that this is a secondary effect of the drug (Nichols and Oberlander, 1990). The most pervasive effect of MDMA, occurring in virtually all people who took a reasonable dose of the drug, was to produce a clenching of the jaws.

The Multi-Drug Rapid Test Cassette yields a positive result when the concentration of Methylenedioxyamphetamine in whole blood/serum/plasma exceeds 50ng/mL.

**Morphine (MOP/OPI)**  
Opiate refers to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semi-synthetic drugs such as heroin. Opioid is more general, referring to any drug that acts on the opioid receptor.

Opioid analgesics comprise a large group of substances which control pain by depressing the CNS. Large doses of morphine can produce higher tolerance levels, physiological dependency in users, and may lead to substance abuse. Morphine is excreted unmetabolized, and is also the major metabolic product of codeine and heroin. Morphine is detectable in the whole blood/serum/plasma for several days after an opiate dose.<sup>8</sup>

The Multi-Drug Rapid Test Cassette yields a positive result when the concentration of morphine in whole blood/serum/plasma exceeds 40ng/mL.

**Propoxyphene (PPX)**  
Propoxyphene (PPX) is a narcotic analgesic compound bearing structural similarity to methadone. As an analgesic, propoxyphene can be from 50-75% as potent as oral codeine. Darvocet™, one of the most common brand names for the drug, contains 50-100 mg of propoxyphene napsylate and 325-650 mg of acetaminophen. Peak plasma concentrations of propoxyphene are achieved from 1 to 2 hours post dose. In the case of overdose, propoxyphene blood concentrations can reach significantly higher levels.

In humans, propoxyphene is metabolized by N-demethylation to yield norpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than parent propoxyphene (6 to 12 hours).The accumulation of norpropoxyphene seen with repeated doses may be largely responsible for resultant toxicity.

The Multi-Drug Rapid Test Cassette yields a positive result when the concentration of Propoxyphene or Norpropoxyphene in whole blood/serum/plasma exceeds 100ng/mL.

**Tricyclic Antidepressants (TCA)**  
TCA (Tricyclic Antidepressants) are commonly used for the treatment of depressive disorders. TCA overdoses can result in profound CNS depression, cardiotoxicity and anticholinergic effects. TCA overdose is the most common cause of death from prescription drugs. TCAs are taken orally or sometimes by injection. TCAs are metabolized in the liver. Both TCAs and their metabolites are excreted in whole blood/serum/plasma mostly in the form of metabolites for up to ten days. The Multi-Drug Rapid Test Cassette yields a positive result when the concentration of tricyclic antidepressants in whole blood/serum/plasma exceeds 100ng/mL.

**Oxycodone (OXY)**

Oxycodone is a semi-synthetic opioid with a structural similarity to codeine. The drug is manufactured by modifying thebaine, an alkaloid found in the opium poppy. Oxycodone, like all opiate agonists, provides pain relief by acting on opioid receptors in the spinal cord, brain, and possibly directly in the affected tissues. Oxycodone is prescribed for the relief of moderate to high pain under the well-known pharmaceutical trade names of OxyContin®, Tylox®, Percodan® and Percocet®. While Tylox®, Percodan® and Percocet® contain only small doses of oxycodone hydrochloride combined with other analgesics such as acetaminophen or aspirin, OxyContin consists solely of oxycodone hydrochloride in a time-release form. Oxycodone is known to metabolize by demethylation into oxymorphone and noroxycodone. In a 24-hour whole blood or serum or plasma, 33-61% of a single, 5 mg oral dose is excreted with the primary constituents being unchanged drug (13-19%), conjugated drug (7-29%) and conjugated oxymorphone (13-14%). The window of detection for Oxycodone in whole blood/serum/plasma is expected to be similar to that of other opioids such as morphine. The Multi-Drug Rapid Test Cassette yields a positive result when Oxycodone in whole blood/serum/plasma exceeds 20ng/mL.

**2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)**  
Methadone is an unusual drug in that its primary urinary metabolites (EDDP and EMDP) are cyclic in structure, making them very difficult to detect using immunoassays targeted to the native compound.<sup>9</sup>Exacerbating this problem, there is a subsection of the population classified as “extensive metabolizers” of methadone. In these individuals, a whole blood or serum or plasma specimen may not contain enough parent methadone to yield a positive drug screen even if the individual is in compliance with their methadone maintenance. EDDP represents a better whole blood or serum or plasma marker for methadone maintenance than unmetabolized methadone. The Multi-Drug Rapid Test Cassette yields a positive result when the concentration of EDDP in whole blood/serum/plasma exceeds 50ng/mL.

**Cotinine (COT10)**  
Cotinine is the first-stage metabolite of nicotine, a toxic alkaloid that produces stimulation of the autonomic ganglia and central nervous system when in humans. Nicotine is a drug to which virtually every member of a tobacco-smoking society is exposed whether through direct contact or second-hand inhalation. In addition to tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as nicotine gum, transdermal patches and nasal sprays. In a 24-hour whole blood/serum/plasma, approximately 5% of a nicotine dose is excreted as unchanged drug with 10% as cotinine and 35% as hydroxy cotinine; the concentrations of other metabolites are believed to account for less than 5%.<sup>10</sup> While cotinine is thought to be an inactive metabolite, it's elimination profile is more stable than that of nicotine which is largely whole blood/serum/plasma pH dependent. As a result, cotinine is considered a good biological marker for determining nicotine use. The plasma half-life of nicotine is approximately 60 minutes following inhalation or parental administration.<sup>11</sup> Nicotine and cotinine are rapidly eliminated by the kidney; the window of detection for cotinine in whole blood/serum/plasma at a cutoff level of 100 ng/mL is expected to be up to 2-3 days after nicotine use.

The COT Rapid Test Cassette (whole blood/serum/plasma) is a rapid whole blood/serum/plasma -screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Cotinine in whole blood or serum or plasma. The COT Rapid Test Cassette (whole blood/serum/plasma) yields a positive result when the Cotinine in whole blood/serum/plasma exceeds the cut-off level (10ng/mL).

**Cotinine (COT100)**  
The Cotinine assay contained within the Multi-Drug Rapid Test Cassette yields a positive result when the Cotinine concentration in whole blood/serum/plasma exceeds 100ng/mL. See Cotinine (COT10ng) for the summary.

**Tramadol (TML)**  
Tramadol (TML) is a quasi-narcotic analgesic used in the treatment of moderate to severe pain. It is a synthetic analog of codeine, but has a low binding affinity to the mu-opioid receptors. Large doses of tramadol can develop tolerance and physiological dependency and lead to its abuse. Tramadol is extensively metabolized after oral administration. Approximately 30% of the dose is excreted in whole blood or serum or plasma as unchanged drug, whereas 60% is excreted as metabolites. The major pathways appear to be N- and O- demethylation, glucuronidation or sulfation in the liver. The Multi-Drug Rapid Test Cassette yields a positive result when the concentration of TML in whole blood/serum/plasma exceeds 50ng/mL.

**Fentanyl (FYL)**  
Fentanyl, belongs to powerful narcotics analgesics, and is a μ special opiates receptor stimulant. Fentanyl is one of the varieties that been listed in management of United Nations “Single Convention of narcotic drug in 1961”. Among the opiates agents that under international control, fentanyl is one of the most commonly used to cure moderate to severe pain.1 After continuous injection of fentanyl, the sufferer will have the performance of protracted opioid abstinence syndrome, such as ataxia and irritability etc.<sup>10,11</sup>, which presents the addiction after taking fentanyl in a long time. Compared with drug addicts of amphetamine, drug addicts who take fentanyl mainly have got the possibility of higher infection rate of HIV, more dangerous injection behavior and more lifelong medication overdose<sup>12</sup>.

The FYL Rapid Test Cassette (whole blood/serum/plasma) is a rapid whole blood/serum/plasma screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Norfentanyl in whole blood/serum/plasma. The FYL Rapid Test Cassette (whole blood/serum/plasma) yields a positive result when Norfentanyl in whole blood/serum/plasma exceeds 15ng/mL.

**3,4-methylenedioxypropylvalerone (MDPV)**  
3, 4-methylenedioxypropylvalerone (MDPV) is a psychoactive recreational drug with stimulant properties which acts as a norepinephrine-dopamine reuptake inhibitor (NDRI). It was first developed in the 1960s by a team at Boehringer Ingelheim. MDPV remained an obscure stimulant until around 2004 when it was reportedly sold as a designer drug. Products labeled as bath salts containing MDPV were previously sold as recreational drugs in gas stations and convenience stores in the United States, similar to the marketing for Spice and K2 as incense.

MDPV is the 3,4-methylenedioxy ring-substituted analog of the compound pyrovalerone, developed in the 1960s, which has been used for the treatment of chronic fatigue and as an anorectic, but caused problems of abuse and dependence. However, despite its structural similarity, the effects of MDPV bear little resemblance to other methylenedioxy phenylalkylamine derivatives such as 3,4-methylenedioxy-N-methylamphetamine (MDMA), instead producing primarily stimulant effects with only mild entactogenic qualities.

MDPV undergoes CYP450 2D6, 2C19, 1A2, and COMT phase 1 metabolism (liver) into methylcatechol and pyrrolidine, which in turn, are glucuronated (uridine 5'-diphospho-glucuronosyl-transferase) allowing it to be excreted by the kidneys, with only a small fraction of the metabolites being excreted into the stools. No free pyrrolidine will be detected in the whole blood/serum/plasma.

The MDPV Rapid Test Cassette is a rapid blood screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of 3,4-methylenedioxypropylvalerone in whole blood or serum or plasma. The MDPV Rapid Test Cassette yields a positive result when 3,4-methylenedioxypropylvalerone in whole blood/serum/plasma exceeds 300ng/mL.

**Synthetic Marijuana (K2)**  
Synthetic Marijuana or K2 is a psychoactive herbal and chemical product that, when consumed, mimics the effects of Marijuana. It is best known by the brand names K2 and Spice, both of which have largely become genericized trademarks used to refer to any synthetic Marijuana product. The studies suggest that synthetic marijuana intoxication is associated with acute psychosis, worsening of previously stable psychotic disorders, and also may have the ability to trigger a chronic (long-term) psychotic disorder among vulnerable individuals such as those with a family history of mental illness. Elevated levels of whole blood/serum/plasma metabolites are found within hours of exposure and remain detectable window up to 24-48 hours after smoking (depending on usage/dosage). The K2 assay contained within the Multi-Drug Rapid Test Cassette yields a positive result when the K2 concentration in whole blood/serum/plasma exceeds 100ng/mL.

**Phencyclidine (PCP)**  
Phencyclidine, the hallucinogen commonly referred to as Angel Dust, can be detected in whole blood/serum/plasma as a result of the exchange of the drug between the circulatory system and the oral cavity. In a paired serum and whole blood/serum/plasma collection of 100 patients in an Emergency

Department, PCP was detected in the whole blood/serum/plasma of 79 patients at levels as low as 2ng/mL and as high as 600ng/mL. The PCP assay contained within the Multi-Drug Rapid Test Cassette yields a positive result when the PCP concentration in whole blood/serum/plasma exceeds 20ng/mL.

**Ketamine (KET)**  
Ketamine is a dissociative anesthetic developed in 1963 to replace PCP (Phencyclidine). While Ketamine is still used in human anesthesia and veterinary medicine, it is becoming increasingly abused as a street drug. Ketamine is molecularly similar to PCP and thus creates similar effects including numbness, loss of coordination, sense of invulnerability, muscle rigidity, aggressive/violent behavior, slurred or blocked speech, exaggerated sense of strength, and a blank state. There is depression of respiratory function but not of the central nervous system, and cardiovascular function is maintained. The effects of Ketamine generally last 4-6 hours following use. The KET assay contained within the Multi-Drug Rapid Test cassette yields a positive result when the KET concentration in whole blood/serum/plasma exceeds 50ng/mL.

**Lysergic acid diethylamide (LSD)**  
Lysergic acid diethylamide (LSD) is a white powder or a clear, colorless liquid. LSD is manufactured from lysergic acid which occurs naturally in the ergot fungus that grows on wheat and rye. It is a Schedule I controlled substance, available in liquid, powder, tablet (microdots), and capsule form. LSD is recreationally used as a hallucinogen for its ability to alter human perception and mood. LSD is primarily used by oral administration, but can be inhaled, injected, and transdermally applied. LSD is a non-selective 5-HT agonist, may exert its hallucinogenic effect by interacting with 5-HT 2 A receptors as a partial agonist and modulating the NMDA receptor-mediated sensory, perceptual, affective and cognitive processes. LSD mimics 5-HT at 5-HT 1A receptors, producing a marked slowing of the firing rate of serotonergic neurons. LSD has a plasma half-life of 2.5-4 hours. Metabolites of LSD include N-desmethyl-LSD, hydroxy-LSD, 2-oxo-LSD, and 2-oxo-3-hydroxy-LSD .These metabolites are all inactive.

The LSD Rapid Test Cassette (whole blood/serum/plasma) is a rapid whole blood/serum/plasma screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Lysergic Acid Diethylamide in whole blood/serum/plasma. The LSD Rapid Test Cassette (whole blood/serum/plasma)yields a positive result when Lysergic Acid Diethylamide in whole blood/serum/plasma exceeds 20 ng/mL.

**3,4-Methylenedioxyamphetamine (MDA)**  
3,4-Methylenedioxyamphetamine (MDA), also known as tenamfetamine (INN), or with the street name "Sally" or "Sass" or "Sass-a-frass", is a psychedelic and entactogenic drug of the phenethylamine and amphetamine chemical classes. It is mainly used as a recreational drug, an entogen, and a tool in use to supplement various types of practices for transcendence, including in meditation, psychoautics, and as an agent in psychedelic psychotherapy. It was first synthesized by G. Mannish and W. Jacobson in 1910. There are about 20 different synthetic routes described in the literature for its preparation.

The MDA Rapid Test Cassette (whole blood/serum/plasma) is a rapid whole blood/serum/plasma screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of 3,4-Methylenedioxyamphetamine in whole blood/serum/plasma. The MDA Rapid Test Cassette (whole blood/serum/plasma) yields a positive result when Amphetamines in whole blood/serum/plasma exceed 80 ng/mL.

**PRINCIPLE**

During testing, a whole blood/serum/plasma specimen migrates upward by capillary action. A drug, if present in the whole blood/serum/plasma specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test region of the specific drug cassette. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test region.

A drug-positive whole blood/serum/plasma specimen will not generate a colored line in the specific test region of the cassette because of drug competition, while a drug-negative whole blood/serum/plasma specimen will generate a line in the test region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

**REAGENTS**

Each test line contains anti-drug mouse monoclonal antibody and corresponding drug-protein conjugates. The control line system contains goat anti-rabbit IgG polyclonal antibodies and rabbit IgG.

**PRECAUTIONS**

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

**STORAGE AND STABILITY**

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30 °C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

**SPECIMEN COLLECTION AND PREPARATION**

- The Multi-Drug Rapid Test Cassette can be performed using whole blood or serum or plasma (from venipuncture or fingerstick).
- To collect **Fingerstick Whole blood specimens:**
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the Fingerstick Whole blood specimen to the test by using **a capillary tube:**
    - Touch the end of the capillary tube to the blood until filled to approximately 40µL. Avoid air bubbles.
    - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen area of the test cassette.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. For long term storage, specimens should be kept below -20 °C. Whole blood collected by venipuncture should be stored at 2-8 °C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

**MATERIALS**

**Materials Provided**

- Test cassettes
- Droppers
- Buffer
- Package insert
- Materials Required But Not Provided**
- Specimen collection containers
- Centrifuge
- Lancets (for fingerstick whole blood only)
- Timer

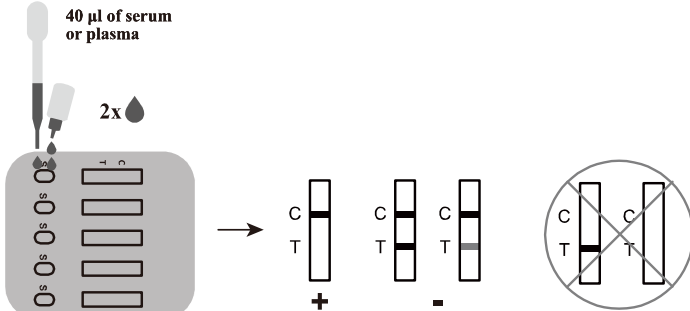
• Deparized capillary tubes and dispensing bulb (for fingerstick whole blood only)

**DIRECTIONS FOR USE**

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30 °C) prior to testing.

**For serum or plasma specimen:**

- Bring the pouch to room temperature (15-30°C) before opening it. Remove the cassette from the sealed pouch and use it within one hour.
- Place the cassette on a clean and level surface. Hold the dropper vertically and transfer 1 full drop of serum or plasma (approximately 40µL), then add 2 drops of buffer (approximately 80 µL) to the specimen well of the cassette, and then start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.
- Wait for the colored line(s) to appear. **Read the result at 5 minutes** when testing a serum or plasma specimen. Do not interpret the result after 10 minutes.



**For whole blood specimen:**

- Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within one hour.
- Place the cassette on a clean and level surface.

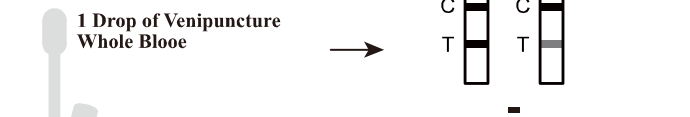
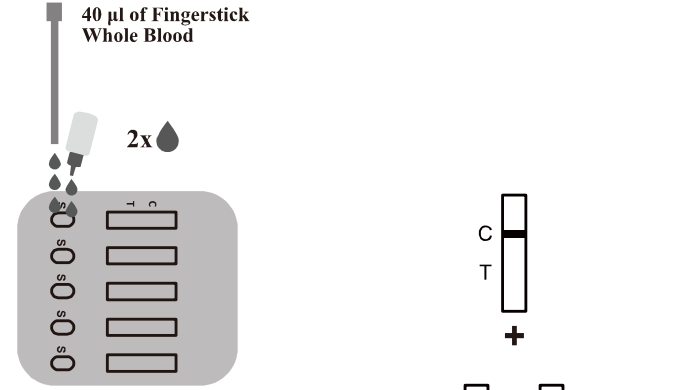
**For Venipuncture Whole blood specimen:**

Hold the dropper vertically and transfer 1 drop of whole blood (approximately 40 µL) to the specimen well, then add 2 drops of buffer (approximately 80 µL), and start the timer. See illustration below.

**For Fingerstick Whole blood specimen:**

To use a capillary tube: Fill the capillary tube and transfer approximately 40µL of fingerstick whole blood specimen to the specimen area of test cassette, then add 2 drops of buffer (approximately 80 µL) and start the timer. See illustration below.

- Wait for the colored line(s) to appear. **Read results at 5 minutes.** Do not interpret the result after 10 minutes.



**INTERPRETATION OF RESULTS**

(Please refer to the illustration above)

**NEGATIVE:** A colored line appears in the Control region (C) and colored lines appears in the Test region (T). This negative result means that the concentrations in the whole blood/serum/plasma sample are below the designated cut-off levels for a particular drug tested.

**\*NOTE:** The shade of the colored lines(s) in the Test region (T) may vary. The result should be considered negative whenever there is even a faint line.

**POSITIVE:** A colored line appears in the Control region (C) and NO line appears in the Test region (T). The positive result means that the drug concentration in the whole blood/serum/plasma is greater than the designated cut-off for a specific drug.

**INVALID:** No line appears in the Control region (C). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for Control line failure. Read the directions again and repeat the test with a new test card. If the result is still invalid, contact your manufacturer.

**QUALITY CONTROL**

A procedural control is included in the test. A colored line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

**LIMITATIONS**

- The Multi-Drug Rapid Test Cassette (whole blood/serum/plasma) provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed

- result. Gas chromatography/ mass spectrometry (GC/MS) is the preferred confirmatory method<sup>13,14</sup>
- It is possible that technical or procedural errors, as well as other interfering substances in the whole blood or serum or plasma specimen may cause erroneous results.
- A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in whole blood or serum or plasma.
- A negative result may not necessarily indicate drug-free whole blood/serum/plasma. Negative results can be obtained when drug is present but below the cut-off level of the test.
- Test does not distinguish between drugs of abuse and certain medications.

**PERFORMANCE CHARACTERISTICS**

**Accuracy**

A side-by-side comparison was conducted using the Multi-Drug Rapid Test Cassette and commercially available drug rapid tests. Testing was performed on approximately 90 specimens per drug type previously collected from subjects presenting for Drug Screen Testing. Except TML who was 97 specimens. Presumptive positive results were confirmed by GC/MS.

**Clinic Result of Whole Blood**

| Method                         | GC/MS    | Positive | Negative | % agreement with GC/MS |
|--------------------------------|----------|----------|----------|------------------------|
| Multi-Drug Rapid Test Cassette | Positive | 20       | 1        | 95.2%                  |
| AMP                            | Positive | 20       | 1        | 95.2%                  |
|                                | Negative | 1        | 68       | 98.6%                  |
| BAR                            | Positive | 20       | 2        | 90.9%                  |
|                                | Negative | 2        | 66       | 97.1%                  |
| BZO                            | Positive | 19       | 2        | 90.5%                  |
|                                | Negative | 2        | 67       | 97.1%                  |
| BUP                            | Positive | 21       | 2        | 95.5%                  |
|                                | Negative | 1        | 66       | 97.1%                  |
| COC                            | Positive | 25       | 1        | 96.2%                  |
|                                | Negative | 1        | 63       | 98.4%                  |
| THC                            | Positive | 24       | 1        | 92.3%                  |
|                                | Negative | 2        | 63       | 98.4%                  |
| MTD                            | Positive | 19       | 2        | 95.0%                  |
|                                | Negative | 1        | 68       | 97.1%                  |
| MET                            | Positive | 25       | 2        | 92.6%                  |
|                                | Negative | 2        | 61       | 96.8%                  |
| MDMA                           | Positive | 20       | 2        | 90.9%                  |
|                                | Negative | 2        | 66       | 97.1%                  |
| MOP/OPI                        | Positive | 23       | 2        | 92.0%                  |
|                                | Negative | 2        | 63       | 96.9%                  |
| PPX                            | Positive | 24       | 2        | 96.0%                  |
|                                | Negative | 1        | 63       | 96.9%                  |
| TCA                            | Positive | 23       | 2        | 92.0%                  |
|                                | Negative | 2        | 63       | 96.9%                  |
| OXY                            | Positive | 27       | 2        | 93.1%                  |
|                                | Negative | 2        | 59       | 96.7%                  |
| COT 100                        | Positive | 23       | 1        | 92.0%                  |
|                                | Negative | 2        | 64       | 98.5%                  |
| COT 10                         | Positive | 23       | 2        | 95.8%                  |
|                                | Negative | 1        | 64       | 97.0%                  |
| EDDP                           | Positive | 18       | 2        | 90.0%                  |
|                                | Negative | 2        | 68       | 97.1%                  |
| TML                            | Positive | 19       | 1        | 90.5%                  |
|                                | Negative | 2        | 75       | 98.7%                  |
| MDPV                           | Positive | 18       | 3        | 90.0%                  |
|                                | Negative | 2        | 67       | 95.7%                  |
| FYL                            | Positive | 24       | 1        | 92.3%                  |
|                                | Negative | 2        | 63       | 98.4%                  |
| K2                             | Positive | 21       | 2        | 91.3%                  |
|                                | Negative | 2        | 65       | 97.0%                  |
| PCP                            | Positive | 21       | 1        | 95.5%                  |
|                                | Negative | 1        | 67       | 98.5%                  |
| KET                            | Positive | 24       | 3        | 92.3%                  |
|                                | Negative | 2        | 61       | 95.3%                  |
| LSD                            | Positive | 20       | 1        | 95.2%                  |
|                                | Negative | 1        | 69       | 98.6%                  |
| MDA                            | Positive | 23       | 1        | 95.8%                  |
|                                | Negative | 1        | 68       | 98.6%                  |

**Clinic Result of Serum or Plasma**

| Method                         | GC/MS    | Positive | Negative | % agreement with GC/MS |
|--------------------------------|----------|----------|----------|------------------------|
| Multi-Drug Rapid Test Cassette | Positive | 20       | 1        | 95.2%                  |
| AMP                            | Positive | 20       | 1        | 95.2%                  |
|                                | Negative | 1        | 68       | 98.6%                  |
| BAR                            | Positive | 20       | 2        | 90.9%                  |
|                                | Negative | 2        | 66       | 97.1%                  |
| BZO                            | Positive | 19       | 2        | 90.5%                  |
|                                | Negative | 2        | 67       | 97.1%                  |
| BUP                            | Positive | 21       | 2        | 95.5%                  |
|                                | Negative | 1        | 66       | 97.1%                  |
| COC                            | Positive | 25       | 1        | 96.2%                  |
|                                | Negative | 1        | 63       | 98.4%                  |
| THC                            | Positive | 24       | 1        | 92.3%                  |
|                                | Negative | 2        | 63       | 98.4%                  |
| MTD                            | Positive | 19       | 2        | 95.0%                  |
|                                | Negative | 1        | 68       | 97.1%                  |
| MET                            | Positive | 25       | 2        | 92.6%                  |
|                                | Negative | 2        | 61       | 96.8%                  |
| MDMA                           | Positive | 20       | 2        | 90.9%                  |
|                                | Negative | 2        | 66       | 97.1%                  |
| MOP/OPI                        | Positive | 23       | 2        | 92.0%                  |
|                                | Negative | 2        | 63       | 96.9%                  |
| PPX                            | Positive | 24       | 2        | 96.0%                  |
|                                | Negative | 1        | 63       | 96.9%                  |
| TCA                            | Positive | 23       | 2        | 92.0%                  |
|                                | Negative | 2        | 63       | 96.9%                  |
| OXY                            | Positive | 27       | 2        | 93.1%                  |
|                                | Negative | 2        | 59       | 96.7%                  |
| COT 100                        | Positive | 23       | 1        | 92.0%                  |
|                                | Negative | 2        | 64       | 98.5%                  |
| COT 10                         | Positive | 23       | 2        | 95.8%                  |
|                                | Negative | 1        | 64       | 97.0%                  |
| EDDP                           | Positive | 18       | 2        | 90.0%                  |
|                                | Negative | 2        | 68       | 97.1%                  |
| TML                            | Positive | 19       | 1        | 90.5%                  |
|                                | Negative | 2        | 75       | 98.7%                  |
| MDPV                           | Positive | 18       | 3        | 90.0%                  |
|                                | Negative | 2        | 67       | 95.7%                  |

| Method                         | GC/MS    | Positive | Negative | % agreement with GC/MS |
|--------------------------------|----------|----------|----------|------------------------|
| Multi-Drug Rapid Test Cassette | Positive | 24       | 1        | 92.3%                  |
| FYL                            | Positive | 24       | 1        | 92.3%                  |
|                                | Negative | 2        | 63       | 98.4%                  |
| K2                             | Positive | 21       | 2        | 91.3%                  |
|                                | Negative | 2        | 65       | 97.0%                  |
| PCP                            | Positive | 21       | 1        | 95.5%                  |
|                                | Negative | 1        | 67       | 98.5%                  |
| KET                            | Positive | 24       | 3        | 92.3%                  |
|                                | Negative | 2        | 61       | 95.3%                  |
| LSD                            | Positive | 20       | 1        | 95.2%                  |
|                                | Negative | 1        | 69       | 98.6%                  |
| MDA                            | Positive | 23       | 1        | 95.8%                  |
|                                | Negative | 1        | 68       | 98.6%                  |

**Precision**

A study was conducted at three hospitals by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical card of coded specimens, containing drugs at concentrations of ± 50% cut-off level, was labeled, blinded and tested at each site. The results are given below:

**AMPHETAMINE (AMP)**

| Amphetamine Concentration (ng/mL) | n per Site | Site A | Site B | Site C |
|-----------------------------------|------------|--------|--------|--------|
| 0                                 | 10         | 10     | 0      | 10     |
| 40                                | 10         | 8      | 2      | 9      |
| 120                               | 10         | 1      | 9      | 2      |

**BARBITURATES (BAR)**

| Secobarbital Concentration (ng/mL) | n per Site | Site A | Site B | Site C |
|------------------------------------|------------|--------|--------|--------|
| 0                                  | 10         | 10     | 0      | 10     |
| 50                                 | 10         | 8      | 2      | 9      |
| 150                                | 10         | 1      | 9      | 2      |

**BENZODIAZEPINES (BZO)**

| Benzodiazepines Concentration (ng/mL) | n per Site | Site A | Site B | Site C |
|---------------------------------------|------------|--------|--------|--------|
| 0                                     | 10         | 10     | 0      | 10     |
| 50                                    | 10         | 8      | 2      | 9      |
| 150                                   | 10         | 1      | 9      | 2      |

**BUPRENORPHINE (BUP)**

| Buprenorphine Concentration (ng/mL) | n per Site | Site A | Site B | Site C |
|-------------------------------------|------------|--------|--------|--------|
| 0                                   | 10         | 10     | 0      | 10     |
| 2.5                                 | 10         | 8      | 2      | 9      |
| 7.5                                 | 10         | 1      | 9      | 2      |

**COCAINE (COC)**

| Benzoylcegonine Concentration (ng/mL) | n per Site | Site A | Site B | Site C |
|---------------------------------------|------------|--------|--------|--------|
| 0                                     | 10         | 10     | 0      | 10     |
| 25                                    | 10         | 8      | 2      | 9      |
| 75                                    | 10         | 1      | 9      | 2      |

**MARIJUANA (THC)**

| Marijuana Concentration (ng/mL) | n per Site | Site A | Site B | Site C |
|---------------------------------|------------|--------|--------|--------|
| 0                               | 10         | 10     | 0      | 10     |
| 17.5                            | 10         | 8      | 2      | 9      |
| 52.5                            | 10         | 1      | 9      | 2      |

**METHADONE (MTD)**

| Methadone Concentration (ng/mL) | n per Site | Site A | Site B | Site C |
|---------------------------------|------------|--------|--------|--------|
| 0                               | 10         | 10     | 0      | 10     |
| 20                              | 10         | 8      | 2      | 9      |
| 60                              | 10         | 1      | 9      | 2      |

**METHAMPHETAMINE (MET)**

| Methamphetamine Concentration (ng/mL) | n per Site | Site A | Site B | Site C |
|---------------------------------------|------------|--------|--------|--------|
| 0                                     | 10         | 10     | 0      | 10     |
| 35                                    | 10         | 8      | 2      | 9      |
| 105                                   | 10         | 1      | 9      | 2      |

**METHYLENEDIOXYMETHAMPHETAMINE (MDMA) Ecstasy**

| MDMA Concentration (ng/mL) | n per Site | Site A | Site B | Site C |
|----------------------------|------------|--------|--------|--------|
| 0                          | 10         | 10     | 0      | 10     |
| 25                         | 10         | 8      | 2      | 9      |
| 75                         | 10         | 1      | 9      | 2      |

**MORPHINE/Opiate (MOP/OPI)**

| Morphine/Opiate Concentration (ng/mL) | n per Site | Site A | Site B | Site C |
|---------------------------------------|------------|--------|--------|--------|
| 0                                     | 10         | 10     | 0      | 10     |
| 20                                    | 10         | 8      | 2      | 9      |
| 60                                    | 10         | 1      | 9      | 2      |

**PROPOXYPHENE (PPX)**

| Propoxyphene Concentration (ng/mL) | n per Site | Site A | Site B | Site C |
|------------------------------------|------------|--------|--------|--------|
| 0                                  | 10         | 10     | 0      | 10     |
| 50                                 | 10         | 8      | 2      | 9      |
| 150                                | 10         | 1      | 9      | 2      |

**TRICYCLIC ANTIDEPRESSANTS (TCA)**

| TCA Concentration (ng/mL) | n per Site | Site A | Site B | Site C |
|---------------------------|------------|--------|--------|--------|
| 0                         | 10         | 10     | 0      | 10     |
| 150                       | 10         | 8      | 2      | 9      |
| 450                       | 10         | 1      | 9      | 2      |

**OXYCODONE (OXY)**

| Oxycodone Concentration (ng/mL) | n per Site | Site A | Site B | Site C |
|---------------------------------|------------|--------|--------|--------|
| 0                               | 10         | 10     | 0      | 10     |
| 10                              | 10         | 8      | 2      | 9      |
| 30                              | 10         | 1      | 9      | 2      |

**COTININE (COT 10)**

| COT Concentration (ng/mL) | n per Site | Site A | Site B | Site C |
|---------------------------|------------|--------|--------|--------|
| 0                         | 10         | 10     | 0      | 10     |
| 5                         | 10         | 8      | 2      | 9      |
| 15                        | 10         | 1      | 9      | 2      |

**COTININE (COT 100)**

| COT Concentration (ng/mL) | n per Site | Site A | Site B | Site C |
|---------------------------|------------|--------|--------|--------|
| 0                         | 10         | 10     | 0      | 10     |
| 50                        | 10         | 8      | 2      | 9      |
| 150                       | 10         | 1      | 9      | 2      |

**2-ETHYLIDENE-1,5-DIMETHYL-3,3-DIPHENYLPYRROLIDINE (EDDP)**

| EDDP Concentration (ng/mL) | n per Site | Site A | Site B | Site C |
|----------------------------|------------|--------|--------|--------|
| 0                          | 10         | 10     | 0      | 10     |
| 25                         | 10         | 8      | 2      | 9      |
| 75                         |            |        |        |        |

| Drug Concentration<br>Cut-off Range | OXY |    | COT10 |    | COT100 |    | EDDP |    | TML |    | K2 |    | PCP |    | KET |    |    |    |
|-------------------------------------|-----|----|-------|----|--------|----|------|----|-----|----|----|----|-----|----|-----|----|----|----|
|                                     | -   | +  | -     | +  | -      | +  | -    | +  | -   | +  | -  | +  | -   | +  | -   | +  |    |    |
| 0% Cut-off                          | 30  | 0  | 30    | 0  | 30     | 0  | 30   | 0  | 30  | 0  | 30 | 0  | 30  | 0  | 30  | 0  |    |    |
| -50% Cut-off                        | 30  | 0  | 30    | 0  | 30     | 0  | 30   | 0  | 30  | 0  | 30 | 0  | 30  | 0  | 30  | 0  | 30 | 0  |
| Cut-off                             | 15  | 15 | 15    | 15 | 14     | 16 | 15   | 15 | 15  | 15 | 15 | 15 | 15  | 15 | 15  | 15 | 15 | 15 |
| +50% Cut-off                        | 0   | 30 | 0     | 30 | 0      | 30 | 0    | 30 | 0   | 30 | 0  | 30 | 0   | 30 | 0   | 30 | 0  | 30 |
| +300% Cut-off                       | 0   | 30 | 0     | 30 | 0      | 30 | 0    | 30 | 0   | 30 | 0  | 30 | 0   | 30 | 0   | 30 | 0  | 30 |

| Drug Concentration<br>Cut-off Range | LSD |    | MDA |    |
|-------------------------------------|-----|----|-----|----|
|                                     | -   | +  | -   | +  |
| 0% Cut-off                          | 30  | 0  | 30  | 0  |
| -50% Cut-off                        | 30  | 0  | 30  | 0  |
| Cut-off                             | 15  | 15 | 15  | 15 |
| +50% Cut-off                        | 0   | 30 | 0   | 30 |
| +300% Cut-off                       | 0   | 30 | 0   | 30 |

**For serum or plasma:**

| Drug Concentration<br>Cut-off Range | AMP |    | BAR |    | BZO |    | BUP |    | COC |    | THC |    | MTD |    |
|-------------------------------------|-----|----|-----|----|-----|----|-----|----|-----|----|-----|----|-----|----|
|                                     | -   | +  | -   | +  | -   | +  | -   | +  | -   | +  | -   | +  | -   | +  |
| 0% Cut-off                          | 30  | 0  | 30  | 0  | 30  | 0  | 30  | 0  | 30  | 0  | 30  | 0  | 30  | 0  |
| -50% Cut-off                        | 30  | 0  | 30  | 0  | 30  | 0  | 30  | 0  | 30  | 0  | 30  | 0  | 30  | 0  |
| Cut-off                             | 15  | 15 | 16  | 14 | 15  | 15 | 14  | 16 | 13  | 17 | 15  | 15 | 15  | 15 |
| +50% Cut-off                        | 0   | 30 | 0   | 30 | 0   | 30 | 0   | 30 | 0   | 30 | 0   | 30 | 0   | 30 |
| +300% Cut-off                       | 0   | 30 | 0   | 30 | 0   | 30 | 0   | 30 | 0   | 30 | 0   | 30 | 0   | 30 |

| Drug Concentration<br>Cut-off Range | MET |    | MDMA |    | MOP/OPI |    | PPX |    | TCA |    | FYL |    | MDPV |    |
|-------------------------------------|-----|----|------|----|---------|----|-----|----|-----|----|-----|----|------|----|
|                                     | -   | +  | -    | +  | -       | +  | -   | +  | -   | +  | -   | +  | -    | +  |
| 0% Cut-off                          | 30  | 0  | 30   | 0  | 30      | 0  | 30  | 0  | 30  | 0  | 30  | 0  | 30   | 0  |
| -50% Cut-off                        | 30  | 0  | 30   | 0  | 30      | 0  | 30  | 0  | 30  | 0  | 30  | 0  | 30   | 0  |
| Cut-off                             | 14  | 16 | 15   | 15 | 15      | 15 | 14  | 16 | 15  | 15 | 15  | 15 | 15   | 15 |
| +50% Cut-off                        | 0   | 30 | 0    | 30 | 0       | 30 | 0   | 30 | 0   | 30 | 0   | 30 | 0    | 30 |
| +300% Cut-off                       | 0   | 30 | 0    | 30 | 0       | 30 | 0   | 30 | 0   | 30 | 0   | 30 | 0    | 30 |

| Drug Concentration<br>Cut-off Range | OXY |    | COT10 |    | COT100 |    | EDDP |    | TML |    | K2 |    | PCP |    | KET |    |
|-------------------------------------|-----|----|-------|----|--------|----|------|----|-----|----|----|----|-----|----|-----|----|
|                                     | -   | +  | -     | +  | -      | +  | -    | +  | -   | +  | -  | +  | -   | +  | -   | +  |
| 0% Cut-off                          | 30  | 0  | 30    | 0  | 30     | 0  | 30   | 0  | 30  | 0  | 30 | 0  | 30  | 0  | 30  | 0  |
| -50% Cut-off                        | 30  | 0  | 30    | 0  | 30     | 0  | 30   | 0  | 30  | 0  | 30 | 0  | 30  | 0  | 30  | 0  |
| Cut-off                             | 15  | 15 | 15    | 14 | 16     | 15 | 15   | 15 | 15  | 15 | 15 | 15 | 15  | 15 | 15  | 15 |
| +50% Cut-off                        | 0   | 30 | 0     | 30 | 0      | 30 | 0    | 30 | 0   | 30 | 0  | 30 | 0   | 30 | 0   | 30 |
| +300% Cut-off                       | 0   | 30 | 0     | 30 | 0      | 30 | 0    | 30 | 0   | 30 | 0  | 30 | 0   | 30 | 0   | 30 |

| Drug Concentration<br>Cut-off Range | LSD |    | MDA |    |
|-------------------------------------|-----|----|-----|----|
|                                     | -   | +  | -   | +  |
| 0% Cut-off                          | 30  | 0  | 30  | 0  |
| -50% Cut-off                        | 30  | 0  | 30  | 0  |
| Cut-off                             | 15  | 15 | 15  | 15 |
| +50% Cut-off                        | 0   | 30 | 0   | 30 |
| +300% Cut-off                       | 0   | 30 | 0   | 30 |

**Analytical Specificity**

The following table lists the concentrations of compounds (ng/mL) that are detected as positive in whole blood or serum or plasma by the Multi-Drug Rapid Test Cassette at 5 minutes.

| Analytes                                            | Concentration (ng/mL) | Analytes                               | Concentration (ng/mL) |
|-----------------------------------------------------|-----------------------|----------------------------------------|-----------------------|
| <b>AMPHETAMINE (AMP)</b>                            |                       |                                        |                       |
| D,L-Amphetamine sulfate                             | 20                    | Phentermine                            | 150                   |
| L-Amphetamine                                       | 3,000                 | Maprotiline                            | 6,000                 |
| (±) 3,4-Methylenedioxyamphetamine                   | 40                    | Methoxyphenamine                       | 1,500                 |
|                                                     |                       | D-Amphetamine                          | 80                    |
| <b>BARBITURATES (BAR)</b>                           |                       |                                        |                       |
| Amobarbital                                         | 1,500                 | Alphenol                               | 200                   |
| 5,5-Diphenylhydantoin                               | 2,500                 | Aprobarbital                           | 150                   |
| Allobarbitol                                        | 200                   | Butabarbital                           | 80                    |
| Barbital                                            | 2,500                 | Butalbital                             | 2,500                 |
| Talbutal                                            | 80                    | Butethal                               | 150                   |
| Cyclopentobarbital                                  | 10,000                | Secobarbital                           | 100                   |
| Pentobarbital                                       | 2,500                 |                                        |                       |
| <b>BENZODIAZEPINES (BZO)</b>                        |                       |                                        |                       |
| Alprazolam                                          | 40                    | Bromazepam                             | 300                   |
| a-hydroxyalprazolam                                 | 500                   | Chlordiazepoxide                       | 300                   |
| Clobazam                                            | 60                    | Nitrazepam                             | 60                    |
| Clonazepam                                          | 150                   | Norchlordiazepoxide                    | 40                    |
| Clorazepate dipotassium                             | 150                   | Nordiazepam                            | 300                   |
| Delorazepam                                         | 300                   | Oxazepam                               | 100                   |
| Desalkylflurazepam                                  | 60                    | Temazepam                              | 40                    |
| Flunitrazepam                                       | 60                    | Diazepam                               | 100                   |
| (±) Lorazepam                                       | 1,000                 | Estazolam                              | 2,000                 |
| RS-Lorazepam glucuronide                            | 60                    | Triazolam                              | 1,000                 |
| Midazolam                                           | 2,000                 | Alprazolam                             | 40                    |
| <b>BUPRENORPHINE (BUP)</b>                          |                       |                                        |                       |
| Buprenorphine                                       | 5                     | Norbuprenorphine                       | 30                    |
| Buprenorphine 3-D-Glucuronide                       | 30                    | Norbuprenorphine 3-D-Glucuronide       | 50                    |
| <b>COCAINE (COC)</b>                                |                       |                                        |                       |
| Benzoylcegonine                                     | 50                    | Cocacethylene                          | 5,000                 |
| Cocaine HCl                                         | 60                    | Ecgonine                               | 7,500                 |
| <b>MARIJUANA (THC)</b>                              |                       |                                        |                       |
| Cannabinol                                          | 25,000                | Δ <sup>8</sup> -THC                    | 12,000                |
| 11-nor-Δ <sup>8</sup> -THC-9 COOH                   | 25                    | Δ <sup>9</sup> -THC                    | 12,000                |
| 11-nor-Δ <sup>9</sup> -THC-9 COOH                   | 35                    |                                        |                       |
| <b>METHADONE (MTD)</b>                              |                       |                                        |                       |
| Methadone                                           | 40                    | Doxylamine                             | 13,000                |
| <b>METHAMPHETAMINE (MET)</b>                        |                       |                                        |                       |
| p-Hydroxymethamphetamine                            | 1,800                 | (±)-3,4-Methylenedioxy-methamphetamine | 900                   |
| D-Methamphetamine                                   | 70                    |                                        |                       |
| L-Methamphetamine                                   | 1,500                 | Mephentermine                          | 3,500                 |
| <b>METHYLENEDIOXYMETHAMPHETAMINE (MDMA) Ecstasy</b> |                       |                                        |                       |
| (±)3,4-Methylenedioxy-methamphetamine HCl           | 50                    | 3,4-Methylenedioxyethyl-amphetamine    | 40                    |
| (±) 3,4-Methylenedioxyamphetamine HCl               | 300                   |                                        |                       |
| <b>MORPHINE/OPIATE (MOP/OPI)</b>                    |                       |                                        |                       |
| Codeine                                             | 50                    | Norcodeine                             | 500                   |
| Levorphanol                                         | 200                   | Normorphine                            | 5,000                 |
| Morphine-3-β-D-Glucuronide                          | 120                   | Oxycodone                              | 4,000                 |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |         |                                               |        |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|-----------------------------------------------|--------|
| Ethylmorphine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 500     | Oxymorphone                                   | 500    |
| Hydrocodone                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 5,000   | Procaine                                      | 1,500  |
| Hydromorphone                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 300     | Thebaine                                      | 500    |
| 6-Monoacetylmorphine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 100     | Morphine                                      | 40     |
| <b>PROPOXYPHENE (PPX)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |         |                                               |        |
| D-Propoxyphene                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 100     | D-Norpropoxyphene                             | 100    |
| <b>TRICYCLIC ANTIDEPRESSANTS (TCA)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |         |                                               |        |
| Nortriptyline                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 300     | Imipramine                                    | 140    |
| Nordoxepine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 150     | Clomipramine                                  | 18,000 |
| Trimipramine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 1,300   | Doxepine                                      | 600    |
| Amitriptyline                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 600     | Maprotiline                                   | 600    |
| Promazine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 1,300   | Promethazine                                  | 18,000 |
| Desipramine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 80      | Perphenazine                                  | 18,000 |
| Cyclobenzaprine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 600     |                                               |        |
| <b>OXYCODONE (OXY)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |         |                                               |        |
| Oxycodone                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 20      | Hydromorphone                                 | 10,000 |
| Oxymorphone                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 60      | Naloxone                                      | 5,000  |
| Levorphanol                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 10,000  | Naltrexone                                    | 5,000  |
| Hydrocodone                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 5,000   |                                               |        |
| <b>COTININE (COT 10)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |         |                                               |        |
| (-)-Cotinine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 10      | (-)-Nicotine                                  | 250    |
| <b>COTININE (COT 100)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |         |                                               |        |
| (-)-Cotinine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 100     | (-)-Nicotine                                  | 2,500  |
| <b>2-ETHYLIDENE-1,5-DIMETHYL-3,3-DIPHENYLPYRROLIDINE (EDDP)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |         |                                               |        |
| 2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |         |                                               | 50     |
| <b>TRAMADOL (TML)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |         |                                               |        |
| n-Desmethyl-cis-tramadol                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 100     | o-Desmethyl-cis-tramadol                      | 5,000  |
| Cis-tramadol                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 50      | Phencyclidine                                 | 50,000 |
| Procyclidine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 50      | d,l-O-Desmethylvenlafaxine                    | 25,000 |
| <b>FENTANYL (FYL)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |         |                                               |        |
| Alfentanil                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 450,000 | Norfentanyl                                   | 15     |
| Fenfluramine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 40,000  | Buspirone                                     | 12,000 |
| Fentanyl                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 75      | Sufentanyl                                    | 40,000 |
| <b>3,4-METHYLENEDIOXYPROVALERONE (MDPV)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |         |                                               |        |
| 3,4-methylenedioxyprovalerone                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 300     |                                               |        |
| <b>SYNTHETIC MARIJUANA (K2)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |         |                                               |        |
| JWH-018 5-Pentanoic acid metabolite                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 100     | JWH-073 4-butanoic acid metabolite            | 100    |
| JWH-018 4-Hydroxypentyl metabolite                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 800     | JWH-018 5-Hydroxypentyl metabolite            | 1,000  |
| JWH-073 4-Hydroxybutyl metabolite                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 1,000   |                                               |        |
| <b>PHENCYCLIDINE (PCP)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |         |                                               |        |
| Phencyclidine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 20      | 4-Hydroxyphencyclidine                        | 5,000  |
| <b>KETAMINE (KET)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |         |                                               |        |
| Ketamine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 200     | Tetrahydrozoline                              | 100    |
| Benzphetamine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 5,000   | d-Methamphetamine                             | 10,000 |
| (+) Chlorpheniramine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 5,000   | l-Methamphetamine                             | 10,000 |
| Clonidine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 2,000   | Methoxyphenamine                              | 5,000  |
| Dextromethorphan                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 400     | (+)-3,4-Methylenedioxy-methamphetamine (MDMA) | 20,000 |
| Disopyramide                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 5,000   | d-Norpropoxyphene                             | 5,000  |
| EDDP                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 10,000  | Pentazocine                                   | 5,000  |
| Mephentermine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 5,000   | Phencyclidine                                 | 5,000  |
| (1R, 2S) (-)-Ephedrine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 20,000  | Promazine                                     | 5,000  |
| 4-Hydroxyphencyclidine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 10,000  | Promethazine                                  | 5,000  |
| Levorphanol                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 10,000  | Thioridazine                                  | 10,000 |
| MDE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 10,000  | Meperidine                                    | 5,000  |
| <b>LYSERGIC ACID DIETHYLAMIDE (LSD)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |         |                                               |        |
| Lysergic Acid Diethylamide                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 20      |                                               |        |
| <b>3,4-METHYLENEDIOXYAMPHETAMINE (MDA)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |         |                                               |        |
| D,L-Amphetamine sulfate                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 40      | (±)-3,4-Methylenedioxy-methamphetamine        | 80     |
| L-Amphetamine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 6,000   |                                               |        |
| Phentermine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 300     | Maprotiline                                   | 12,000 |
| Methoxyphenamine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 3,000   | D-Amphetamine                                 | 160    |
| <b>Cross-Reactivity</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |         |                                               |        |
| A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free whole blood/serum/plasma or drug positive whole blood/serum/plasma containing, Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Marijuana, Methadone, Methamphetamine, Methylenedioxy-methamphetamine, Morphine, Propoxyphene, Tricyclic Antidepressants, Cotinine, EDDP, KET and TML. The following compounds show no cross-reactivity when tested with the Multi-Drug Rapid Test Cassette at a concentration of 100 µg/mL. |         |                                               |        |
| <b>Non Cross-Reacting Compounds</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |         |                                               |        |
| Acetophenetidin                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |         | Cortisone                                     |        |
| N-Acetylprocainamide                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |         | Creatinine                                    |        |
| Acetylsalicylic acid                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |         | Deoxycorticosterone                           |        |
| Aminopyrine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |         | Dextromethorphan                              |        |
| Amoxicillin                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |         | Diclofenac                                    |        |
| Ampicillin                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |         | Diflunisal                                    |        |
| l-Ascorbic acid                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |         | Digoxin                                       |        |
| Apomorphine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |         | Diphenhydramine                               |        |
| Aspartame                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |         | Ethyl-p-aminobenzoate                         |        |
| Atropine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |         | β-Estradiol                                   |        |
| Benzilic acid                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |         | Estrone-3-sulfate                             |        |
| Benzoic acid                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |         | Erythromycin                                  |        |
| Bilirubin                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |         | Fenpropfen                                    |        |
| d,l-Brompheniramine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |         | Furosemide                                    |        |
| Caffeine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |         | Genticic acid                                 |        |
| Cannabidiol                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |         | Hemoglobin                                    |        |
| Chloral hydrate                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |         | Hydralazine                                   |        |
| Chloramphenicol                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |         | Hydrochlorothiazide                           |        |
| Chlorothiazide                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |         | Hydrocortisone                                |        |
| d,l-Chlorpheniramine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |         | o-Hydroxyhippuric acid                        |        |
| Chlorpromazine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |         | 3-Hydroxytyramine                             |        |
| Cholesterol                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |         | d,l-Isoproterenol                             |        |
| Clonidine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |         | Isoxsuprine                                   |        |
| Zomepirac                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |         | d-Pseudoephedrine                             |        |
| Ketoprofen                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |         | Quinidine                                     |        |
| Labetalol                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |         | Quinine                                       |        |
| Loperamide                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |         | Salicylic acid                                |        |

|                  |                      |
|------------------|----------------------|
| Meprobamate      | Serotonin            |
| Methoxyphenamine | Sulfamethazine       |
| Methylphenidate  | Sulindac             |
| Nalidixic acid   | Tetracycline         |
| Naproxen         | Tetrahydrocortisone, |
| Niacinamide      | 3-acetate            |
| Nifedipine       | Tetrahydrocortisone  |
| Norethindrone    | Tetrahydrozoline     |
| Noscapine        | Thiamine             |
| d,l-Octopamine   | Thioridazine         |
| Oxalic acid      | d,l-Tyrosine         |
| Oxolinic acid    | Tolbutamide          |
| Oxymetazoline    | Triamterene          |
| Papaverine       | Trifluoperazine      |
| Penicillin-G     | Trimethoprim         |
| Perphenazine     | d,l-Tryptophan       |
| Phenelzine       | Uric acid            |
| Prednisone       | Verapamil            |
| d,l-Propranolol  |                      |

**BIBLIOGRAPHY**

- Hawks RL, CN Chiang. *Whole blood or serum or plasma Testing for Drugs of Abuse*. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.
- Tietz NW. *Textbook of Clinical Chemistry*. W.B. Saunders Company. 1986; 1735.
- Glass, IB. *The International Handbook of Addiction Behavior*. Routledge Publishing, New York, NY. 1991; 216
- Stewart DJ, Inaba T, Lucassen M, Kalow W. *Clin. Pharmacol. Ther.* April 1979; 25 ed: 464, 264-8.
- Ambre J. *J. Anal. Toxicol.* 1985; 9:241.
- Winger, Gail, *A Handbook of Drug and Alcohol Abuse*, Third Edition, Oxford Press, 1992, page 146.
- Robert DeCresce. *Drug Testing in the workplace*, 1989 page 114.
- B. Cody, J.T., "Specimen Adulteration in drug urinalysis. *Forensic Sci. Rev.*, 1990, 2:63.
- Baselt RC. *Disposition of Toxic Drugs and Chemicals in Man*, 6th Ed. Biomedical Publ., Foster City, CA 2002.
- Lane JC, Tennon MB, Lawless ST, et al. Movement disorder after withdrawal of fentanyl infusion. *J Pediatr*, 1991, 119 (4) : 649-651
- Dominguez KD, Lomako DM, Katz RW, et al. Opioid withdraw in critically ill neonates. *Ann Pharmacotherm*, 2003, 37 (4) : 473-477
- European Monitoring Centre for Drugs and Drug Addiction. Annual Report 2009[R]. Lisbon: EMCDDA, 2010
- C. Tsai, S.C. et.al., *J. Anal. Toxicol.* 1998; 22 (6): 474
- Hardman JG, Limbird LE. *Goodman and Gilman's: The Pharmacological Basis for Therapeutics*. 10th Edition. McGraw Hill Medical Publishing, 2001; 208-209.

**INDEX OF SYMBOLS**

|  |                                                                         |
|--|-------------------------------------------------------------------------|
|  | In vitro diagnostic medical device                                      |
|  | Temperature limit                                                       |
|  | Do not use if package is damaged and consult instructions for use       |
|  | Catalogue number                                                        |
|  | Contains sufficient for <n> tests                                       |
|  | Use-by date                                                             |
|  | Batch code                                                              |
|  | Manufacturer                                                            |
|  | Do not re-use                                                           |
|  | Consult instructions for use or consult electronic instructions for use |
|  | Caution                                                                 |
|  | Authorized representative in the European Community                     |

Number: CT54997  
 Rev 04  
 Date: 09/16/2025

A rapid test for the qualitative detection of Morphine in human urine.  
For professional *in vitro* diagnostic use only.

### INTENDED USE

The MOP Rapid Test Cassette is a rapid chromatographic immunoassay for the detection of Morphine in human urine at the cut-off concentration of 300ng/mL. This test will detect other compounds, please refer to analytical specificity table in this package insert. This assay provides only a qualitative, preliminary test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used. The test results can be used to provide evidence and basis for therapy and treatment plans of drug dependence and toxic psychosis. For laboratory professional *in vitro* diagnostic use only. The MOP Rapid Test Cassette (Urine) should only be performed by health professionals in a clinical/hospital setting to aid in screening of drug of abuse to determine the follow-up treatment measures in combination of clinical symptoms.

### SUMMARY

Opioid analgesics comprise a large group of substances which control pain by depressing the central nervous system. Large doses of Morphine can produce higher tolerance levels and physiological dependency in users, and may lead to substance abuse. Morphine is excreted unmetabolized, and is also the major metabolic product of codeine and heroin. Morphine is detectable in the urine for several days after an opiate dose.<sup>1</sup>

The MOP Rapid Test Cassette is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Morphine in urine. The MOP Rapid Test Cassette yields a positive result when Morphine in urine reaches 300ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

### PRINCIPLE

The MOP Rapid Test Cassette is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a urine specimen migrates upward by capillary action. Morphine, if present in the urine specimen below 300ng/mL, will not saturate the binding sites of the antibody coated particles in the test device. The antibody coated particles will then be captured by immobilized Morphine conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the Morphine level is at or above 300ng/mL because it will saturate all the binding sites of anti-Morphine antibodies.

A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

### REAGENTS

The test contains mouse monoclonal anti-Morphine antibody-coupled particles and Morphine-protein conjugate. A goat antibody is employed in the control line system.

### PRECAUTIONS

- For medical and other professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.

- The used test should be discarded according to local regulations.

### STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30 °C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

### SPECIMEN COLLECTION AND PREPARATION

#### Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible particles should be centrifuged, filtered, or allowed to settle to obtain clear specimen for testing.

#### Specimen Storage

Urine specimens may be stored at 2-8 °C for up to 48 hours prior to assay. For long-term storage, specimens may be frozen and stored below -20 °C. Frozen specimens should be thawed and mixed before testing.

### MATERIALS

#### Materials provided

- Test cassettes
- Droppers
- Package insert

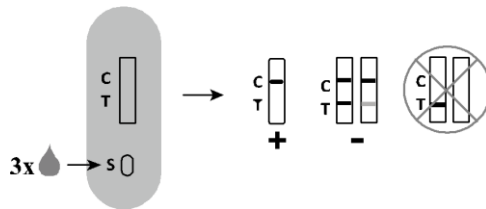
#### Materials required but not provided

- Specimen collection containers
- Timer

### DIRECTIONS FOR USE

**Allow the test, urine specimen and/or controls to reach room temperature (15-30 °C) prior to testing.**

- Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within one hour.
- Place the test cassette on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 120 µL) to the specimen well (S) of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
- Wait for the color line(s) to appear. **The result should be read at 5 minutes.** Do not interpret the result after 10 minutes.



### INTERPRETATION OF RESULTS

(Please refer to the illustration above)

**NEGATIVE: Two colored lines appear.** One color line should be in the control region (C) and another color line should be in the test region (T). This negative result indicates that the Morphine concentration is below the detectable cutoff level.

**\*NOTE:** The shade of color in the test region (T) may vary, but it should be considered negative whenever there is even a faint color line.

**POSITIVE: One color line appears in the control region (C).** No line appears in the test region (T). This positive result indicates that the Morphine concentration is above the detectable cutoff level.

**INVALID: Control line fails to appear.** Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test cassette immediately and contact your local distributor.

### QUALITY CONTROL

A procedural control is included in the test. A color line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this test cassette; however it is recommended that positive and negative controls be tested as good laboratory testing practices to confirm the test procedure and to verify proper test performance.

### LIMITATIONS

- The MOP Rapid Test Cassette provides only a qualitative, preliminary result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method<sup>2,3</sup>.
- It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
- A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
- A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
- Test does not distinguish between drugs of abuse and certain medications.

### PERFORMANCE CHARACTERISTICS

#### Accuracy

A side-by-side comparison was conducted using the MOP Rapid Test Cassette and a commercially available MOP rapid test. Testing was performed on 100 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

| Method                  | Other MOP Rapid Test |                  | Total Results    |
|-------------------------|----------------------|------------------|------------------|
|                         | Results Positive     | Negative         |                  |
| MOP Rapid Test Cassette | 43                   | 0                | 43               |
|                         | Negative             | 57               | 57               |
| <b>Total Results</b>    | <b>43</b>            | <b>57</b>        | <b>100</b>       |
| <b>% Agreement</b>      | <b>&gt;99.9%</b>     | <b>&gt;99.9%</b> | <b>&gt;99.9%</b> |

A side-by-side comparison was conducted using the MOP Rapid Test Cassette and GC/MS at the cut-off of 300ng/mL. Testing was performed on 250 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

| Method                  | GC/MS            |              | Total Results |
|-------------------------|------------------|--------------|---------------|
|                         | Results Positive | Negative     |               |
| MOP Rapid Test Cassette | 95               | 7            | 102           |
|                         | Negative         | 143          | 148           |
| <b>Total Results</b>    | <b>100</b>       | <b>150</b>   | <b>250</b>    |
| <b>% Agreement</b>      | <b>95%</b>       | <b>95.3%</b> | <b>95.2%</b>  |

#### Analytical Sensitivity

A drug-free urine pool was spiked with Morphine at the following concentrations: 0ng/mL, 150ng/mL, 225ng/mL, 300ng/mL, 375ng/mL, 450ng/mL and 900ng/mL. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

| Morphine Concentration (ng/mL) | Percent of Cut-off | n  | Visual Result |          |
|--------------------------------|--------------------|----|---------------|----------|
|                                |                    |    | Negative      | Positive |
| 0                              | 0                  | 30 | 30            | 0        |
| 150                            | -50%               | 30 | 30            | 0        |
| 225                            | -25%               | 30 | 26            | 4        |

| Concentration (ng/mL) | Cut-off | 30 | 15 | 15 |
|-----------------------|---------|----|----|----|
| 300                   | -       | 30 | 3  | 27 |
| 375                   | +25%    | 30 | 0  | 30 |
| 450                   | +50%    | 30 | 0  | 30 |
| 900                   | 3x      | 30 | 0  | 30 |

### Analytical Specificity

The following table lists compounds that are positively detected in urine by the MOP Rapid Test Cassette at 5 minutes.

| Compound                   | Concentration (ng/mL) |
|----------------------------|-----------------------|
| Codeine                    | 200                   |
| Ethylmorphine              | 6,000                 |
| Hydrocodone                | 50,000                |
| Hydromorphone              | 3,000                 |
| Levorphanol                | 1,500                 |
| 6-Monoacetylmorphine       | 300                   |
| Morphine 3-β-D-glucuronide | 800                   |
| Morphine                   | 300                   |
| Norcodeine                 | 6,000                 |
| Normorphine                | 50,000                |
| Oxycodone                  | 30,000                |
| Oxymorphone                | 50,000                |
| Procaine                   | 15,000                |
| Thebaine                   | 6,000                 |

### Precision

A study was conducted at three hospitals using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens containing, according to GC/MS, no Morphine, 25% Morphine above and below the cut-off and 50% Morphine above and below the 300ng/mL cut-off was provided to each site. The results are given below:

| Morphine Concentration (ng/mL) | n per Site | Site A |    | Site B |    | Site C |    |
|--------------------------------|------------|--------|----|--------|----|--------|----|
|                                |            | -      | +  | -      | +  | -      | +  |
| 0                              | 10         | 10     | 0  | 10     | 0  | 10     | 0  |
| 150                            | 10         | 10     | 0  | 10     | 0  | 10     | 0  |
| 225                            | 10         | 9      | 1  | 9      | 1  | 9      | 1  |
| 375                            | 10         | 1      | 9  | 1      | 9  | 2      | 8  |
| 450                            | 10         | 0      | 10 | 0      | 10 | 0      | 10 |

### Effect of Urinary Specific Gravity

Fifteen urine specimens of normal, high, and low specific gravity ranges were spiked with 150ng/mL and 450ng/mL of Morphine. The MOP Rapid Test Cassette was tested in duplicate using the fifteen neat and spiked urine specimens. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

### Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with Morphine to 150ng/mL and 450ng/mL. The spiked, pH-adjusted urine was tested with the MOP Rapid Test Cassette in duplicate. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

### Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Morphine positive urine. The following compounds show no cross-reactivity when tested with the MOP Rapid Test Cassette at a concentration of 100µg/mL.

### Non Cross-Reacting Compounds













|                      |                     |
|----------------------|---------------------|
| 4-Acetamidophenol    | Creatinine          |
| Acetophenetidin      | Deoxycorticosterone |
| N-Acetylprocainamide | Dextromethorphan    |
| Acetylsalicylic acid | Diazepam            |
| Aminopyrine          | Diclofenac          |
| Amityryptiline       | Diflunisal          |
| Amobarbital          | Digoxin             |

|                                        |                           |
|----------------------------------------|---------------------------|
| Amoxicillin                            | Diphenhydramine           |
| Ampicillin                             | Doxylamine                |
| L-Ascorbic acid                        | Egonine hydrochloride     |
| D,L-Amphetamine                        | Egonine methylester       |
| Apomorphine                            | (-)-ψ-Ephedrine           |
| Aspartame                              | Erythromycin              |
| Atropine                               | β-Estradiol               |
| Benzilic acid                          | Estrone-3-sulfate         |
| Benzoic acid                           | Ethyl-p-aminobenzoate     |
| Benzoylcegonine                        | Fenoprofen                |
| Benzphetamine                          | Furosemide                |
| Bilirubin                              | Gentisic acid             |
| (±) - Brompheniramine                  | Hemoglobin                |
| Caffeine                               | Hydralazine               |
| Cannabidiol                            | Hydrochlorothiazide       |
| Chloralhydrate                         | Hydrocortisone            |
| Chloramphenicol                        | O-Hydroxyhippuric acid    |
| Chlordiazepoxide                       | p-Hydroxy-methamphetamine |
| Chlorothiazide                         | 3-Hydroxytyramine         |
| (±) Chlorpheniramine                   | Ibuprofen                 |
| Chlorpromazine                         | Imipramine                |
| Chlorquine                             | Iproniazid                |
| Cholesterol                            | (±) Isoproterenol         |
| Clomipramine                           | Isoxsuprine               |
| Clonidine                              | Ketamine                  |
| Cocaine hydrochloride                  | Ketoprofen                |
| Cortisone                              | Labetalol                 |
| (-) Cotinine                           | β-Phenylethylamine        |
| Loperamide                             | Phenylpropanolamine       |
| Maprotiline                            | Prednisone                |
| Meperidine                             | D,L-Propranolol           |
| Meprobamate                            | D-Propoxyphene            |
| Methadone                              | D-Pseudoephedrine         |
| Methoxyphenamine                       | Quinidine                 |
| (+) 3,4-Methylenedioxy-amphetamine     | Quinine                   |
| (+) 3,4-Methylenedioxy-methamphetamine | Ranitidine                |
| Nalidixic acid                         | Salicylic acid            |
| Nalorphine                             | Secobarbital              |
| Naloxone                               | Serotonin                 |
| Naltrexone                             | (5-Hydroxytyramine)       |
| Naproxen                               | Sulfamethazine            |
| Niacinamide                            | Sulindac                  |
| Nifedipine                             | Temazepam                 |
| Norethindrone                          | Tetracycline              |
| D-Norpropoxyphene                      | Tetrahydrocortisone,      |
| Noscapine                              | 3-Acetate                 |
| D,L-Octopamine                         | Tetrahydrocortisone       |
| Oxalic acid                            | 3-(β-D glucuronide)       |
| Oxazepam                               | Tetrahydrozoline          |
| Oxolinic acid                          | Thiamine                  |
| Oxymetazoline                          | Thioridazine              |
| Papaverine                             | D, L-Tyrosine             |
| Penicillin-G                           | Tolbutamide               |
| Pentazocine                            | Triamterene               |
| Pentobarbital                          | Trifluoperazine           |
| Perphenazine                           | Trimethoprim              |
| Phencyclidine                          | Trimipramine              |
| Phenelzine                             | Tryptamine                |
| Phenobarbital                          | D, L-Tryptophan           |
| Phentermine                            | Tyramine                  |
| L-Phenylephrine                        | Uric acid                 |
| Zomepirac                              | Verapamil                 |

**BIBLIOGRAPHY**

1. Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company. 1986; 1735
2. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd Ed. Biomedical Publ., Davis, CA. 1982; 488
3. Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73. 1986

**INDEX OF SYMBOLS**

|                                                                                   |                                                                         |
|-----------------------------------------------------------------------------------|-------------------------------------------------------------------------|
|  | In vitro diagnostic medical device                                      |
|  | Temperature limit                                                       |
|  | Do not use if package is damaged and consult instructions for use       |
|  | Catalogue number                                                        |
|  | Contains sufficient for <n> tests                                       |
|  | Use-by date                                                             |
|  | Batch code                                                              |
|  | Manufacturer                                                            |
|  | Do not re-use                                                           |
|  | Consult instructions for use or consult electronic instructions for use |
|  | Caution                                                                 |
|  | Authorized representative in the European Community                     |

REF: DMO-102  
Number: CT50675  
Rev: 02  
Date: 07/16/2025

A rapid test for the qualitative detection of Ethyl Glucuronide in human urine.

For medical and other professional *in vitro* diagnostic use only.

### INTENDED USE

The Ethyl Glucuronide (ETG) Rapid Test Cassette (Urine) is a rapid chromatographic immunoassay for the detection of Ethyl Glucuronide in human urine. The Ethyl Glucuronide detected by the test includes, but are not limited to, the metabolites of Ethanol.

This assay provides only a preliminary test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

The test results can be used to provide evidence and basis for therapy and treatment plans of drug dependence and toxic psychosis. For laboratory professional *in vitro* diagnostic use only. The Ethyl Glucuronide (ETG) Rapid Test Cassette (Urine) should only be performed by health professionals in a clinical/hospital setting to aid in screening of drug of abuse to determine the follow-up treatment measures in combination of clinical symptoms.

### SUMMARY

Ethyl Glucuronide (ETG) is a metabolite of ethyl alcohol which is formed in the body by glucuronidation following exposure to ethanol, such as by drinking alcoholic beverages. It is used as a biomarker to test for ethanol use and to monitor alcohol abstinence in situations where drinking is prohibited, such as in the military, in professional monitoring programs (health professionals, attorneys, airline pilots in recovery from addictions), in schools, in liver transplant clinics, or in recovering alcoholic patients. ETG can be measured in urine by Traditional laboratory methods (GC/MS or LC/MS) up to approximately 80 hours after ethanol is ingested (greatly dependent on the amount of alcoholic and non-alcoholic drinks). ETG is a more accurate indicator of the recent exposure to alcohol than measuring for the presence of ethanol itself.

The Ethyl Glucuronide (ETG) Rapid Test Cassette (Urine) is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of ethyl glucuronide in human urine. The Ethyl Glucuronide (ETG) Rapid Test Strip (Urine) yields a positive result when the Ethyl Glucuronide in urine exceeds 1,000 ng/mL.

### PRINCIPLE

The Ethyl Glucuronide (ETG) Rapid Test Cassette (Urine) is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a urine specimen migrates upward by capillary action. Ethyl Glucuronide, if present in the urine specimen below 1,000ng/mL, will not saturate the binding sites of antibody-coated particles in the test device. The antibody-coated particles will then be captured by immobilized Ethyl Glucuronide conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the Ethyl Glucuronide level exceeds 1,000ng/mL because it will saturate all the binding sites of anti- Ethyl Glucuronide antibodies.

A drug-positive urine specimen will not generate a colored line in the test line region, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

### REAGENTS

The test contains mouse monoclonal anti-ethyl glucuronide antibody-coupled particles and ethyl glucuronide -protein conjugate. A goat antibody is employed in the control line system.

### PRECAUTIONS

- For medical and other professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until use.

- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test should be discarded according to local regulations.

### STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30 °C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

### SPECIMEN COLLECTION AND PREPARATION

#### Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible particles should be centrifuged, filtered, or allowed to settle to obtain clear specimen for testing.

#### Specimen Storage

ETG is not very stable in urine. After the urine is collected, the ETG will gradually degrade. The urine specimen containing ETG should be tested as soon as possible. In general, the specimen should be tested within 2 hours, and it must not be stored beyond 8 hours. For long-term storage, specimens may be frozen and stored below -20 °C. Frozen specimens should be thawed and mixed before testing. If you intend to send specimens for quantitative follow-up testing into the lab you should stabilize the urine (e.g. boric acid) beforehand. Do not use the stabilized specimen for the rapid test.

### MATERIALS

#### Materials Provided

- Test cassettes
- Droppers
- Package insert

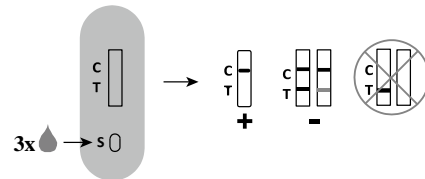
#### Materials Required But Not Provided

- Specimen collection containers
- Timer

### DIRECTIONS FOR USE

Allow the test, urine specimen and/or controls to reach room temperature (15-30 °C) prior to testing.

- Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within one hour.
- Place the test cassette on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 120 µL) to the specimen well (S) of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
- Wait for the colored line(s) to appear. **Read results at 5 minutes.** Do not interpret the result after 10 minutes.



### INTERPRETATION OF RESULTS

(Please refer to the illustration above)

**NEGATIVE: Two colored lines appear.** One colored line should be in the control line region (C) and another colored line should be in the test line region (T). A negative result indicates that the Ethyl Glucuronide concentration is below the detectable level (1,000ng/mL).

**\*NOTE:** The shade of color in the test line region (T) may vary, but it should be considered negative whenever there is even a faint colored line.

**POSITIVE: One colored line appears in the control line region (C).** No line appears in the test line region (T). A positive result indicates that the Ethyl Glucuronide concentration exceeds the detectable level (1,000ng/mL).

**INVALID: Control line fails to appear.** Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test. If the problem persists, discontinue using the lot immediately and contact your

local distributor.

### QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory testing practice to confirm the test procedure and to verify proper test performance.

### LIMITATIONS

- The Ethyl Glucuronide (ETG) Rapid Test Cassette (Urine) provides only a qualitative, preliminary result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.<sup>1,2</sup>
- It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
- A positive result indicates presence of ETG but does not indicate level of intoxication, administration route or concentration in urine.
- A negative result may not necessarily indicate ETG-free urine. Negative results can be obtained when ETG is present but below the cut-off level of the test.
- Test does not distinguish between legal or illicit use of alcohol.

### PERFORMANCE CHARACTERISTICS

#### Accuracy

A side-by-side comparison was conducted using the Ethyl Glucuronide (ETG) Rapid Test Cassette (Urine) and GC/MS. The following results were tabulated:

| Method                                      | GC/MS    |          | Total Results |
|---------------------------------------------|----------|----------|---------------|
|                                             | Results  | Positive |               |
| Ethyl Glucuronide (ETG) Rapid Test Cassette | Positive | 81       | 82            |
|                                             | Negative | 4        | 164           |
| <b>Total Results</b>                        |          | 85       | 165           |
| <b>% Agreement</b>                          |          | 95.3%    | 99.4%         |

#### Analytical Sensitivity

A drug-free urine pool was spiked with ETG at the following concentrations: 0 ng/mL, 500 ng/mL, 750 ng/mL, 1,000 ng/mL, 1,250 ng/mL, 1,500 ng/mL and 3,000 ng/mL. The results demonstrate >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

| Ethyl Glucuronide Concentration (ng/mL) | Percent of Cut-off | n  | Visual Result |          |
|-----------------------------------------|--------------------|----|---------------|----------|
|                                         |                    |    | Negative      | Positive |
| 0                                       | 0%                 | 30 | 30            | 0        |
| 500                                     | -50%               | 30 | 30            | 0        |
| 750                                     | -25%               | 30 | 26            | 4        |
| 1,000                                   | Cut-off            | 30 | 15            | 15       |
| 1,250                                   | +25%               | 30 | 3             | 27       |
| 1,500                                   | +50%               | 30 | 0             | 30       |
| 3,000                                   | 3X                 | 30 | 0             | 30       |

#### Analytical Specificity

The following table lists compounds that are positively detected in urine by the Ethyl Glucuronide (ETG) Rapid Test Cassette (Urine) at 5 minutes.

| Compound               | Concentration (ng/mL) |
|------------------------|-----------------------|
| Ethyl-β-D-Glucuronide  | 1,000                 |
| Propyl β-D-glucuronide | 100,000               |
| Glucuronic Acid        | >100,000              |
| Ethanol                | >100,000              |
| Methanol               | >100,000              |

#### Precision

A study was conducted at three hospitals using three different lots of product to demonstrate the within run, between run and between operator precision.

An identical panel of coded specimens containing, according to GC/MS, no Ethyl Glucuronide, 25% Ethyl Glucuronide above and below the cut-off, and 50% Ethyl Glucuronide above and below the 1,000ng/mL cut-off was provided to each site. The following results were tabulated:

| Ethyl Glucuronide Concentration (ng/mL) | n per Site | Site A |    | Site B |    | Site C |    |
|-----------------------------------------|------------|--------|----|--------|----|--------|----|
|                                         |            | -      | +  | -      | +  | -      | +  |
| 0                                       | 10         | 10     | 0  | 10     | 0  | 10     | 0  |
| 500                                     | 10         | 10     | 0  | 10     | 0  | 10     | 0  |
| 750                                     | 10         | 8      | 2  | 8      | 2  | 9      | 1  |
| 1,250                                   | 10         | 1      | 9  | 2      | 8  | 2      | 8  |
| 1,500                                   | 10         | 0      | 10 | 0      | 10 | 0      | 10 |

#### Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high and low specific gravity ranges were spiked with 500ng/mL and 1,500ng/mL of Ethyl Glucuronide. The Ethyl Glucuronide (ETG) Rapid Test Cassette (Urine) was tested in duplicate using the fifteen neat and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity (1.005-1.045) do not affect the test results.

#### Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with Ethyl Glucuronide to 500ng/mL and 1,500ng/mL. The spiked, pH-adjusted urine was tested with the Ethyl Glucuronide (ETG) Rapid Test Cassette (Urine) in duplicate. The results demonstrated that varying ranges of pH do not interfere with the performance of the test.

#### Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Ethyl Glucuronide positive urine. The following compounds show no cross-reactivity when tested with the Ethyl Glucuronide (ETG) Rapid Test Cassette (Urine) at a concentration of 100 µg/mL.

#### Non Cross-Reacting Compounds

|                      |                           |
|----------------------|---------------------------|
| 4-Acetaminophenol    | 4-Dimethylaminoantipyrine |
| Acetone              | Diphenhydramine           |
| Acetophenetidin      | 5,5-Diphenylhydantoin     |
| N-Acetylprocainamide | Disopyramide              |
| Acetylsalicylic acid | Doxylamine                |
| Albumin              | Ecgonine                  |
| Amiripityline        | Ecgonine methylester      |
| Amobarbital          | EMDP                      |
| Amoxapine            | Ephedrine                 |
| Amoxicillin          | l-Ephedrine               |
| Ampicillin           | l-Epinephrine             |
| Ascorbic acid        | (±)-Epinephrine           |
| Erythromycin         | Erythromycin              |
| Apomorphine          | β-Estradiol               |
| Aspartame            | Estrone-3-sulfate         |
| Atropine             | 5,5-Diphenylhydantoin     |
| Benzilic acid        | Ethyl-p-aminobenzoate     |
| Benzoic acid         | Etodolac                  |
| Benzphetamine        | Famprofazone              |
| Bilirubin            | Fentanyl                  |
| Brompheniramine      | Fluoxetine                |
| Bupirone             | Furosemide                |
| Cannabiol            | Genticic acid             |
| Cimetidine           | d-Glucose                 |
| Chloral hydrate      | Guaiaicol glyceryl ether  |
| Chloramphenicol      | Hemoglobin                |
| Chlordiazepoxide     | Hydralazine               |
| Chloroquine          | Hydrochlorothiazide       |
| Chlorothiazide       | Hydrocortisone            |
| (+)-Chlorpheniramine | o-Hydroxyhippuric acid    |
| (±)-Chlorpheniramine | p-Hydroxymethamphetamine  |
| Chlorpromazine       | 3-Hydroxytyramine         |
| Chlorprothixene      | (Dopamine)                |
| Cholesterol          | Hydroxyzone               |

|                          |                           |
|--------------------------|---------------------------|
| Clomipramine             | Ibuprofen                 |
| Codeine                  | Imipramine                |
| Cortisone                | Iproniazide               |
| (-)-Cotinine             | (-)-Isoproterenol         |
| Creatinine               | Isoxsuprine               |
| Cyclobarbitol            | Kanamycin                 |
| Cyclobenzaprine          | Ketamine                  |
| Deoxycorticosterone      | Ketoprofen                |
| R (-)Deprenyl            | Labetalol                 |
| Dextromethorphan         | Levorphanol               |
| Diazepam                 | Lidocaine                 |
| Diclofenac               | Lindane                   |
| Dicyclomine              | (Hexachlorocyclohexane)   |
| Diflunisal               | Loperamide                |
| 4-Acetaminophenol        | 4-Dimethylaminoantipyrine |
| Acetone                  | Diphenhydramine           |
| Acetophenetidin          | Temazepam                 |
| Procaine                 | Tetracycline              |
| Promazine                | Tetrahydrocortexolone     |
| Promethazine             | Tetrahydrocortisone,      |
| l-Propoxyphene           | 3-acetate                 |
| d,l-Propranolol          | Tetrahydrozoline          |
| d-Pseudoephedrine        | Thebaine                  |
| Quinacrine               | Thiamine                  |
| Quinidine                | Thioridazine              |
| Quinine                  | l-Thyroxine               |
| Ranitidine               | Tolbutamide               |
| Riboflavin               | cis-Tramadol              |
| Salicylic acid           | trans-2-                  |
| Serotonin                | Phenylcyclopropylamine    |
| (5-Hydroxytryptamine)    | Trazodone                 |
| Sodium chloride          | Trimethobenzamide         |
| Sulfamethazine           | Triamterene               |
| Maprotiline              | Oxymorphone               |
| Meperidine               | Papaverine                |
| Meprobamate              | Pemoline                  |
| d-Methamphetamine        | Penicillin-G              |
| l-Methamphetamine        | Pentazocine               |
| Methadone                | Perphenazine              |
| Methoxyphenamine         | Phencyclidine             |
| (+)-3,4-Methylenedioxy-  | Phenelzine                |
| Methylphenidate          | Pheniramine               |
| Mephentermine            | Phenobarbital             |
| Metoprolol               | Phenothiazine             |
| Meprobamate              | Phentermine               |
| Morphine sulfate         | Prednisolone              |
| Methyprylon              | Prednisone                |
| Nalidixic acid           | Maprotiline               |
| Nalorphine               | Meperidine                |
| Naloxone                 | d,l-Tryptophan            |
| Naltrexone               | Tyramine                  |
| α-Naphthaleneacetic acid | d,l-Tyrosine              |
| Naproxen                 | Uric acid                 |
| Niacinamide              | Verapamil                 |
| Nifedipine               | Digoxin                   |
| Nimesulide               | Lithium carbonate         |
| Norcodeine               | l-Phenylephrine           |
| Norethindrone            | Procaine                  |
| d-Norpropoxyphene        | Promazine                 |
| Noscapine                | Promethazine              |
| d,l-Octopamine           | Trimipramine              |
| Orphenadrine             | Tryptamine                |
| Oxalic acid              | Trifluoperazine           |
| Oxazepam                 | Trimethoprim              |
| Oxolinic acid            | Sulindac                  |
| Oxycodone                | Sustiva (Efavirenz)       |
| Oxymetazoline            |                           |

### BIBLIOGRAPHY

- Baselt RC. *Disposition of Toxic Drugs and Chemicals in Man*. 2nd Ed. Biomedical Publ., Davis, CA. 1982; 488
- Hawks RL, CN Chiang. *Urine Testing for Drugs of Abuse*. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986

### INDEX OF SYMBOLS

|  |                                                                         |
|--|-------------------------------------------------------------------------|
|  | In vitro diagnostic medical device                                      |
|  | Temperature limit                                                       |
|  | Do not use if package is damaged and consult instructions for use       |
|  | Catalogue number                                                        |
|  | Contains sufficient for <n> tests                                       |
|  | Use-by date                                                             |
|  | Batch code                                                              |
|  | Manufacturer                                                            |
|  | Do not re-use                                                           |
|  | Consult instructions for use or consult electronic instructions for use |
|  | Caution                                                                 |
|  | Authorized representative in the European Community                     |

REF: DET-102  
Number: CT51356  
Rev: 03  
Date: 07/02/2025

A rapid test for the qualitative detection of Marijuana in human urine.

For professional *in vitro* diagnostic use only.

### INTENDED USE

The THC Rapid Test Cassette (Urine) is a rapid chromatographic immunoassay for the detection of 11-nor- $\Delta^9$ -THC-9 COOH (THC metabolite) in human urine at a cut-off concentration of 50ng/mL.

This assay provides only a preliminary test result. A more specific alternate chemical method must be used in order to obtain a confirmed result. Gas chromatography/mass spectrophotometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

The test results can be used to provide evidence and basis for therapy and treatment plans of drug dependence and toxic psychosis. For laboratory professional *in vitro* diagnostic use only. The THC Rapid Test Cassette should only be performed by health professionals in a clinical/hospital setting to aid in screening of drug of abuse to determine the follow-up treatment measures in combination of clinical symptoms.

### SUMMARY

THC ( $\Delta^9$ -tetrahydrocannabinol) is the primary active ingredient in cannabinoids (Marijuana). When smoked or orally administered, it produces euphoric effects. Users have impaired short term memory and slowed learning. Users may also experience transient episodes of confusion and anxiety. Long term relatively heavy use may be associated with behavioral disorders. The peak effect of smoking Marijuana occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette. Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 3-10 days after smoking. The main metabolite excreted in the urine is 11-nor- $\Delta^9$ -tetrahydrocannabinol-9-carboxylic acid ( $\Delta^9$ -THC-COOH).

The THC Rapid Test Cassette (Urine) is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Marijuana in urine. The THC Rapid Test Cassette yields a positive result when the concentration of Marijuana in urine exceeds 50ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

### PRINCIPLE

The THC Rapid Test Cassette (Urine) is a rapid chromatographic immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody. During testing, a urine specimen migrates upward by capillary action. Marijuana, if present in the urine specimen below 50ng/mL, will not saturate the binding sites of the antibody coated particles in the Cassette. The antibody coated particles will then be captured by immobilized THC conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the Marijuana level is above 50ng/mL because it will saturate all the binding sites of anti-Marijuana antibodies. A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

### REAGENTS

The test contains mouse monoclonal anti-THC antibody-coupled particles and THC-protein conjugate. A goat antibody is employed in the control line system.

### PRECAUTIONS

- For medical and other professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test should be discarded according to local regulations.

### STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30 °C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

### SPECIMEN COLLECTION AND PREPARATION

#### Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible particles should be centrifuged, filtered or allowed to settle to obtain clear specimen for testing.

#### Specimen Storage

Urine specimens may be stored at 2-8 °C for up to 48 hours prior to assay. For long-term storage, specimens may be frozen and stored below -20 °C. Frozen specimens should be thawed and mixed before testing.

### MATERIALS

#### Materials Provided

- Test cassettes
- Package insert
- Droppers

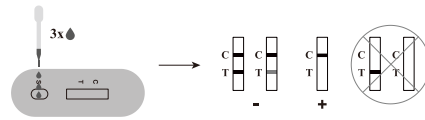
#### Materials Required But Not Provided

- Specimen collection containers
- Timer

### INSTRUCTIONS

**Allow the test, urine specimen and/or controls to reach room temperature (15-30 °C) prior to testing.**

- Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within one hour.
- Place the test cassette on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 120  $\mu$ L) to the specimen well (S) of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
- Wait for the color line(s) to appear. **The result should be read at 5 minutes.** Do not interpret the result after 10 minutes.



### INTERPRETATION OF RESULTS

(Please refer to the illustration above)

**NEGATIVE: \* Two colored lines appear.** One colored line should be in the control region (C) and another colored line should be in the test region (T). This negative result indicates that the Marijuana concentration is below the detectable level of 50ng/mL.

**\*NOTE:** The intensity of the color in the test line region (T) may vary depending on the concentration of 11-nor- $\Delta^9$ -THC-9 COOH (THC metabolite) present in the specimen. Therefore, any shade of color in the test line region (T) should be considered negative.

**POSITIVE: One colored line appears in the control region (C).** No line appears in the test region (T). This positive result indicates that the Marijuana concentration is above the detectable level of 50ng/mL.

**INVALID: Control line fails to appear.** Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test Cassette. If the problem persists, discontinue using the test Cassette immediately and contact your local distributor.

### QUALITY CONTROL

A procedural control is included in the test. A color line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this test kit; however it is recommended that positive and negative controls be tested as good laboratory testing practices to confirm the test procedure and to verify proper test performance.

### LIMITATIONS

- The THC Rapid Test Cassette (Urine) provides only a qualitative, preliminary result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrophotometry (GC/MS) is the preferred confirmatory method.<sup>1,2</sup>
- It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
- A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
- A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
- Test does not distinguish between drugs of abuse and certain medications.

### PERFORMANCE CHARACTERISTICS

#### Accuracy

A side-by-side comparison was conducted using the THC Rapid Test Cassette and a commercially available THC rapid test. Testing was performed on 100 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

| Method                  | Other THC Rapid Test |          |          | Total Results |
|-------------------------|----------------------|----------|----------|---------------|
|                         | Results              | Positive | Negative |               |
| THC Rapid Test Cassette | Positive             | 41       | 0        | 41            |
|                         | Negative             | 0        | 59       | 59            |
|                         | <b>Total Results</b> | 41       | 59       | 100           |
| <b>% Agreement</b>      | >99.9%               | >99.9%   | >99.9%   |               |

A side-by-side comparison was conducted using the THC Rapid Test Cassette and GC/MS at the cut-off of 50ng/mL. Testing was performed on 250 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

| Method                  | GC/MS                |          | Total Results |          |
|-------------------------|----------------------|----------|---------------|----------|
|                         | Results              | Positive |               | Negative |
| THC Rapid Test Cassette | Positive             | 92       | 3             | 95       |
|                         | Negative             | 2        | 153           | 155      |
|                         | <b>Total Results</b> | 94       | 156           | 250      |
| <b>% Agreement</b>      | 97.9%                | 98.1%    | 98.0%         |          |

#### Analytical Sensitivity

A drug-free urine pool was spiked with 11-nor- $\Delta^9$ -Tetrahydrocannabinol-9-COOH at the following concentrations: 0ng/mL, 12.5ng/mL, 18.75ng/mL, 25ng/mL, 31.25ng/mL, 37.5ng/mL and 75ng/mL. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

| 11-nor- $\Delta^9$ -THC-9 COOH Concentration (ng/mL) | Percent of Cut-off | n  | Visual Result |          |
|------------------------------------------------------|--------------------|----|---------------|----------|
|                                                      |                    |    | Positive      | Negative |
| 0                                                    | 0                  | 30 | 0             | 30       |
| 25                                                   | -50%               | 30 | 0             | 30       |
| 37.5                                                 | -25%               | 30 | 4             | 26       |
| 50                                                   | Cut-off            | 30 | 16            | 14       |
| 62.5                                                 | +25%               | 30 | 27            | 3        |
| 75                                                   | +50%               | 30 | 30            | 0        |
| 150                                                  | 3X                 | 30 | 30            | 0        |

#### Analytical Specificity

The following table lists compounds and their respective concentrations in urine

that yield a positive result in the THC Rapid Test Cassette (Urine) at 5 minutes.

| Compound                       | Concentration (ng/mL) |
|--------------------------------|-----------------------|
| Cannabinol                     | 35,000                |
| 11-nor- $\Delta^9$ -THC-9 COOH | 30                    |
| 11-nor- $\Delta^9$ -THC-9 COOH | 50                    |
| $\Delta^9$ -THC                | 17,000                |
| $\Delta^9$ -THC                | 17,000                |

#### Precision

A study was conducted at three hospitals using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens containing, according to GC/MS, no 11-nor- $\Delta^9$ -Tetrahydrocannabinol-9-carboxylic acid, 25% 11-nor- $\Delta^9$ -Tetrahydrocannabinol-9-carboxylic acid above and below the cut-off, and 50% 11-nor- $\Delta^9$ -Tetrahydrocannabinol-9-carboxylic acid above and below the 25ng/mL cut-off was provided to each site. The following results were tabulated:

| 11-nor- $\Delta^9$ -THC-9 COOH Concentration (ng/mL) | n per Site | Site A |    | Site B |    | Site C |    |
|------------------------------------------------------|------------|--------|----|--------|----|--------|----|
|                                                      |            | -      | +  | -      | +  | -      | +  |
| 0                                                    | 10         | 10     | 0  | 10     | 0  | 10     | 0  |
| 25                                                   | 10         | 10     | 0  | 10     | 0  | 10     | 0  |
| 37.5                                                 | 10         | 9      | 1  | 8      | 2  | 9      | 1  |
| 62.5                                                 | 10         | 1      | 9  | 1      | 9  | 2      | 8  |
| 75                                                   | 10         | 0      | 10 | 0      | 10 | 0      | 10 |

#### Effect of Urinary Specific Gravity

Fifteen urine specimens of normal, high and low specific gravity ranges were spiked with 25ng/mL and 75ng/mL of 11-nor- $\Delta^9$ -Tetrahydrocannabinol-9-carboxylic acid. The THC Rapid Test Cassette (Urine) was tested in duplicate using the fifteen neat and spiked urine specimens. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

#### Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with 11-nor- $\Delta^9$ -Tetrahydrocannabinol-9-carboxylic acid to 25ng/mL and 75ng/mL. The spiked, pH-adjusted urine was tested with the THC Rapid Test Cassette (Urine) in duplicate. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

#### Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Marijuana positive urine. The following compounds show no cross-reactivity when tested with the THC Rapid Test Cassette (Urine) at a concentration of 100 $\mu$ g/mL.

#### Non Cross-Reacting Compounds

|                      |                        |
|----------------------|------------------------|
| 4-Acetamidophenol    | Deoxycorticosterone    |
| Acetophenetidin      | Dextromethorphan       |
| N-Acetylprocainamide | Diazepam               |
| Acetylsalicylic acid | Diclofenac             |
| Aminopyrine          | Diflunisal             |
| Amitypyline          | Digoxin                |
| Amobarbital          | Diphenhydramine        |
| Amoxicillin          | Doxylamine             |
| Ampicillin           | Ecgonine hydrochloride |
| L-Ascorbic acid      | Ecgonine methylester   |
| D,L-Amphetamine      | (-)- $\psi$ -Ephedrine |
| L-Amphetamine        | Erythromycin           |
| Apomorphine          | $\beta$ -Estradiol     |
| Aspartame            | Estrone-3-sulfate      |
| Atropine             | Ethyl-p-aminobenzoate  |
| Benzilic acid        | Fenoprofen             |
| Benzoic acid         | Furosemide             |
| Benzoylcegonine      | Genistic acid          |
| Benzphetamine        | Hemoglobin             |

|                                            |                               |
|--------------------------------------------|-------------------------------|
| Bilirubin                                  | Hydralazine                   |
| (±) Brompheniramine                        | Hydrochlorothiazide           |
| Caffeine                                   | Hydrocodone                   |
| Cannabidiol                                | Hydrocortisone                |
| Chloralhydrate                             | O-Hydroxyhippuric acid        |
| Chloramphenicol                            | 3-Hydroxytyramine             |
| Chlordiazepoxide                           | Ibuprofen                     |
| Chlorothiazide                             | Imipramine                    |
| (±) Chlorpheniramine                       | Iproniazid                    |
| Chlorpromazine                             | (±) - Isoproterenol           |
| Chlorquine                                 | Isoxsuprine                   |
| Cholesterol                                | Ketamine                      |
| Clomipramine                               | Ketoprofen                    |
| Clonidine                                  | Labetalol                     |
| Cocaine hydrochloride                      | Levorphanol                   |
| Codeine                                    | Loperamide                    |
| Cortisone                                  | Maprotiline                   |
| (-) Cotinine                               | Meprobamate                   |
| Creatinine                                 | Methadone                     |
| Prednisolone                               | Methoxyphenamine              |
| Prednisone                                 | Quinidine                     |
| Procaine                                   | Quinine                       |
| Promazine                                  | Ranitidine                    |
| Promethazine                               | Salicylic acid                |
| D,L-Propranolol                            | Secobarbital                  |
| D-Propoxyphene                             | Serotonin                     |
| Verapamil                                  | (5-Hydroxytyramine)           |
| D-Pseudoephedrine                          | Sulfamethazine                |
| Sulindac                                   | Tetrahydrocortisone,          |
| Temazepam                                  | 3-Acetate                     |
| Tetracycline                               | Tetrahydrocortisone           |
| Thioridazine                               | 3 (β-D-glucuronide)           |
| Thiamine                                   | Tetrahydrozoline              |
| Zomepirac                                  | Thebaine                      |
| (+) 3,4-Methylenedioxy-<br>amphetamine     | Oxolinic acid                 |
| (+) 3,4-Methylenedioxy-<br>methamphetamine | Oxycodone                     |
| Methylphenidate                            | Oxymetazoline                 |
| Methyprylon                                | p-Hydroxy-<br>methamphetamine |
| Morphine-3-<br>β-D-glucuronide             | Papaverine                    |
| Nalidixic acid                             | Penicillin-G                  |
| Nalorphine                                 | Pentazocine                   |
| Naloxone                                   | Pentobarbital                 |
| Naltrexone                                 | Perphenazine                  |
| Naproxen                                   | Phencyclidine                 |
| Niacinamide                                | Phenelzine                    |
| Nifedipine                                 | Phenobarbital                 |
| Norcodein                                  | Phentermine                   |
| Norethindrone                              | L-Phenylephrine               |
| D-Norpropoxyphene                          | β-Phenylethylamine            |
| Noscapine                                  | Phenylpropanolamine           |
| D,L-Octopamine                             | D, L-Thyroxine                |
| Oxalic acid                                | Tolbutamine                   |
| Oxazepam                                   | Triamterene                   |
| Tyramine                                   | Trifluoperazine               |
| D, L-Tyrosine                              | Trimethoprim                  |
| Uric acid                                  | Trimipramine                  |
|                                            | Tryptamine                    |
|                                            | D, L-Tryptophan               |

2. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd Ed.  
Biomedical Publ., Davis, CA. 1982; 488

### INDEX OF SYMBOLS

|  |                                                                         |
|--|-------------------------------------------------------------------------|
|  | In vitro diagnostic medical device                                      |
|  | Temperature limit                                                       |
|  | Do not use if package is damaged and consult instructions for use       |
|  | Catalogue number                                                        |
|  | Contains sufficient for <n> tests                                       |
|  | Use-by date                                                             |
|  | Batch code                                                              |
|  | Manufacturer                                                            |
|  | Do not re-use                                                           |
|  | Consult instructions for use or consult electronic instructions for use |
|  | Caution                                                                 |
|  | Authorized representative in the European Community                     |

REF: DTH-102  
Number: CT51399  
Rev: 02  
Date: 08/01/2025

### BIBLIOGRAPHY

1. Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986

A rapid test for the qualitative detection of Methcathinone in human urine.

For medical and other professional *in vitro* diagnostic use only.

### INTENDED USE

The MCAT Rapid Test Cassette (Urine) is a rapid chromatographic immunoassay for the detection of methcathinone in urine at a cut-off concentration of 500 ng/mL. This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

This assay provides only a qualitative, preliminary test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

The test results can be used to provide evidence and basis for therapy and treatment plans of drug dependence and toxic psychosis. For laboratory professional *in vitro* diagnostic use only. The MCAT Rapid Test Cassette (Urine) should only be performed by health professionals in a clinical/hospital setting to aid in screening of drug of abuse to determine the follow-up treatment measures in combination of clinical symptoms.

### SUMMARY

Methcathinone, is a monoamine alkaloid and psychoactive stimulant, a substituted cathinone. Methcathinone is a highly addictive drug, primarily psychologically addicting and most of the signs of addiction to the drug are emotional or psychological. It has been popularized and continues to be sold under misleading names such as "bath salts", "plant fertilizers" or "research chemicals", but it is actually a powerful psycho-stimulant used as a recreational drug. Effects of this drug typically last from 4 to 6 hours. It is used as a recreational drug due to its potent stimulant and euphoric effects and is considered to be addictive, with both physical and psychological withdrawal occurring if its use is discontinued after prolonged or high-dosage administration<sup>1</sup>. It is usually snorted, but can be smoked, injected, or taken orally. Methcathinone is listed as a Schedule I controlled substance by the Convention on Psychotropic Substances and the United States' Controlled Substances Act, and as such it is not considered to be safe or effective in the treatment, diagnosis, prevention, or cure of any disease, and has no approved medical use. Methcathinone has very strong affinities for the dopamine transporter and the norepinephrine (noradrenaline) transporter. Its affinity for the serotonin transporter is less than that of methamphetamine.<sup>2</sup>

Effects of short term intoxication are similar to those produced by crack cocaine or methamphetamine: stimulation of heart rate and respiration; feeling of euphoria; loss of appetite; increased alertness; pupils may be dilated; body temperature may be slightly elevated. Acute intoxication at higher doses may also result in insomnia, tremors and muscle twitching, fever, headaches, convulsions, irregular heart rate and respirations, anxiety, restlessness, paranoia, hallucinations and delusions.

### PRINCIPLE

The MCAT Rapid Test Cassette (Urine) is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a urine specimen migrates upward by capillary action. Methcathinone, if present in the urine specimen below the cut-off level, will not saturate the binding sites of the antibody in the test. The antibody coated particles will then be captured by immobilized methcathinone-protein conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if methcathinone level exceeds the cut-off level, because it will saturate all the binding sites of anti-methcathinone antibody.

A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a

procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

### REAGENTS

The test contains mouse monoclonal anti-methcathinone antibody coupled particles and methcathinone-protein conjugate. A goat antibody is employed in the control line system.

### PRECAUTIONS

- For medical and other professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test should be discarded according to local regulations.

### STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30 °C). The test is stable through the expiration date printed on the sealed pouch or label of the closed canister. The test must remain in the sealed pouch or closed canister until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

### SPECIMEN COLLECTION AND PREPARATION

#### Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible particles should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

#### Specimen Storage

Urine specimens may be stored at 2-8 °C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20 °C. Frozen specimens should be thawed and mixed before testing.

### MATERIALS

#### Materials Provided

- Test Cassettes
- Package Insert
- Droppers

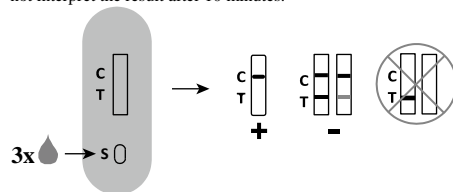
#### Materials Required But Not Provided

- Specimen Collection Containers
- Timer

### DIRECTIONS FOR USE

Allow the test, urine specimen, and/or controls to reach room temperature (15-30 °C) prior to testing.

- Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within one hour.
- Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 120 µL) to the specimen well (S) of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
- Wait for the colored line(s) to appear. Read results at 5 minutes. Do not interpret the result after 10 minutes.



### INTERPRETATION OF RESULTS

(Please refer to the illustration above)

**NEGATIVE: Two colored lines appear.** One colored line should be in the control line region (C), and another apparent colored line should be in the test line region (T). This negative result indicates that the methcathinone concentration is below the detectable cut-off level.

\*NOTE: The shade of color in the test line region (T) may vary, but it

should be considered negative whenever there is even a faint colored line.

**POSITIVE: One colored line appears in the control line region (C).** No line appears in the test line region (T). This positive result indicates that the methcathinone concentration exceeds the detectable cut-off level.

**INVALID: Control line fails to appear.** Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

### QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory testing practice to confirm the test procedure and to verify proper test performance.

### LIMITATIONS

- The MCAT Rapid Test Cassette (Urine) provides only a qualitative, preliminary result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
- It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
- A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
- A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
- Test does not distinguish between drugs of abuse and certain medications.

### PERFORMANCE CHARACTERISTICS

A side-by-side comparison was conducted using The MCAT Rapid Test Cassette and GC/MS at the cut-off of 500ng/mL. Testing was performed on 102 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

| Method                   | GC/MS    |          |          | Total Results |
|--------------------------|----------|----------|----------|---------------|
|                          | Results  | Positive | Negative |               |
| MCAT Rapid Test Cassette | Positive | 20       | 4        | 24            |
|                          | Negative | 2        | 76       | 78            |
| <b>Total Results</b>     |          | 22       | 80       | 102           |
| <b>% Agreement</b>       |          | 90.9%    | 95.0%    | 94.1%         |

#### Analytical Sensitivity

A drug-free urine pool was spiked with methcathinone at the following concentrations: 0 ng/mL, 250 ng/mL, 375 ng/mL, 500 ng/mL, 625 ng/mL, 750 ng/mL and 1500 ng/mL. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

| Methcathinone Concentration (ng/mL) | Percent of Cut-off | N  | Visual Result |          |
|-------------------------------------|--------------------|----|---------------|----------|
|                                     |                    |    | Negative      | Positive |
| 0                                   | 0                  | 30 | 30            | 0        |
| 250                                 | -50%               | 30 | 30            | 0        |
| 375                                 | -25%               | 30 | 28            | 2        |
| 500                                 | Cut-off            | 30 | 17            | 13       |
| 625                                 | +25%               | 30 | 3             | 27       |
| 750                                 | +50%               | 30 | 0             | 30       |
| 1500                                | 3X                 | 30 | 0             | 30       |

### Analytical Specificity

The following table lists compounds that are positively detected in urine by the MCAT Rapid Test Cassette (Urine) at 5 minutes.

| Compound                  | Concentration(ng/mL) |
|---------------------------|----------------------|
| S(-)-Methcathinone HCl    | 500                  |
| Methoxyphenamine          | 100000               |
| R(+)-Methcathinone HCl    | 1500                 |
| 3-Fluoromethcathinone HCl | 1500                 |

### Precision

A study was conducted at three hospitals by using three different lots of product to demonstrate the within run, between run and between operator precision. An identical Cassette of coded specimens containing, according to GC/MS, no methcathinone, 25% above and below the cut-off and 50% above and below the cut-off of methcathinone was provided to each site. The following results were tabulated:

| Methcathinone Concentration (ng/mL) | n per Site | Site A |    | Site B |    | Site C |    |
|-------------------------------------|------------|--------|----|--------|----|--------|----|
|                                     |            | -      | +  | -      | +  | -      | +  |
| 0                                   | 10         | 10     | 0  | 10     | 0  | 10     | 0  |
| 250                                 | 10         | 10     | 0  | 10     | 0  | 10     | 0  |
| 375                                 | 10         | 9      | 1  | 8      | 2  | 9      | 1  |
| 625                                 | 10         | 2      | 8  | 2      | 8  | 2      | 8  |
| 750                                 | 10         | 0      | 10 | 0      | 10 | 0      | 10 |

### Effect of Urinary Specific Gravity

Fifteen urine specimens of normal, high, and low specific gravity ranges were spiked with 250 ng/mL and 750 ng/mL of methcathinone. The MCAT Rapid Test Cassette (Urine) was tested in duplicate using the fifteen neat and spiked urine specimens. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

### Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with methcathinone to 250 ng/mL and 750 ng/mL. The spiked, pH-adjusted urine was tested with the MCAT Rapid Test Cassette (Urine) in duplicate. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

### Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or methcathinone positive urine. The following compounds show no cross-reactivity when tested with the MCAT Rapid Test Cassette (Urine) at a concentration of 100 µg/mL.

### Non Cross-Reacting Compounds

|                                   |                         |
|-----------------------------------|-------------------------|
| Acetophenetidin (phenacetin)      | Promethazine            |
| N-Acetylprocainamide (acecainide) | Papaverine              |
| Acetylsalicylic acid(aspirin)     | Penicillin              |
| AminopyrineAminophenazone         | Perphenazine            |
| Amitriptyline                     | Phenelzine              |
| Amobarbital                       | Phenobarbital           |
| Amoxicillin                       | l-Phenylephrine         |
| Aspartame Asp-Phemethylester      | (R)-(-)-Phenylephrine   |
| Atropine                          | β-Phenylethylamine      |
| Benzilic acid                     | Prednisolone            |
| Benzoic acid                      | Prednisone              |
| Bilirubin                         | Procaine                |
| Chloramphenicol                   | Quinidine               |
| Chlorothiazide                    | Quinine                 |
| Chlorpromazine                    | Serotonin               |
| Chloroquine                       | (5-Hydroxytryptamine)   |
| Cholesterol                       | Sulfamethazine          |
| Clomipramine                      | Temazepam               |
| Clonidine                         | Tetracycline            |
| Cocaine                           | Tetrahydrozoline        |
| Cortisone                         | Thiamine (vitamin B1)   |
| (-)Cotinine                       | Thioridazine            |
| Creatinine                        | d,L-Tyrosine L-Tyrosine |
| Dextromethorphan                  | Tolbutamide             |













Diazepam  
Diclofenac  
Diflunisal  
Digoxin  
Diphenhydramine  
Doxylamine  
Erythromycin  
β-Estradiol Estradiol  
Estrone-3- Sulfate  
Ethyl-p-aminobenzoate (Benzocaine)  
Fenopropfen  
Furosemide  
Gentisic acid  
Hydralazine  
Hydrochlorothiazide  
Hydrocodone  
O-Hydroxyhippuric acid  
p-Hydroxymethamphetamine  
3-Hydroxytyramine (Dopamine)  
Ibuprofen  
Imipramine  
(-) Isoproterenol [(-)isoprenaline]  
Isoxsuprine  
Ketoprofen  
Labetalol  
Maprotiline  
Methadone  
Meperidine (Pethidine)  
Methoxyphenamine  
Methylphenidate (Ritalin)  
Nalidixic acid  
Naloxone  
Naltrexone  
Niacinamide (nicotinamide)  
Nifedipine  
Norethindrone Norethisterone  
d-Norpropoxyphene  
Noscapine  
d,l- Octopamine  
Oxazepam  
Sodium chloride  
Pemoline  
Fluoxetine  
Metoprolol  
Amantadine  
Chlorpropamide  
Clozapine  
Baclofen  
Amikacin  
Droperidol  
Gentamicin  
Indomethacin  
Sulfamethoxazole  
Sulfisoxazole  
Salbutamol  
Tobramycin  
Zopiclone  
Cephalexin  
Clindamycin  
Dexamethasone  
Dicumarol  
Carisoprodol  
Metoclopramide  
(+)-cis-Diltiazem  
Propritiyline  
Haloperidol

Triamterene  
Trimethoprim  
Tryptamine  
d,l-Tryptophan  
Uric acid  
Verapamil  
Zomepirac  
Ampicillin  
Caffeine  
(+/-)-Chlorpheniramine  
Ranitidine  
Quinacrine  
Trans-2-Phenylcyclopropylamine  
(1R, 2S) - (-)-Ephedrine=184  
l-Ephedrine  
Dicyclomine  
Trazodone  
Nimesulide  
Buspirone  
l-Thyroxine  
(2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine)  
Oxymorphone  
Cyclobenzaprine  
Lidocaine  
Guaiacol Glyceryl Ether carbamate  
Guaiacol Glyceryl Ether  
Amoxapine  
(+) Chlorpheniramine  
Chlorprothixene (meprobamate)  
R (-)Deprenyl (selegiline)  
Pheniramine  
4-Dimethylaminoantipyrine  
Riboflavin (vitamine B2)  
α -Naphthaleneacetic Acid  
(+/-) Epinephrine  
Ephedrine  
Phenothiazine  
Albumin  
d (+) Glucose  
Disopyramide  
Metronidazole  
Vancomycin  
Spironolactone  
Emetine  
Sertraline  
Heroin (diacetylmorphine)  
R(+)-Cathinone  
S(-)-Cathinone  
Barbital  
Lansoprazole  
Aprobabital  
Butalbital (Tetralobarbital)  
Butethal  
Cyclopentobarbital  
Estazolam  
Lorazepam  
Lorazepam glucuronide  
Midazolam  
Nitrazepam  
Triazolam  
Alprazolam  
Clobazam  
3,4-Methylenedioxyethylamphet  
Amine (3,4-MDE)

**BIBLIOGRAPHY**

1. Calkins RF, Aktan GB, Hussain KL (1995). "Methcathinone: the next illicit stimulant epidemic?". Journal of Psychoactive Drugs. 27 (3): 277–85. doi:10.1080/02791072.1995.10472472. PMID 8594170.
2. Rothman, B. R.; et al. (June 2003). "In Vitro Characterization of Ephedrine-Related Stereoisomers at Biogenic Amine Transporters and the Receptorome Reveals Selective Actions as Norepinephrine Transporter Substrates". The Journal of Pharmacology and Experimental Therapeutics. 307 (1): 138–45.

**INDEX OF SYMBOLS**

|                                                                                   |                                                                         |
|-----------------------------------------------------------------------------------|-------------------------------------------------------------------------|
|  | In vitro diagnostic medical device                                      |
|  | Temperature limit                                                       |
|  | Do not use if package is damaged and consult instructions for use       |
|  | Catalogue number                                                        |
|  | Contains sufficient for <n> tests                                       |
|  | Use-by date                                                             |
|  | Batch code                                                              |
|  | Manufacturer                                                            |
|  | Do not re-use                                                           |
|  | Consult instructions for use or consult electronic instructions for use |
|  | Caution                                                                 |
|  | Authorized representative in the European Community                     |

REF: DMCA-102  
Number: CT541960  
Rev: 03  
Date: 07/10/2025

A rapid test for the qualitative detection of Benzodiazepines in human urine.

For medical and other professional *in vitro* diagnostic use only.

**INTENDED USE**

The BZO Rapid Test Cassette (Urine) is a rapid chromatographic immunoassay for the detection of Oxazepam (major metabolite) in urine at a cut-off concentration of 200ng/mL. This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

This assay provides only a qualitative, preliminary test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

The test results can be used to provide evidence and basis for therapy and treatment plans of drug dependence and toxic psychosis. For laboratory professional *in vitro* diagnostic use only. The BZO Rapid Test Cassette should only be performed by health professionals in a clinical/hospital setting to aid in screening of drug of abuse to determine the follow-up treatment measures in combination of clinical symptoms

**SUMMARY**

Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors involving a neurochemical called gamma aminobutyric acid (GABA). Because they are safer and more effective, Benzodiazepines have replaced Barbiturates in the treatment of both anxiety and insomnia. Benzodiazepines are also used as sedatives before some surgical and medical procedures, and for the treatment of seizure disorders and alcohol withdrawal.

Risk of physical dependence increases if Benzodiazepines are taken regularly (e.g., daily) for more than a few months, especially at higher than normal doses. Stopping abruptly can bring on such symptoms as trouble sleeping, gastrointestinal upset, feeling unwell, loss of appetite, sweating, trembling, weakness, anxiety and changes in perception. Only trace amounts (less than 1%) of most Benzodiazepines are excreted unaltered in the urine; most of the concentration in urine is conjugated drug. The detection period for the Benzodiazepines in the urine is 3-7 days.

The BZO Rapid Test Cassette (Urine) is a rapid urine-screening test that can be performed without the use of an instrument. The test utilizes the antibody to selectively detect elevated levels of Benzodiazepines in urine. The BZO Rapid Test Cassette (Urine) yields a positive result when the Benzodiazepines in urine exceeds the cut-off level.

**PRINCIPLE**

The BZO Rapid Test Cassette (Urine) is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a urine specimen migrates upward by capillary action. Benzodiazepines, if present in the urine specimen below the cut-off level, will not saturate the binding sites of the antibody in the test. The antibody coated particles will then be captured by immobilized Benzodiazepines-protein conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the Benzodiazepines level exceeds the cut-off level, because it will saturate all the binding sites of anti-Benzodiazepines antibody.

A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

**REAGENTS**

The test contains mouse monoclonal anti-Benzodiazepines antibody coupled particles and Benzodiazepines-protein conjugate. A goat antibody is employed in the control line system.

**PRECAUTIONS**

- For medical and other professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until used.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test should be discarded according to local regulations.

**STORAGE AND STABILITY**

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

**SPECIMEN COLLECTION AND PREPARATION**

**Urine Assay**

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible particles should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

**Specimen Storage**

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

**MATERIALS**

**Materials Provided**

- Test cassettes
- Droppers
- Package insert

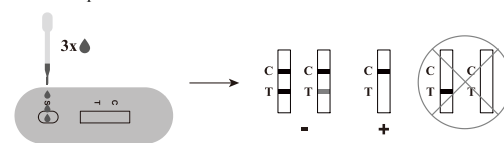
**Materials Required But Not Provided**

- Specimen collection container
- Timer

**DIRECTIONS FOR USE**

Allow the test, urine specimen, and/or controls to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within one hour.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 120 µL) to the specimen well (S) of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
3. Wait for the colored line(s) to appear. Read results at 5 minutes. Do not interpret the result after 10 minutes.



**INTERPRETATION OF RESULTS**

(Please refer to the illustration above)

**NEGATIVE: Two colored lines appear.** One colored line should be in the control line region (C), and another colored line should be in the test line region (T). This negative result indicates that the Benzodiazepine concentration is below the detectable cut-off level.

\*NOTE: The shade of color in the test line region (T) may vary, but it should be considered negative whenever there is even a faint colored line.

**POSITIVE: One colored line appears in the control line region (C).**

No line appears in the test line region (T). This positive result indicates that the Benzodiazepine concentration exceeds the detectable cut-off level.

**INVALID: Control line fails to appear.** Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

**QUALITY CONTROL**

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory testing practice to confirm the test procedure and to verify proper test performance.

**LIMITATIONS**

1. The BZO Rapid Test Cassette (Urine) provides only a qualitative, preliminary result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.<sup>1,2</sup>
2. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. Test does not distinguish between drugs of abuse and certain medications.

**PERFORMANCE CHARACTERISTICS**

**Accuracy**

A side-by-side comparison was conducted using the BZO Rapid Test Cassette (Urine) and a commercially available BZO rapid test. Testing was performed on 95 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

| Method                  | Other BZO Rapid Test |          | Total Results |
|-------------------------|----------------------|----------|---------------|
|                         | Positive             | Negative |               |
| BZO Rapid Test Cassette | Positive             | 0        | 43            |
|                         | Negative             | 52       | 52            |
| <b>Total Results</b>    | 43                   | 52       | 95            |
| <b>% Agreement</b>      | >99.9%               | >99.9%   | >99.9%        |

A side-by-side comparison was conducted using the BZO Rapid Test Cassette (Urine) and GC/MS at the cut-off of 200ng/mL. Testing was performed on 250 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

| Method                  | GC/MS    |          | Total Results |
|-------------------------|----------|----------|---------------|
|                         | Positive | Negative |               |
| BZO Rapid Test Dipstick | Positive | 2        | 129           |
|                         | Negative | 120      | 121           |
| <b>Total Results</b>    | 128      | 122      | 250           |
| <b>% Agreement</b>      | 99.2%    | 98.4%    | 98.8%         |

**Analytical Sensitivity**

A drug-free urine pool was spiked with Oxazepam at the following concentrations: 0ng/mL, 100ng/mL, 150ng/mL, 200ng/mL, 250ng/mL,

300ng/mL and 600ng/mL. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

| Oxazepam Concentration (ng/mL) | Percent of Cut-off | n  | Visual Result |          |
|--------------------------------|--------------------|----|---------------|----------|
|                                |                    |    | Negative      | Positive |
| 0                              | 0                  | 30 | 30            | 0        |
| 100                            | -50%               | 30 | 30            | 0        |
| 150                            | -25%               | 30 | 27            | 3        |
| 200                            | Cut-off            | 30 | 16            | 14       |
| 250                            | +25%               | 30 | 3             | 27       |
| 300                            | +50%               | 30 | 0             | 30       |
| 600                            | 3X                 | 30 | 0             | 30       |

**Analytical Specificity**

The following table lists compounds that are positively detected in urine by the BZO Rapid Test Cassette (Urine) at 5 minutes.

| Compound                 | Concentration (ng/mL) |
|--------------------------|-----------------------|
| Alprazolam               | 70                    |
| a-hydroxyalprazolam      | 1,000                 |
| Clobazam                 | 120                   |
| Clonazepam               | 300                   |
| Clorazepate dipotassium  | 300                   |
| Delorazepam              | 600                   |
| Desalkylflurazepam       | 120                   |
| Flunitrazepam            | 120                   |
| (±) Lorazepam            | 2,000                 |
| RS-Lorazepam glucuronide | 120                   |
| Midazolam                | 4,000                 |
| Bromazepam               | 600                   |
| Chlordiazepoxide         | 600                   |
| Nitrazepam               | 120                   |
| Norchlordiazepoxide      | 70                    |
| Nordiazepam              | 600                   |
| Oxazepam                 | 200                   |
| Temazepam                | 70                    |
| Diazepam                 | 200                   |
| Estazolam                | 4,000                 |
| Triazolam                | 2,000                 |

**Precision**

A study was conducted at three hospitals by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens containing, according to GC/MS, no Oxazepam, 25% Oxazepam above and below the cut-off and 50% Oxazepam above and below the 200ng/mL cut-off was provided to each site. The following results were tabulated:

| Oxazepam Concentration (ng/mL) | n per Site | Site A |    | Site B |    | Site C |    |
|--------------------------------|------------|--------|----|--------|----|--------|----|
|                                |            | -      | +  | -      | +  | -      | +  |
| 0                              | 10         | 10     | 0  | 10     | 0  | 10     | 0  |
| 100                            | 10         | 10     | 0  | 10     | 0  | 10     | 0  |
| 150                            | 10         | 9      | 1  | 8      | 2  | 9      | 1  |
| 250                            | 10         | 1      | 9  | 1      | 9  | 2      | 8  |
| 300                            | 10         | 0      | 10 | 0      | 10 | 0      | 10 |

**Effect of Urinary Specific Gravity**

Fifteen urine specimens of normal, high, and low specific gravity ranges were spiked with 100ng/mL and 300ng/mL of Oxazepam. The BZO Rapid Test Cassette (Urine) was tested in duplicate using the fifteen neat and spiked urine specimens. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

**Effect of Urinary pH**

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with Oxazepam to 100ng/mL and 300ng/mL. The spiked, pH-adjusted urine was tested with the BZO Rapid Test Cassette (Urine) in duplicate. The results

demonstrate that varying ranges of pH do not interfere with the performance of the test.

**Cross-Reactivity**

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Oxazepam positive urine. The following compounds show no cross-reactivity when tested with the BZO Rapid Test Cassette (Urine) at a concentration of 100 µg/mL.

**Non Cross-Reacting Compounds**

|                                          |                           |
|------------------------------------------|---------------------------|
| Acetaminophen                            | Deoxycorticosterone       |
| Acetophenetidin                          | Dextromethorphan          |
| N-Acetylprocainamide                     | Diclofenac                |
| Acetylsalicylic acid                     | Diflunisal                |
| Aminopyrine                              | Digoxin                   |
| Amitypyline                              | Diphenhydramine           |
| Amobarbital                              | Doxylamine                |
| Amoxicillin                              | Ecgonine                  |
| Ampicillin                               | Ecgonine methylester      |
| L-Ascorbic acid                          | (-)-ψ-Ephedrine           |
| D,L-Amphetamine sulfate                  | [1R,2S] (-) Ephedrine     |
| Apomorphine                              | (L) - Epinephrine         |
| Aspartame                                | Erythromycin              |
| Atropine                                 | β-Estradiol               |
| Benzoic acid                             | Estrone-3-sulfate         |
| Benzoic acid                             | Ethyl-p-aminobenzoate     |
| Benzoylcegonine                          | Fenoprofen                |
| Benzphetamine                            | Furosemide                |
| Bilirubin                                | Gentisic acid             |
| (±) – Brompheniramine                    | Hemoglobin                |
| Caffeine                                 | Hydralazine               |
| Cannabidiol                              | Hydrochlorothiazide       |
| Cannabinal                               | Hydrocodone               |
| Chloralhydrate                           | Hydrocortisone            |
| Chloramphenicol                          | O-Hydroxyhippuric acid    |
| Chlorothiazide                           | p-Hydroxyamphetamine      |
| (±) – Chlorpheniramine                   | p-Hydroxy-methamphetamine |
| Chlorpromazine                           | 3-Hydroxytyramine         |
| Chlorquine                               | Ibuprofen                 |
| Cholesterol                              | Imipramine                |
| Clomipramine                             | Iproniazid                |
| Clonidine                                | (±) - Isoproterenol       |
| Cocaeethylene                            | Isoxsuprine               |
| Cocaine                                  | Ketamine                  |
| Codeine                                  | Ketoprofen                |
| Cortisone                                | Labetalol                 |
| (-) Cotinine                             | Loperamide                |
| Creatinine                               | Maprotiline               |
| MDE                                      | β-Phenylethylamine        |
| Meperidine                               | Phenylpropanolamine       |
| Meprobamate                              | Prednisolone              |
| Methadone                                | Prednisone                |
| L-Methamphetamine                        | Procaine                  |
| Methoxyphenamine                         | Promazine                 |
| (±) - 3,4-Methylenedioxy-amphetamine     | Promethazine              |
| (±) - 3,4-Methylenedioxy-methamphetamine | D,L-Propranolol           |
| Morphine-3-β-D glucuronide               | D-Propoxyphene            |
| Morphine Sulfate                         | D-Pseudoephedrine         |
| Nalidixic acid                           | Quinacrine                |
| Naloxone                                 | Quinidine                 |
| Naltrexone                               | Quinine                   |
| Naproxen                                 | Ranitidine                |
| Niacinamide                              | Salicylic acid            |
| Nifedipine                               | Secobarbital              |
| Norcodein                                | Serotonin                 |
|                                          | Sulfamethazine            |

|                                               |                      |
|-----------------------------------------------|----------------------|
| Norethindrone                                 | Sulindac             |
| D-Norpropoxyphene                             | Tetracycline         |
| Noscapine                                     | Tetrahydrocortisone, |
| D,L-Octopamine                                | 3-Acetate            |
| Oxalic acid                                   | Tetrahydrocortisone  |
| Oxolinic acid                                 | 3-(β-D-glucuronide)  |
| Oxycodone                                     | Tetrahydrozoline     |
| Oxymetazoline                                 | Thiamine             |
| Papaverine                                    | Thioridazine         |
| Penicillin-G                                  | D,L-Tyrosine         |
| Pentazocine                                   | Tolbutamide          |
| Pentobarbital                                 | Triamterene          |
| Perphenazine                                  | Trifluoperazine      |
| Phencyclidine                                 | Trimethoprim         |
| Phenelzine                                    | Trimipramine         |
| Phenobarbital                                 | Tryptamine           |
| Phentermine                                   | D,L-Tryptophan       |
| Trans-2-phenylcyclo-propylamine hydrochloride | Tyramine             |
| L-Phenylephrine                               | Uric acid            |
| Zomepirac                                     | Verapamil            |

**BIBLIOGRAPHY**

- Baselt RC. *Disposition of Toxic Drugs and Chemicals in Man*. 2nd Ed. Biomedical Publ., Davis, CA. 1982; 488
- Hawks RL, CN Chiang. *Urine Testing for Drugs of Abuse*. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986

**INDEX OF SYMBOLS**

|  |                                                                         |
|--|-------------------------------------------------------------------------|
|  | In vitro diagnostic medical device                                      |
|  | Temperature limit                                                       |
|  | Do not use if package is damaged and consult instructions for use       |
|  | Catalogue number                                                        |
|  | Contains sufficient for <n> tests                                       |
|  | Use-by date                                                             |
|  | Batch code                                                              |
|  | Manufacturer                                                            |
|  | Do not re-use                                                           |
|  | Consult instructions for use or consult electronic instructions for use |
|  | Caution                                                                 |
|  | Authorized representative in the European Community                     |

REF: DBZ-102  
Number: CT54669  
Rev: 03  
Date: 03/03/2026

A rapid test for the qualitative detection of α-PVP in human urine.  
For medical and other professional *in vitro* diagnostic use only.

### INTENDED USE

The α-PVP Rapid Test Cassette (Urine) is a rapid chromatographic immunoassay for the detection of alpha-Pyrrolidinovalerophenone (α-PVP) in human urine at a cut-off concentration of 1000ng/mL.

This assay provides only a qualitative, preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) or Liquid Chromatography/mass spectrometry (LC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

The test results can be used to provide evidence and basis for therapy and treatment plans of drug dependence and toxic psychosis. For laboratory professional *in vitro* diagnostic use only. The α-PVP Rapid Test Cassette should only be performed by health professionals in a clinical/hospital setting to aid in screening of drug of abuse to determine the follow-up treatment measures in combination of clinical symptoms.

### SUMMARY

α-Pyrrolidinovalerophenone (also known as α-PVP, A-PVP, alpha-PVP, and Flakka) is a synthetic stimulant substance of the cathinone and pyrrolidine chemical classes.<sup>1</sup> α-PVP may be quantified in blood, plasma or urine to confirm a diagnosis of poisoning in hospitalized patients or to provide evidence in a medicolegal death investigation.<sup>2</sup> It generally comes in the form of either a crystalline powder or crystallized shards which users can ingest to produce powerful but short-lived euphoric stimulant effects which are comparable to those of methamphetamine and cocaine when insufflated or vaporized. α-PVP has been reported to be the cause, or a significant contributory cause of death in suicides and overdoses caused by combinations of drugs.<sup>3,4</sup> It has also been linked to at least one death where it was combined with pentedrone and caused heart failure.

The α-PVP Rapid Test Cassette (Urine) is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of alpha-Pyrrolidinovalerophenone in urine. The α-PVP Rapid Test Cassette (Urine) yields a positive result when alpha-Pyrrolidinovalerophenone in urine exceeds 1000ng/mL.

### PRINCIPLE

The α-PVP Rapid Test Cassette (Urine) is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody. During testing, a urine specimen migrates upward by capillary action. alpha-Pyrrolidinovalerophenone, if present in the urine specimen below 1000ng/mL, will not saturate the binding sites of antibody-coated particles in the test. The antibody-coated particles will then be captured by immobilized alpha-Pyrrolidinovalerophenone conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the alpha-Pyrrolidinovalerophenone level exceeds 1000ng/mL because it will saturate all the binding sites of anti-alpha-Pyrrolidinovalerophenone antibodies. A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration lower than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

### REAGENTS

The test contains mouse monoclonal alpha-Pyrrolidinovalerophenone antibody-coupled particles and alpha-Pyrrolidinovalerophenone-protein conjugate. A goat antibody is employed in the control line system.

### PRECAUTIONS

- For medical and other professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test should be discarded according to local regulations.

### STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30 °C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

### SPECIMEN COLLECTION AND PREPARATION

#### Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed settle to obtain a clear specimen for testing.

#### Specimen Collection

Urine specimens may be stored at 2-8 °C for up to 48 hours prior to assay. For prolonged storage, specimens may be frozen and stored below -20 °C. Frozen specimens should be thawed and mixed before testing.

### MATERIALS

#### Materials Provided

- Test Cassettes
- Package Insert
- Droppers

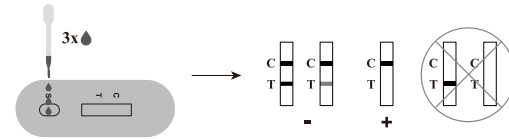
#### Materials Required But Not Provided

- Specimen collection containers
- Timer

### DIRECTIONS FOR USE

Allow the test, urine specimen, and/or controls to reach room temperature (15-30°C) prior to testing.

- Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within one hour.
- Place the test device on a clean and level surface. Hold the dropper vertically and transfer **3 full drops of urine** (approx. 120 µL) to the specimen well (S) of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
- Wait for the colored line(s) to appear. **Read results at 5 minutes.** Do not interpret the result after 10 minutes.



### INTERPRETATION OF RESULTS

(Please refer to the illustration above)

**NEGATIVE: \* Two colored lines appear.** One colored line should be in the control line region (C), and another colored line should be in the test line region (T). This negative result indicates that the alpha-Pyrrolidinovalerophenone concentrations are below the detectable level (1000 ng/mL).

**\*NOTE:** The shade of color in the test line region (T) will vary, but it should be considered negative whenever there is even a faint colored line.

**POSITIVE: One colored line appears in the control region (C).** No line appears in the test line region (T). This positive result indicates that the alpha-Pyrrolidinovalerophenone concentration exceeds the detectable level (1000 ng/mL).

**INVALID: Control line (C) fails to appear.** Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test. If the problem persists, discontinue using the lot immediately and contact your local distributor.

### QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit; however it is recommended that positive and negative controls be tested as good laboratory practice to

confirm the test procedure and to verify proper test performance.

### LIMITATIONS

- The α-PVP Rapid Test Cassette (Urine) provides only a qualitative, preliminary result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/ mass spectrometry (GC/MS) is the preferred confirmatory method.
- It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
- A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
- A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
- Test does not distinguish between drugs of abuse and certain medications.

### PERFORMANCE CHARACTERISTICS

#### Accuracy

A side-by-side comparison was conducted using the α-PVP Rapid Test Cassette and GC/MS at the cut-off of 1000ng/mL. Testing was performed on 100 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

| Method                    | GC/MS    |          | Total Results |
|---------------------------|----------|----------|---------------|
|                           | Positive | Negative |               |
| α-PVP Rapid Test Cassette | 35       | 2        | 37            |
|                           | 3        | 60       | 63            |
| <b>Total Results</b>      | 38       | 62       | 100           |
| <b>% Agreement</b>        | 92.1%    | 96.8%    | 95.0%         |

#### Analytical Sensitivity

A drug-free urine pool was spiked with alpha-Pyrrolidinovalerophenone at the following concentrations: 0 ng/mL, 500 ng/mL, 750ng/mL, 1000ng/mL, 1250ng/mL, 1500ng/mL and 3000ng/mL. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

| alpha-Pyrrolidinovalerophenone Concentration (ng/mL) | Percent of Cut-off | n  | Visual Result |          |
|------------------------------------------------------|--------------------|----|---------------|----------|
|                                                      |                    |    | Negative      | Positive |
| 0                                                    | 0%                 | 30 | 30            | 0        |
| 500                                                  | -50%               | 30 | 30            | 0        |
| 750                                                  | -25%               | 30 | 26            | 4        |
| 1000                                                 | Cut-off            | 30 | 15            | 15       |
| 1250                                                 | +25%               | 30 | 3             | 27       |
| 1500                                                 | +50%               | 30 | 0             | 30       |
| 3000                                                 | 3X                 | 30 | 0             | 30       |

#### Analytical Specificity

The following table lists compounds that are positively detected in urine by the α-PVP Rapid Test Cassette (Urine) at 5 minutes.

| Compound                       | Concentration (ng/mL) |
|--------------------------------|-----------------------|
| alpha-Pyrrolidinovalerophenone | 1000                  |

#### Precision

A study was conducted at 3 hospitals by laypersons using 3 different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens containing no alpha-Pyrrolidinovalerophenone, 25% alpha-Pyrrolidinovalerophenone above and below the cutoff and 50% alpha-Pyrrolidinovalerophenone above and below the 1000ng/mL cutoff were provided to each site. The following results were tabulated:

| alpha-Pyrrolidinovalerophenone Concentration (ng/mL) | n per Site | Site A |    | Site B |    | Site C |    |
|------------------------------------------------------|------------|--------|----|--------|----|--------|----|
|                                                      |            | -      | +  | -      | +  | -      | +  |
| 0                                                    | 10         | 10     | 0  | 10     | 0  | 10     | 0  |
| 500                                                  | 10         | 10     | 0  | 10     | 0  | 10     | 0  |
| 750                                                  | 10         | 8      | 2  | 9      | 1  | 9      | 1  |
| 1250                                                 | 10         | 2      | 8  | 3      | 7  | 1      | 9  |
| 1500                                                 | 10         | 0      | 10 | 0      | 10 | 0      | 10 |

### Effect of Urinary Specific Gravity

Fifteen urine samples with specific gravities ranging from 1.004 to 1.035 were spiked with alpha-Pyrrolidinovalerophenone to the concentrations of 500ng/mL, and 1500 ng/mL. The α-PVP Rapid Test Cassette (Urine) was tested in duplicate using the fifteen neat and spiked urine specimens. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

### Effect of the Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with alpha-Pyrrolidinovalerophenone to 500ng/mL and 1500 ng/mL. The spiked, pH-adjusted urine was tested with the α-PVP Rapid Test Cassette (Urine) in duplicate. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

### Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or alpha-Pyrrolidinovalerophenone positive urine. The following compounds show no cross-reactivity when tested with the α-PVP Rapid Test Cassette (Urine) at a concentration of 100 µg/mL.

### Non Cross-Reacting Compounds

|                                |                                         |
|--------------------------------|-----------------------------------------|
| Acetophenetidin                | (±) 3,4-Methylenedioxy amphetamine      |
| N-Acetylprocainamide           | Nalidixic acid                          |
| Acetylsalicylic acid           | Naloxone                                |
| Aminopyrine                    | Niacinamide                             |
| Amiripityline                  | Nifedipine                              |
| Amobarbital                    | Norethindrone -                         |
| Amoxicillin                    | Norethisterone                          |
| Atropine                       | d-Norpropoxyphene                       |
| Aspartame - Asp-Phemethylester | Noscapine                               |
| (-)Cotinine                    | d,l- Octopamine                         |
| Benzilic acid                  | Oxazepam                                |
| Benzoic acid                   | Oxymetazoline                           |
| Bilirubin                      | Papaverine                              |
| Chloramphenicol                | Penicillin                              |
| Chlorothiazide                 | Promethazine                            |
| Chlorpromazine                 | Hydrochloride                           |
| Chloroquine                    | Perphenazine                            |
| Cholesterol                    | Phenelzine                              |
| Clomipramine                   | Phenobarbital                           |
| Clonidine Hydrochloride        | β-Phenylethylamine                      |
| Cocaine                        | Prednisolone                            |
| Codeine                        | Prednisone                              |
| Cortisone                      | l-Phenylephrine - (R)-(-)-Phenylephrine |
| Creatinine                     | Procaine                                |
| Deoxycorticosterone            | Quinidine                               |
| Diazepam                       | Quinine                                 |
| Diffunisal                     | 5-Hydroxytryptamine                     |
| Digoxin                        | Sulfamethazine                          |
| Doxylamine                     | Temazepam                               |
| Erythromycin                   | Tetracycline                            |
| β-Estradiol Estradiol          | Tetrahydrozoline                        |
| Diphenhydramine -Hydrochloride | Thebaine                                |
| Barbital                       | Thiamine                                |
| Estrone                        | Thioridazine                            |
| Ethyl-p-aminobenzoate          | Tolbutamide                             |
| Fenoprofen                     | Triamterene                             |
| Furosemide                     | Trimethoprim                            |
| Genisic acid                   | Trimipramine                            |
| Hydralazine                    | Tryptamine                              |
| Hydrochlorothiazide            | d,l-Tyrosine -                          |
| O-Hydroxyhippuric acid         | L-Tyrosine                              |
| 3-Hydroxytyramine              | d,l-Tryptophan                          |
| Ibuprofen                      | Uric acid                               |
| p-Hydroxy - methamphetamine    | Verapamil                               |
| Imipramine                     | Zomepirac                               |
| (-) Isoproterenol              | Ampicillin                              |
| Ketoprofen                     | Caffeine                                |
| Maprotiline                    | (+/-)-Chlorpheniramine                  |
|                                | Ranitidine                              |

|                                    |                                    |
|------------------------------------|------------------------------------|
| Meprobamate                        | Quinacrine                         |
| Meperidine                         | Dicyclomine                        |
| Methoxyphenamine                   | Trazodone                          |
| Atomoxetine                        | Trans-2-Phenylcy-                  |
| levetiracetam                      | clopropylamine                     |
| Metronidazole                      | Estazolam                          |
| Vancomycin                         | Bromazepam                         |
| Spironolactone                     | Ethylmorphine                      |
| Emetine                            | Clorazepam dipotassium             |
| Paroxetine                         | Norchlordiazepoxide                |
| Diacetylmorphine                   | Methotrexate                       |
| S(-)-Cathinone                     | Nortriptyline                      |
| R(+)-Methcathinone                 | Doxepin                            |
| S(-)-Methcathinone                 | Desipramine                        |
| Carbamazepine                      | Nordoxepin                         |
| Diphenoxylate                      | Desalkylflurazepam                 |
| 7-Amino-clonazepam                 | Ciprofloxacin Hydrochloride        |
| p-Acetamidophenyl-β-               | pantoprazole                       |
| Clonazepam                         | Pseudoephedrine -                  |
| Terbutaline hemisulfate salt       | Hydrochloride                      |
| Zolpiden hemitartrate              | PEG-400                            |
| Valproic acid                      | Amlodipine Besylate                |
| Isoniazid                          | Lansoprazole                       |
| 7-Amino-flunitrazepam              | Valsartan capsules                 |
| DL-Homatropine -Hydrobromide       | Sildenafil Citate                  |
| Alprazolam                         | Tizanidine HCL                     |
| 3,4-Methylenedioxy-                | Pantoprazole Sodium                |
| ethylamphetamine                   | Enteric-Coated                     |
| Estazolam                          | Pyridoxine HCL                     |
| Dihydrocodeine                     | Oxymorphone                        |
| Nimesulide                         | Cyclobenzaprine                    |
| Buspirone                          | Lidocaine                          |
| 5,5-Diphenylhydantoin              | Guaiifenesin                       |
| Cyclobenzaprine                    | (+) Chlorpheniramine               |
| l-Thyroxine                        | Amoxapine                          |
| EDDP                               | Guaiacol Glyceryl -Ether carbamate |
| l-Thyroxine                        | Chlorprothixene                    |
| Oxymorphone                        | R (-)Deprenyl                      |
| Lidocaine                          | Pheniramine                        |
| Dihydrocodeine                     | 4-Dimethylaminoantipyrine          |
| Guaiifenesin                       | Riboflavin                         |
| Pemoline                           | α -Naphthaleneacetic Acid          |
| Amoxapine                          | (+/-) Epinephrine                  |
| Guaiacol Glyceryl -Ether carbamate | Phenothiazine                      |
| (+) Chlorpheniramine               | Albumin                            |
| Gabapentin                         | d (+) Glucose                      |
| (+)-Nopseudoephedrine              | Sodium chloride                    |
| Pregablin                          | Cimetidine                         |
| Clorazepam dipotassium             | Disopyramide                       |
| (1R, 2S) - (-)-Ephedrine           | Hexachlorocyclohexane              |
| Norchlordiazepoxide                | Etodolac                           |
| Methotrexate                       | Metoprolol                         |
| Nortriptyline                      | Amikacin                           |
| Doxepin                            | Amantadine                         |
| Desipramine                        | Chlorpropamide                     |
| Nordoxepin                         | Clozapine                          |
| Desalkylflurazepam                 | Baclofen                           |
| Ciprofloxacin Hydrochloride        | Droperidol                         |
| pantoprazole                       | Gentamicin                         |
| Pseudoephedrine -                  | Indomethacin                       |
| Hydrochloride                      | Ethylmorphine                      |
| PEG-400                            | Sulfamethoxazole                   |
| Amlodipine Besylate                | Sulfisoxazole                      |
| Bromazepam                         | Nimesulide                         |
| Valsartan capsules                 | Buspirone                          |
| Sildenafil Citate                  | D-glucuronide                      |
| Tizanidine HCL                     | 5,6-Diphenylhydantoin              |
| Pantoprazole Sodium                | S(-)-(+)-Methoxy-α-Methyl-2-       |

Enteric-Coated naphthaleneacetic acid

Pyridoxine HCL  
(S)-(+)-Methoxy-α-Methyl-2-  
naphthaleneacetic acid

**BIBLIOGRAPHY**

- "Drugs of Abuse Emerging Trends". National Institute on Drug Abuse. 6 April 2015.
- Eiden, C.; Mathieu, O.; Catala, P. (2013). "Toxicity and death following recreational use of 2-pyrrolidino valerophenone.". *Clinical Toxicology*. 51: 899-903. PMID 24111554. doi:10.3109/15563650.2013.847187.
- Marinetti, L. J.; Antonides, H. M. (2013). "Analysis of synthetic cathinones commonly found in bath salts in human performance and postmortem toxicology: Method development, drug distribution and interpretation of results". *Journal of Analytical Toxicology*. 37 (3): 135-46. PMID 23361867. doi:10.1093/jat/bks136.
- Waugh; et al. (2013). "Deaths Involving the Recreational Use of α-PVP (α-pyrrolidinopentiophenone)" (PDF). *AAFS Proceedings*. Abstract K16.

**INDEX OF SYMBOLS**

|  |                                                                         |
|--|-------------------------------------------------------------------------|
|  | In vitro diagnostic medical device                                      |
|  | Temperature limit                                                       |
|  | Do not use if package is damaged and consult instructions for use       |
|  | Catalogue number                                                        |
|  | Contains sufficient for <n> tests                                       |
|  | Use-by date                                                             |
|  | Batch code                                                              |
|  | Manufacturer                                                            |
|  | Do not re-use                                                           |
|  | Consult instructions for use or consult electronic instructions for use |
|  | Caution                                                                 |
|  | Authorized representative in the European Community                     |

REF: DAP-102  
Number: CT57223  
Rev: 02  
Date: 06/13/2025

A rapid test for the qualitative detection of GHB in urine.  
For medical and professional *in vitro* diagnostic use only.

**INTENDED USE**  
The GHB Rapid Test Cassette is a rapid biochemical-based assay to detect the presence of GHB in urine and provide a presumptive result for presence of GHB in urine at concentrations between 10 µg/mL to 50 µg/mL.

This test provides a preliminary result only. A more specific alternate chemical method is recommended. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmation method. Clinical consideration and professional judgment should be applied to any test result, particularly when preliminary positive screens are indicated.

**SUMMARY**  
γ-Hydroxybutyric acid (GHB), also known as 4-hydroxybutanoic acid, is a naturally occurring neurotransmitter and a psychoactive drug. It has been used in a medical setting as a general anesthetic and as a treatment for cataplexy, narcolepsy, and alcoholism.<sup>1,2</sup> It is also used illegally as an intoxicant, to try to increase athletic performance, and as a date rape drug.<sup>3</sup> It is commonly used in the form of a salt, such as sodium γ-hydroxybutyrate (Na.GHB, sodium oxybate) or potassium γ-hydroxybutyrate (K.GHB, potassium oxybate).

Urine is often the preferred specimen for routine drug abuse monitoring purposes. Both γ-butyrolactone (GBL) and 1,4-butanediol are converted to GHB in the body.<sup>4,5,6</sup> Other liquids such as suspected spiked drinks can also be tested. However, cross-reactivity with Ascorbic Acid and Alcohol need to be taken into account, while interpreting the test results.

**PRINCIPLE**  
GHB-DH catalyses the reaction of GHB and NAD to produce NADH, and a diaphorase couple tetrazolium dye reaction results in the production of a purple dye complex. The reagents were stabilized and used to produce the test to screen for GHB in urine at 10 µg/mL.

**REAGENTS**  
GHB-DH  
NAD  
Diaphorase  
Tetrazolium Dye  
Other additives

- PRECAUTIONS**
- The GHB Rapid Test Cassette is a visually read test system, where color change due to enzymatic catabolism is used to provide a visual result for presence of GHB in human urine at a concentration between 10 µg/mL to 50 µg/mL.
  - For medical and other professional *in vitro* diagnostic use only. Do not use after the expiration date.
  - The test should remain in the sealed pouch and store in 2-30°C until use.
  - All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
  - The used test should be discarded according to local regulations.

**STORAGE AND STABILITY**  
The GHB Rapid Test Cassette should be stored as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). **However enzyme-based tests work best when stored at 2-8°C. Therefore, even though the kit is stable up to 30°C, storage at 2-8°C range is advised for enhanced performances.**  
The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

**SPECIMEN COLLECTION AND PREPARATION**

**Urine Assay**  
The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible particles should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

**Specimen Storage**  
Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

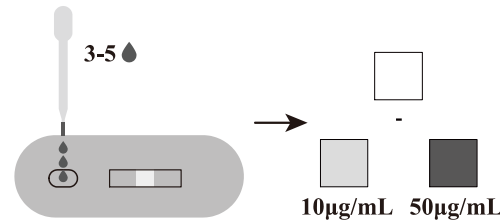
**MATERIALS**

- Materials Provided**
- Test Cassettes
  - Droppers
  - Package Insert
- Materials Required But Not Provided**
- Timer

**DIRECTIONS FOR USE**

**Allow the test, urine specimen and/or controls to reach room temperature (15-30°C) prior to testing.**

1. Remove the test cassette from the sealed pouch and use it within 30 minutes. Observe the reactive pad on the central window of the cassette. **If the reaction pad has a purple color before applying urine sample, do not use.**
2. Place the test cassette on a clean and level surface. Add **3-5 drops of specimen (About 120-200 µL)** to the specimen well (S) and start the timer.
3. **Read the results after 10 minutes** by comparing the color in the Test area with the color card on the foil pouch to determine the relative GHB concentration. Testing may take 15 minutes when testing a concentration of 10 µg/mL. **Do not interpret the results after 15 minutes.**



**INTERPRETATION OF RESULTS**

**Positive:** The GHB Rapid Test Cassette will produce a color change in the presence of GHB. The color will range from light purple color at 10 µg/mL of GHB to a dark purple color greater than or equal 50 µg/mL of GHB.

**Negative:** When the GHB Rapid Test Cassette shows no color change or a color less intense than the color specifying 10 µg/mL of GHB, it should be interpreted as a negative result indicating that GHB concentration in the sample is below the detectable level (10 µg/mL).

**Invalid:** If the color pad has a purple color before applying urine sample, do not use the test.

**NOTE:** A result where the outer edges of the color pad produces a slight color but the majority of the pad remains colorless the test should be repeated to ensure complete saturation of the pad with specimen. The test is not reusable.

**LIMITATIONS**

1. Highly colored samples such as those urines containing high amounts of blood or riboflavin can interfere with interpretation of the color signal. Grossly hemolyzed samples will require clean-up or possibly re-sampling.
2. The GHB Rapid Test Cassette reaction zone is sensitive to moisture. Handle with care in areas with potential high moisture exposure.
3. Storage of the devices in the original packaging materials is critical for stability.

**ASSAY SPECIFICITY**

Detect whether the following compounds with similar structures cross-react.  
None of the compounds tested produced a GHB depth of 10 µg/mL at a concentration of 500 µg/mL, and the calculated cross reactivity was expected:

| Compounds                     | Cross reaction percentage |
|-------------------------------|---------------------------|
| GHB                           | 100%                      |
| 1,4-butanediol                | <2%                       |
| γ butyrolactone               | <2%                       |
| Succinate semialdehyde        | <2%                       |
| Gabapentin                    | <2%                       |
| α-Hydroxy-gamma-butyrolactone | <2%                       |

**INTERFERING SUBSTANCES**

The following substances may interfere with the GHB Rapid Test Cassette when using samples other than urine. Substances listed below do not normally appear in sufficient quantity in urine to interfere with the test.

- A. Agents which will enhance color development
  - Alcohol
  - Ascorbic acid >100mg/dL
- B. Agents which will inhibit color development
  - Disodium EDTA
  - Potassium Oxalate

**BIBLIOGRAPHY**

1. "Sodium Oxybate: MedlinePlus Drug Information". Nlm.nih.gov. 28 July 2010. Retrieved 2010-08-01.
2. Benzer, Theodore I (8 January 2007). "Toxicity, Gamma Hydroxybutyrate". Medicine.
3. US Drug Enforcement Administration. "GHB, GBL and 1,4BD as Date Rape Drugs". Archived from the original on 10 May 2012. Retrieved 2012-05-10
4. Schep LJ, Knudsen K, Slaughter RJ, Vale JA, Mégarbane B (July 2012). "The clinical toxicology of gamma-hydroxybutyrate, gamma-butyrolactone and 1, 4-butanediol". Clin Toxicol (Phila). 50 (6): 458-70. PMID 22746383. Doi:10.3109/15563650.2012.702218.
5. "Erowid GHB Valut: Basics". Erowid. 2012-03-27. Retrieved 2014-01-22. GHB; G; Liquid X; Liquid E
6. Galloway GP, Frederick-Osborne SL, Seymour R, Contini SE, Smith DE (2000). "Abuse and therapeutic potential of gamma-hydroxybutyric acid". Alcohol. 20 (3): 263-9. PMID 10869868. Doi: 10.1016/S0741-8329(99)00090-7.

**INDEX OF SYMBOLS**

|  |                                                                   |
|--|-------------------------------------------------------------------|
|  | In vitro diagnostic medical device                                |
|  | Temperature limit                                                 |
|  | Do not use if package is damaged and consult instructions for use |
|  | Catalogue number                                                  |

|  |                                                                         |
|--|-------------------------------------------------------------------------|
|  | Contains sufficient for <n> tests                                       |
|  | Use-by date                                                             |
|  | Batch code                                                              |
|  | Manufacturer                                                            |
|  | Do not re-use                                                           |
|  | Consult instructions for use or consult electronic instructions for use |
|  | Caution                                                                 |
|  | Authorized representative in the European Community                     |

REF: DGHB-102  
Number: CT57795  
Rev: 05  
Date: 10/30/2025

A rapid test for the qualitative detection of Cannabinol in human urine.

For medical and other professional *in vitro* diagnostic use only.

### INTENDED USE

The CNB Rapid Test Cassette (Urine) is a rapid immunochromatographic assay for the qualitative detection of Cannabinol (CNB) at a cut-off concentration of 500 ng/mL. This assay provides only a preliminary test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

The test results can be used to provide evidence and basis for therapy and treatment plans of drug dependence and toxic psychosis. For laboratory professional *in vitro* diagnostic use only. The CNB Rapid Test Cassette should only be performed by health professionals in a clinical/hospital setting to aid in screening of drug of abuse to determine the follow-up treatment measures in combination of clinical symptoms.

### SUMMARY

Cannabinol (CNB) is a non-psychoactive cannabinoid found only in trace amounts in Cannabis,<sup>1</sup> and is mostly found in aged Cannabis.<sup>2</sup> Pharmacologically relevant quantities are formed as a metabolite of tetrahydrocannabinol (THC).<sup>3</sup> CNB acts as a partial agonist at the CB1 receptors, but has a higher affinity to CB2 receptors; however, it has lower affinities relative to THC.<sup>4,5</sup> Degraded or oxidized cannabis products, such as low-quality baled cannabis and traditionally produced hashish, are high in CNB, but modern production processes minimize the formation of CNB.

Unlike other cannabinoids, CNB does not stem from cannabigerol (CBG). There is no clinical evidence that THC breaks down naturally into CNB once the THC has become decarboxylated and forms delta-9 THC. CNB is formed by decarboxylation of cannabinolic acid.

The CNB Rapid Test Cassette (Urine) is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of CNB in urine. The CNB Rapid Test Cassette (Urine) yields a positive result when CNB in urine exceeds 500 ng/mL.

### PRINCIPLE

The CNB Rapid Test Cassette (Urine) is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a urine specimen migrates upward by capillary action. CNB, if present in the urine specimen below 500ng/mL, will not saturate the binding sites of antibody-coated particles in the test line region. The antibody-coated particles will then be captured by immobilized CNB conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the CNB level exceeds 500ng/mL because it will saturate all the binding sites of anti-CNB antibodies.

A drug-positive urine specimen will not generate a colored line in the test line region, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

### REAGENTS

The test contains mouse monoclonal anti-CNB antibody-coupled particles and CNB-protein conjugate. A goat antibody is employed in the control line system.

### PRECAUTIONS

- For medical and other professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test should be discarded according to local regulations.

### STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30 °C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

### SPECIMEN COLLECTION AND PREPARATION

#### Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible particles should be centrifuged, filtered, or allowed to settle to obtain clear specimen for testing.

#### Specimen Storage

Urine specimens may be stored at 2-8 °C for up to 48 hours prior to testing. For long-term storage, specimens may be frozen and stored below -20 °C. Frozen specimens should be thawed and mixed before testing.

### MATERIALS

#### Materials Provided

- Test Cassettes
- Droppers
- Package Insert

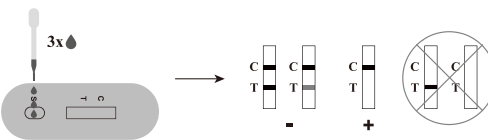
#### Materials Required But Not Provided

- Specimen Collection Containers
- Timer

### DIRECTIONS FOR USE

Allow the test, urine specimen and/or controls to reach room temperature (15-30 °C) prior to testing.

- Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within one hour.
- Place the test cassette on a clean and level surface. Hold the dropper vertically and **transfer 3 full drops of urine (approx. 120 µL)** to the specimen well (S) of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
- Wait for the colored line(s) to appear. **Read results at 5 minutes.** Do not interpret the result after 10 minutes.



### INTERPRETATION OF RESULTS

(Please refer to the illustration above)

**NEGATIVE: Two colored lines appear.** One colored line should be in the control line region (C) and another colored line should be in the test line region (T). A negative result indicates that the CNB concentration is below the detectable level (500ng/mL).

**\*NOTE:** The shade of color in the test line region (T) may vary, but it should be considered negative whenever there is even a faint colored line.

**POSITIVE: One colored line appears in the control line region (C).** No line appears in the test line region (T). A positive result indicates that the CNB concentration exceeds the detectable level

(500ng/mL).

**INVALID: Control line fails to appear.** Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test. If the problem persists, discontinue using the lot immediately and contact your local distributor.

### QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory testing practice to confirm the test procedure and to verify proper test performance.

### LIMITATIONS

- The CNB Rapid Test Cassette (Urine) provides only a qualitative, preliminary result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.<sup>6,7</sup>
- It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
- A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
- A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
- Test does not distinguish between drugs of abuse and certain medications.

### PERFORMANCE CHARACTERISTICS

#### Accuracy

A side-by-side comparison was conducted using the CNB Rapid Test Cassette (Urine) and GC/MS. The following results were tabulated:

| Method                  | GC/MS    |          |          | Total Results |
|-------------------------|----------|----------|----------|---------------|
|                         | Results  | Positive | Negative |               |
| CNB Rapid Test Cassette | Positive | 23       | 1        | 24            |
|                         | Negative | 1        | 40       | 41            |
| <b>Total Results</b>    |          | 24       | 41       | 65            |
| <b>% Agreement</b>      |          | 95.8%    | 97.6%    | 96.9%         |

#### Analytical Sensitivity

A drug-free urine pool was spiked with CNB at the following concentrations: 0 ng/mL, 250 ng/mL, 375 ng/mL, 500 ng/mL, 625 ng/mL, 750 ng/mL and 1,500 ng/mL. The results demonstrate >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

| CNB Concentration (ng/mL) | Percent of Cut-off | Visual Results |          |          |
|---------------------------|--------------------|----------------|----------|----------|
|                           |                    | n              | Negative | Positive |
| 0                         | 0%                 | 30             | 30       | 0        |
| 250                       | -50%               | 30             | 30       | 0        |
| 375                       | -25%               | 30             | 27       | 3        |
| 500                       | Cut-off            | 30             | 14       | 16       |
| 625                       | +25%               | 30             | 4        | 26       |
| 750                       | +50%               | 30             | 0        | 30       |
| 1,500                     | 300%               | 30             | 0        | 30       |

### Analytical Specificity

The following table lists compounds that are positively detected in urine by the CNB Rapid Test Cassette (Urine) at 5 minutes.

| Compound                          | Concentration (ng/mL) |
|-----------------------------------|-----------------------|
| Cannabinol                        | 500                   |
| Δ <sup>9</sup> -THC               | 10,000                |
| 11-nor-Δ <sup>9</sup> -THC-9 COOH | 300                   |

### Precision

A study was conducted at three hospitals using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens containing, according to HPLC, no CNB, 25% CNB above and below the cut-off and 50% CNB above and below the 500ng/mL cut-off was provided to each site. The following results were tabulated:

| CNB Concentration (ng/mL) | n per Site | Site A |    | Site B |    | Site C |    |
|---------------------------|------------|--------|----|--------|----|--------|----|
|                           |            | -      | +  | -      | +  | -      | +  |
| 0                         | 10         | 10     | 0  | 10     | 0  | 10     | 0  |
| 250                       | 10         | 10     | 0  | 10     | 0  | 10     | 0  |
| 375                       | 10         | 9      | 1  | 9      | 1  | 9      | 1  |
| 625                       | 10         | 2      | 8  | 1      | 9  | 1      | 9  |
| 750                       | 10         | 0      | 10 | 0      | 10 | 0      | 10 |

### Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high and low specific gravity ranges were spiked with 250 ng/mL and 750 ng/mL of CNB. The CNB Rapid Test Cassette (Urine) was tested in duplicate using the fifteen neat and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

### Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 4 to 9 in 1 pH unit increments and spiked with CNB to 250 ng/mL and 750 ng/mL. The spiked, pH-adjusted urine was tested with the CNB Rapid Test Cassette (Urine) in duplicate. The results demonstrated that varying ranges of pH do not interfere with the performance of the test.

### Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or CNB positive urine. The following compounds show no cross-reactivity when tested with the CNB Rapid Test Cassette (Urine) at a concentration of 100 µg/mL.

### Non Cross-Reacting Compounds

|                      |                           |
|----------------------|---------------------------|
| 4-Acetaminophenol    | 4-Dimethylaminoantipyrine |
| Acetone              | Diphenhydramine           |
| Acetophenetidin      | 5,5-Diphenylhydantoin     |
| N-Acetylprocainamide | Disopyramide              |
| Acetylsalicylic acid | Doxylamine                |
| Albumin              | Egogone                   |
| Amitriptyline        | Ecgonine methylester      |
| Amobarbital          | EMDP                      |
| Amoxapine            | Ephedrine                 |
| Amoxicillin          | l-Ephedrine               |
| Ampicillin           | l-Epinephrine             |
| Ascorbic acid        | (±)-Epinephrine           |
| Aminopyrine          | Erythromycin              |
| Apomorphine          | β-Estradiol               |
| Aspartame            | Estrone-3-sulfate         |
| Atropine             | Ethanol (Ethyl alcohol)   |
| Benzilic acid        | Ethyl-p-aminobenzoate     |
| Benzoic acid         | Etodolac                  |
| Benzphetamine        | Famprofazone              |
| Bilirubin            | Fenfluramine              |

Brompheniramine  
Buspirone  
Caffeine  
Cannabidiol  
Cimetidine  
Chloral hydrate  
Chloramphenicol  
Chlordiazepoxide  
Chloroquine  
Chlorothiazide  
(+)-Chlorpheniramine  
(±)-Chlorpheniramine  
Chlorpromazine  
Chlorprothixene  
Cholesterol  
Clomipramine  
Clonidine  
Codeine  
Cortisone  
(-)-Cotinine  
Creatinine  
Cyclobarbitol  
Cyclobenzaprine  
Deoxycorticosterone  
R (-)-Deprenyl  
Dextromethorphan  
Diazepam  
Diclofenac  
Dicyclimine  
Diflunisal  
Prednisolone  
Prednisone  
Procaine  
Promazine  
Promethazine  
l-Propoxyphene  
d,l-Propranolol  
d-Pseudoephedrine  
Quinacrine  
Quinidine  
Quinine  
Ranitidine  
Riboflavin  
Salicylic acid  
Secobarbital  
d,l-Tryptophan  
Tyramine  
Gentisic acid  
Loperamide  
Maprotiline  
Meperidine  
Meprobamate  
d-Methamphetamine  
l-Methamphetamine  
Methaqualone  
Methadone  
Methoxyphenamine  
(+)-3,4-Methylenedioxy-  
methamphetamine  
Methylphenidate

Fenopron  
Fentanyl  
Fluoxetine  
Furosemide  
d-Glucose  
Guaiacol glyceryl ether  
Hemoglobin  
Hydralazine  
Hydrochlorothiazide  
Hydrocodone  
Hydrocortisone  
o-Hydroxyhippuric acid  
p-Hydroxymethamphetamine  
Hydromorphone  
3-Hydroxytyramine  
(Dopamine)  
Hydroxyzine  
Ibuprofen  
Imipramine  
Iproniastide  
(-)-Isoproterenol  
Isoxsuprine  
Kanamycin  
Ketamine  
Ketoprofen  
Labetalol  
Levorphanol  
Lidocaine  
Lindane  
(Hexachlorocyclohexane)  
Serotonin  
(5-Hydroxytryptamine)  
Sodium chloride  
Sulfamethazine  
Sulindac  
Sustiva (Efavirenz)  
Temazepam  
Tetracycline  
Tetrahydrocortexolone  
Tetrahydrocortisone  
3-acetate  
Tetrahydrozoline  
Thebaine  
Theophylline  
Verapamil  
Lithium carbonate  
d,l-Tyrosine  
Nifedipine  
α-Naphthaleneacetic acid  
Naproxen  
Niacinamide  
Nimesulide  
Norcodeine  
Normorphine  
Norethindrone  
d-Norpropoxyphene  
Noscapine  
d,l-Octopamine  
Orphenadrine  
Oxalic acid

Mephentermine  
Metoprolol  
Morphine-3-β-D-  
Morphine sulfate  
Methyprylon  
Nalidixic acid  
Nalorphine  
Naloxone  
Naltrexone  
Phenelzine  
Pheniramine  
Phenobarbital  
Phenothiazine  
Phentermine  
Thiamine  
Thioridazine  
l-Thyroxine  
Tolbutamide  
cis-Tramadol  
trans-2-  
Phenylcyclopropylamine  
Trazodone

Oxazepam  
Oxolinic acid  
Oxycodone  
Oxymetazoline  
Oxymorphone  
Papaverine  
Pemoline  
Penicillin-G  
Pentazocine  
Pentobarbital  
Perphenazine  
Phencyclidine  
Trimethobenzamide  
Triamterene  
Trifluoperazine  
Trimethoprim  
Trimipramine  
Tryptamine  
Digoxin  
l-Phenylephrine  
Uric acid

**BIBLIOGRAPHY**

- Karniol IG, Shirakawa I, Takahashi RN, Knobel E, Musty RE (1975). "Effects of delta9-tetrahydrocannabinol and cannabinol in man". *Pharmacology*. 13 (6): 502–12.
- Andre, Christelle M.; Hausman, Jean-Francois; Guerriero, Gea (2016-02-04). "Cannabis sativa: The Plant of the Thousand and One Molecules". *Frontiers in Plant Science*. 7: 19
- McCallum ND, Yagen B, Levy S, Mechoulam R (May 1975). "Cannabinol: a rapidly formed metabolite of delta-1- and delta-6-tetrahydrocannabinol". *Experientia*. 31 (5): 520–1
- Mahadevan A, Siegel C, Martin BR, Abood ME, Beletskaya I, Razdan RK (October 2000). "Novel cannabinol probes for CB1 and CB2 cannabinoid receptors". *Journal of Medicinal Chemistry*. 43 (20): 3778–85.
- Petitot F, Jeantaud B, Reibaud M, Imperato A, Dubroeuq MC (1998).
- Baselt RC. *Disposition of Toxic Drugs and Chemicals in Man*. 2nd Ed. Biomedical Publ., Davis, CA. 1982; 488
- Hawks RL, CN Chiang. *Urine Testing for Drugs of Abuse*. National Institute for Drug Abuse (NIDA), Research Monograph 73. 1986

**INDEX OF SYMBOLS**

|  |                                                                   |
|--|-------------------------------------------------------------------|
|  | In vitro diagnostic medical device                                |
|  | Temperature limit                                                 |
|  | Do not use if package is damaged and consult instructions for use |
|  | Catalogue number                                                  |
|  | Contains sufficient for <n> tests                                 |
|  | Use-by date                                                       |
|  | Batch code                                                        |
|  | Manufacturer                                                      |

|  |                                                                         |
|--|-------------------------------------------------------------------------|
|  | Do not re-use                                                           |
|  | Consult instructions for use or consult electronic instructions for use |
|  | Caution                                                                 |
|  | Authorized representative in the European Community                     |

REF: DCNB-102  
Number: CT58623  
Rev: 03  
Date: 06/26/2025

A rapid test for the qualitative detection of Gabapentin in human urine.  
For medical and other professional *in vitro* diagnostic use only.

### INTENDED USE

The GAB Rapid Test Cassette (Urine) is a rapid chromatographic immunoassay for the detection of Gabapentin in urine at a cut-off concentration of 2,000ng/mL. This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert. This assay provides only a qualitative, preliminary test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

The test results can be used to provide evidence and basis for therapy and treatment plans of drug dependence and toxic psychosis. For laboratory professional *in vitro* diagnostic use only. The GAB Rapid Test Cassette (Urine) should only be performed by health professionals in a clinical/hospital setting to aid in screening of drug of abuse to determine the follow-up treatment measures in combination of clinical symptoms.

### SUMMARY

Gabapentin, sold under the brand name Neurontin among others, is a medication which is used to treat epilepsy (specifically partial seizures), neuropathic pain, hot flashes, and restless legs syndrome.<sup>1,2</sup> Common side effects of gabapentin include sleepiness and dizziness. Serious side effects include an increased risk of suicide, aggressive behavior, and drug reaction with eosinophilia and systemic symptoms.<sup>1</sup> In 2009 the U.S. Food and Drug Administration issued a warning of an increased risk of suicidal thoughts and behaviors in patients taking some anticonvulsant drugs, including gabapentin,<sup>3</sup> modifying the packaging inserts to reflect this.<sup>4</sup>

The oral bioavailability of gabapentin enacarbil (as gabapentin) is greater than or equal to 68%, across all doses assessed (up to 2,800 mg), with a mean of approximately 75%.<sup>5,6</sup> Gabapentin undergoes little or no metabolism.<sup>7,8</sup> The T-max of the instant-release (IR) formulation of gabapentin enacarbil (as active gabapentin) is about 2.1 to 2.6 hours across all doses (350–2,800 mg) with single administration and 1.6 to 1.9 hours across all doses (350–2,100 mg) with repeated administration.<sup>9</sup>

The GAB Rapid Test Cassette (Urine) is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes an antibody to selectively detect elevated levels of gabapentin in urine. The GAB Rapid Test Cassette (Urine) yields a positive result when gabapentin in urine exceeds 2,000ng/mL.

### PRINCIPLE

The GAB Rapid Test Cassette (Urine) is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a urine specimen migrates upward by capillary action. Gabapentin, if present in the urine specimen below the cut-off level, will not saturate the binding sites of the antibody in the test. The antibody coated particles will then be captured by immobilized drug-protein conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the Gabapentin level exceeds the cut-off level, because it will saturate all the binding sites of anti-drug antibody.

A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane

wicking has occurred.

### REAGENTS

The test contains mouse monoclonal anti-drug antibody coupled particles and drug-protein conjugate. A goat antibody is employed in the control line system.

### PRECAUTIONS

- For medical and other professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test should be discarded according to local regulations.

### STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30 °C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

### SPECIMEN COLLECTION AND PREPARATION

#### Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible particles should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

#### Specimen Storage

Urine specimens may be stored at 2-8 °C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20 °C. Frozen specimens should be thawed and mixed before testing.

### MATERIALS

#### Materials Provided

- Test Cassettes
- Droppers
- Package Insert

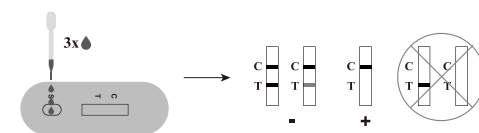
#### Materials Required But Not Provided

- Specimen Collection Containers
- Timer

### DIRECTIONS FOR USE

Allow the test, urine specimen and/or controls to reach room temperature (15-30°C) prior to testing.

- Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within one hour.
- Place the test cassette on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 120 µL) to the specimen well (S) of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
- Wait for the colored line(s) to appear. Read results at 5 minutes. Do not interpret the result after 10 minutes.



### INTERPRETATION OF RESULTS

(Please refer to the illustration above)

**NEGATIVE: Two colored lines appear.** One colored line should be in

the control line region (C), and another apparent colored line should be in the test line region (T). This negative result indicates that the Gabapentin concentration is below the detectable cut-off level.

**\*NOTE:** The shade of color in the test line region (T) may vary, but it should be considered negative whenever there is even a faint colored line. **POSITIVE: One colored line appears in the control line region (C).** No line appears in the test line region (T). This positive result indicates that the Gabapentin concentration exceeds the detectable cut-off level.

**INVALID: Control line fails to appear.** Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

### QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory testing practice to confirm the test procedure and to verify proper test performance.

### LIMITATIONS

- The GAB Rapid Test Cassette (Urine) provides only a qualitative, preliminary result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
- It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
- A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
- A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
- Test does not distinguish between drugs of abuse and certain medications.

### PERFORMANCE CHARACTERISTICS

A side-by-side comparison was conducted using the GAB Rapid Test Cassette and GC/MS at the cut-off of 2,000ng/mL. Testing was performed on 92 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

| Method                  | GC/MS    |          | Total Results |          |
|-------------------------|----------|----------|---------------|----------|
|                         | Results  | Positive |               | Negative |
| GAB Rapid Test Cassette | Positive | 24       | 1             | 25       |
|                         | Negative | 2        | 65            | 67       |
| <b>Total Results</b>    |          | 26       | 66            | 92       |
| <b>% Agreement</b>      |          | 92.3%    | 98.5%         | 96.7%    |

#### Analytical Sensitivity

A drug-free urine pool was spiked with Gabapentin at the following concentrations: 0ng/mL, 1,000ng/mL, 1,500ng/mL, 2,000ng/mL, 2,500ng/mL, 3,000ng/mL and 6,000ng/mL. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

| Gabapentin Concentration (ng/mL) | Percent of Cut-off | n  | Visual Results |          |
|----------------------------------|--------------------|----|----------------|----------|
|                                  |                    |    | Negative       | Positive |
| 0                                | 0                  | 30 | 30             | 0        |
| 1,000                            | -50%               | 30 | 30             | 0        |
| 1,500                            | -25%               | 30 | 28             | 2        |
| 2,000                            | Cut-off            | 30 | 16             | 14       |
| 2,500                            | +25%               | 30 | 3              | 27       |
| 3,000                            | +50%               | 30 | 0              | 30       |
| 6,000                            | 3X                 | 30 | 0              | 30       |

#### Analytical Specificity

The following table lists compounds that are positively detected in urine by the GAB Rapid Test Cassette (Urine) at 5 minutes.

| Compound   | Concentration (ng/mL) |
|------------|-----------------------|
| Gabapentin | 2,000                 |

#### Precision

A study was conducted using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens containing, according to GC/MS, no Gabapentin, 25% Gabapentin above and below the cut-off and 50% Gabapentin above and below the 2,000ng/mL cut-off were provided to each site. The following results were tabulated:

| Gabapentin Concentration (ng/mL) | n per Site | Site A |    | Site B |    | Site C |    |
|----------------------------------|------------|--------|----|--------|----|--------|----|
|                                  |            | -      | +  | -      | +  | -      | +  |
| 0                                | 10         | 10     | 0  | 10     | 0  | 10     | 0  |
| 1,000                            | 10         | 10     | 0  | 10     | 0  | 10     | 0  |
| 1,500                            | 10         | 9      | 1  | 9      | 1  | 8      | 2  |
| 2,500                            | 10         | 2      | 8  | 2      | 8  | 2      | 8  |
| 3,000                            | 10         | 0      | 10 | 0      | 10 | 0      | 10 |

#### Effect of Urinary Specific Gravity

Fifteen urine specimens of normal, high and low specific gravity ranges were spiked with 1,000 ng/mL and 3,000 ng/mL of Gabapentin. The GAB Rapid Test Cassette (Urine) was tested in duplicate using the fifteen neat and spiked urine specimens. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

#### Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with Gabapentin to 1,000ng/ml and 3,000ng/mL. The spiked, pH-adjusted urine was tested with the GAB Rapid Test Cassette (Urine) in duplicate. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

#### Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Gabapentin positive urine. The following compounds show no cross-reactivity when tested with the GAB Rapid Test Cassette (Urine) at a concentration of 100µg/mL.

#### Non Cross-Reacting Compounds













|                      |                      |
|----------------------|----------------------|
| Acetaminophen        | d/l-Chlorpheniramine |
| N-Acetylprocainamide | Chloroquine          |
| Aminopyrine          | Clonidine            |
| Ampicillin           | l-Cotinine           |
| Apomorphine          | Deoxycorticosterone  |
| Atropine             | Diclofenac           |

|                           |                                |
|---------------------------|--------------------------------|
| Benzoic acid              | Digoxin                        |
| d/l-Brompheniramine       | l - $\Psi$ -Ephedrine          |
| Chloral-hydrate           | Estrone-3-sulfate              |
| Chlorothiazide            | l(-)-Epinephrine               |
| Chlorpromazine            | Fenoprofen                     |
| Cholesterol               | Gentisic acid                  |
| Cortisone                 | Hydralazine                    |
| Creatinine                | Hydrocortisone                 |
| Dextromethorphan          | p-Hydroxytyramine              |
| Diflunisal                | Iproniazid                     |
| Diphenhydramine           | Isoxsuprine                    |
| $\beta$ -Estradiol        | Ketamine                       |
| Caffeine                  | Quindine                       |
| Erythromycin              | Meperidine                     |
| Furosemide                | Methylphenidate                |
| Hemoglobin                | Naproxen                       |
| Hydrochlorothiazide       | Nifedipine                     |
| Verapamil                 | d-Norpropoxyphene              |
| Ibuprofen                 | d/l-Octopamine                 |
| d/l-Isoproterenol         | Oxolinic acid                  |
| Acetophenetidin           | Papaverine                     |
| Acetylsalicylic acid      | Labetalol                      |
| Amoxicillin               | Phenelzine                     |
| l-Ascorbic acid           | Phenylpropanolamine            |
| Aspartame                 | Prednisone                     |
| Benzilic acid             | d-Propoxyphene                 |
| Benzphetamine             | Quinacrine                     |
| Tetrahydrocortisone       | Trans-2-phenylcyclopropylamine |
| ( $\beta$ -D-glucuronide) | hydrochloride                  |
| o-Hydroxyhippuric acid    | Ethyl-p-aminobenzoate          |
| Sulfamethazine            | Penicillin-G                   |
| Tetracycline              | Perphenazine                   |
| Salicylic acid            | Chloramphenicol                |
| Thioridazine              | Prednisolone                   |
| Tolbutamide               | d/l-Propranolol                |
| Trifluoperazine           | d-Pseudoephedrine              |
| d/l-Tryptophan            | Quinine                        |
| Uric acid                 | Ranitidine                     |
| Ketoprofen                | Serotonin                      |
| Loperamide                | Sulindac                       |
| Meprobamate               | Zomepirac                      |
| Nalidixic acid            | Thiamine                       |
| Niacinamide               | d/l-Tyrosine                   |
| Norethindrone             | Triamterene                    |
| Noscapine                 | Trimethoprim                   |
| Oxalic acid               | Tyramine                       |
| Oxymetazoline             | Tetrahydrocortisone 3-acetate  |
| Pentazocine hydrochloride |                                |

**BIBLIOGRAPHY**

1. "Gabapentin". The American Society of Health-System Pharmacists. Archived from the original on 8 September 2017. Retrieved 23 Oct 2015.
2. Wijemanne, S; Jankovic, J (June 2015). "Restless legs syndrome: clinical presentation diagnosis and treatment". Sleep medicine. 16 (6): 678–90.
3. "Suicidal Behavior and Ideation and Antiepileptic Drugs". U.S. Food and Drug Administration (FDA). Archived from the original on 1 August 2009.
4. "Neurontin packaging insert" U.S. Food and Drug Administration (FDA). 1 May 2009. Archived from the original on 14 December 2010. Retrieved 16 July 2010.

5. Agarwal P, Griffith A, Costantino HR, Vaish N (2010). "Gabapentin enacarbil - clinical efficacy in restless legs syndrome". Neuropsychiatr Dis Treat. 6: 151–8.
6. Calandre EP, Rico-Villademoros F, Slim M (2016). "Alpha2delta ligands, gabapentin, pregabalin and mirogabalin: a review of their clinical pharmacology and therapeutic use". Expert Rev Neurother. 16 (11): 1263–1277.
7. Calandre EP, Rico-Villademoros F, Slim M (2016). "Alpha2delta ligands, gabapentin, pregabalin and mirogabalin: a review of their clinical pharmacology and therapeutic use". Expert Rev Neurother. 16 (11): 1263–1277.
8. Bockbrader HN, Wesche D, Miller R, Chapel S, Janiczek N, Burger P (2010). "A comparison of the pharmacokinetics and pharmacodynamics of pregabalin and gabapentin". Clin Pharmacokinet. 49(10): 661–9.
9. Cundy KC, Sastry S, Luo W, Zou J, Moors TL, Canafax DM (2008). "Clinical pharmacokinetics of XP13512, a novel transported prodrug of gabapentin". J Clin Pharmacol. 48 (12): 1378–88.

| INDEX OF SYMBOLS                                                                    |                                                                         |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------|
|    | In vitro diagnostic medical device                                      |
|    | Temperature limit                                                       |
|    | Do not use if package is damaged and consult instructions for use       |
|    | Catalogue number                                                        |
|    | Contains sufficient for <n> tests                                       |
|    | Use-by date                                                             |
|    | Batch code                                                              |
|    | Manufacturer                                                            |
|   | Do not re-use                                                           |
|  | Consult instructions for use or consult electronic instructions for use |
|  | Caution                                                                 |
|  | Authorized representative in the European Community                     |

REF: DGAB-102  
Number: CT58647  
Rev: 03  
Date: 07/07/2025

A rapid test for the qualitative detection of Mephedrone HCl in human urine.

For medical and other professional *in vitro* diagnostic use only.

### INTENDED USE

The MEP Rapid Test Cassette (Urine) is a rapid chromatographic immunoassay for the detection of Mephedrone HCl in urine at a cut-off concentration of 100ng/mL. This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

This assay provides only a qualitative, preliminary test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

The test results can be used to provide evidence and basis for therapy and treatment plans of drug dependence and toxic psychosis. For laboratory professional *in vitro* diagnostic use only. The MEP Rapid Test Cassette (Urine) should only be performed by health professionals in a clinical/hospital setting to aid in screening of drug of abuse to determine the follow-up treatment measures in combination of clinical symptoms.

### SUMMARY

Mephedrone, also known as 4-methylmethcathinone (4-MMC) or 4-methylphedrone is a synthetic stimulant drug of the amphetamine and cathinone classes. Slang names include drone,<sup>1</sup> M-CAT,<sup>2</sup> White Magic<sup>3</sup> and meow meow.<sup>4</sup> It is chemically similar to the cathinone compounds found in the khat plant of eastern Africa.

Mephedrone comes in the form of tablets or a powder, which users can swallow, snort or inject, producing similar effects to MDMA, amphetamines and cocaine. In addition to its stimulant effects, mephedrone produces side effects, of which teeth grinding are the most common. A number of metabolites are possible, however the n-demethyl metabolite of Mephedrone will be 4-Methylcathinone. This metabolite appears to be nearly inactive as a Monoamine Oxidase Inhibitor. On further metabolism of this metabolite one of the possible metabolites is 4-Methylnorephedrine, caused by the reduction of the Keto. A dose of 150mg-250mg is the average, giving a duration of around 2 hours. The duration will lengthen in larger 250mg+ dosages.

### PRINCIPLE

The MEP Rapid Test Cassette (Urine) is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody. During testing, a urine specimen migrates upward by capillary action. Mephedrone HCl, if present in the urine specimen below the cut-off level, will not saturate the binding sites of the antibody in the test. The antibody coated particles will then be captured by immobilized Mephedrone-protein conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the Mephedrone HCl level exceeds the cut-off level, because it will saturate all the binding sites of anti-mephedrone antibody.

A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper

volume of specimen has been added and membrane wicking has occurred.

### REAGENTS

The test contains mouse monoclonal anti-Mephedrone antibody coupled particles and Mephedrone-protein conjugate. A goat antibody is employed in the control line system.

### PRECAUTIONS

- For medical and other professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test should be discarded according to local regulations.

### STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30 °C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

### SPECIMEN COLLECTION AND PREPARATION

#### Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible particles should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

#### Specimen Storage

Urine specimens may be stored at 2-8 °C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20 °C. Frozen specimens should be thawed and mixed before testing.

### MATERIALS

#### Materials Provided

- Test cassettes
- Droppers
- Package insert

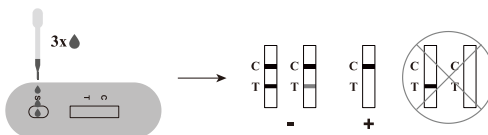
#### Materials Required But Not Provided

- Timer
- Specimen collection containers

### DIRECTIONS FOR USE

Allow the test, urine specimen and/or controls to reach room temperature (15-30°C) prior to testing.

- Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within one hour.
- Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 120 µL) to the specimen well (S) of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
- Wait for the colored line(s) to appear. **Read results at 5 minutes.** Do not interpret the result after 10 minutes.



### INTERPRETATION OF RESULTS

(Please refer to the illustration above)

**NEGATIVE: Two colored lines appear.** One colored line should be in the control line region (C) and another colored line should be in the test line region (T). This negative result indicates that the Mephedrone HCl concentration is below the detectable cut-off level.

\*NOTE: The shade of color in the test line region (T) may vary, but it should be considered negative whenever there is even a faint colored line.

**POSITIVE: One colored line appears in the control line region (C).** No line appears in the test line region (T). This positive result indicates that the Mephedrone HCl concentration exceeds the detectable cut-off level.

**INVALID: Control line fails to appear.** Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

### QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory testing practice to confirm the test procedure and to verify proper test performance.

### LIMITATIONS

- The MEP Rapid Test Cassette (Urine) provides only a qualitative, preliminary result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
- It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
- A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
- A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
- Test does not distinguish between drugs of abuse and certain medications.

### PERFORMANCE CHARACTERISTICS

A side-by-side comparison was conducted using the MEP Rapid Test Cassette and GC/MS at the cut-off of 100ng/mL. Testing was performed on 87 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

| Method                  | Results  | GC/MS    |          | Total Results |
|-------------------------|----------|----------|----------|---------------|
|                         |          | Positive | Negative |               |
| MEP Rapid Test Cassette | Positive | 19       | 2        | 21            |
|                         | Negative | 2        | 64       | 66            |
| <b>Total Results</b>    |          | 21       | 66       | 87            |
| <b>% Agreement</b>      |          | 90.5%    | 97.0%    | 95.4%         |

### Analytical Sensitivity

A drug-free urine pool was spiked with Mephedrone HCl at the following concentrations: 0ng/mL, 50ng/mL, 75ng/mL, 100ng/mL, 125ng/mL, 150ng/mL and 300ng/mL. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

| Mephedrone HCl Concentration (ng/mL) | Percent of Cut-off | n  | Visual Result |          |
|--------------------------------------|--------------------|----|---------------|----------|
|                                      |                    |    | Negative      | Positive |
| 0                                    | 0                  | 30 | 30            | 0        |
| 50                                   | -50%               | 30 | 30            | 0        |
| 75                                   | -25%               | 30 | 27            | 3        |
| 100                                  | Cut-off            | 30 | 17            | 13       |
| 125                                  | +25%               | 30 | 5             | 25       |
| 150                                  | +50%               | 30 | 0             | 30       |
| 300                                  | 3X                 | 30 | 0             | 30       |

### Analytical Specificity

The following table lists compounds that are positively detected in urine by the MEP Rapid Test Cassette (Urine) at 5 minutes.

| Compound                  | Concentration(ng/mL) |
|---------------------------|----------------------|
| Mephedrone HCl            | 100                  |
| S(-)-Methcathinone HCl    | 500                  |
| 4-Fluoromethcathinone HCl | 300                  |
| R(+)-Methcathinone HCl    | 1,500                |
| 3-Fluoromethcathinone HCl | 1,500                |
| Methoxyphenamine          | 100,000              |

### Precision

A study was conducted at three hospitals using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens containing, according to GC/MS, no Mephedrone HCl, 25% Mephedrone HCl above and below the cut-off and 50% Mephedrone HCl above and below the 100ng/mL cut-off was provided to each site. The following results were tabulated:

| Mephedrone HCl Concentration (ng/mL) | n per Site | Site A |    | Site B |    | Site C |    |
|--------------------------------------|------------|--------|----|--------|----|--------|----|
|                                      |            | -      | +  | -      | +  | -      | +  |
| 0                                    | 10         | 10     | 0  | 10     | 0  | 10     | 0  |
| 50                                   | 10         | 10     | 0  | 10     | 0  | 10     | 0  |
| 75                                   | 10         | 9      | 1  | 8      | 2  | 9      | 1  |
| 125                                  | 10         | 2      | 8  | 2      | 8  | 2      | 8  |
| 150                                  | 10         | 0      | 10 | 0      | 10 | 0      | 10 |

### Effect of Urinary Specific Gravity

Fifteen urine specimens of normal, high, and low specific gravity ranges were spiked with 50ng/mL and 150ng/mL of Mephedrone HCl. The MEP Rapid Test Cassette (Urine) was tested in duplicate using the fifteen neat and spiked urine specimens. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

### Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with Mephedrone HCl to 50ng/mL and 150ng/mL. The spiked, pH-adjusted urine was tested with the MEP Rapid Test Cassette (Urine) in duplicate. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

### Cross-Reactivity













A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Mephedrone HCl

positive urine. The following compounds show no cross-reactivity when tested with the MEP Rapid Test Cassette (Urine) at a concentration of 100 µg/mL.

**Non Cross-Reacting Compounds**

|                                              |                      |
|----------------------------------------------|----------------------|
| Acetaminophen                                | d/l-Chlorpheniramine |
| N-Acetylprocainamide                         | Chloroquine          |
| Aminopyrine                                  | Clonidine            |
| Ampicillin                                   | l-Cotinine           |
| Apomorphine                                  | Deoxycorticosterone  |
| Atropine                                     | Diclofenac           |
| Benzoic acid                                 | Digoxin              |
| d/l-Brompheniramine                          | l -Ψ-Ephedrine       |
| Chloral-hydrate                              | Estrone-3-sulfate    |
| Chlorothiazide                               | l(-)-Epinephrine     |
| Chlorpromazine                               | Fenoprofen           |
| Cholesterol                                  | Gentisic acid        |
| Cortisone                                    | Hydralazine          |
| Creatinine                                   | Hydrocortisone       |
| Dextromethorphan                             | p-Hydroxytyramine    |
| Diffenhydramine                              | Iproniazid           |
| β-Estradiol                                  | Isoxsuprine          |
| Ethyl-p-aminobenzoate                        | Ketamine             |
| Erythromycin                                 | Labetalol            |
| Furosemide                                   | Meperidine           |
| Hemoglobin                                   | Methylphenidate      |
| Hydrochlorothiazide                          | Naproxen             |
| o-Hydroxyhippuric acid                       | Nifedipine           |
| Ibuprofen                                    | d-Norpropoxyphene    |
| d/l-Isoproterenol                            | d/l-Octopamine       |
| Acetophenetidin                              | Oxolinic acid        |
| Acetylsalicylic acid                         | Papaverine           |
| Amoxicillin                                  | Zomepirac            |
| l-Ascorbic acid                              | Phenelzine           |
| Aspartame                                    | Phenylpropanolamine  |
| Benzilic acid                                | Prednisone           |
| Benzphetamine                                | d-Propoxyphene       |
| Caffeine                                     | Quinacrine           |
| Tetrahydrocortisone                          | Quindine             |
| (β-D-glucuronide)                            | Pentazocine          |
| Sulfamethazine                               | hydrochloride        |
| Tetracycline                                 | Oxalic acid          |
| Salicylic acid                               | Oxymetazoline        |
| Thioridazine                                 | Penicillin-G         |
| Tolbutamide                                  | Perphenazine         |
| Trifluoperazine                              | Chloramphenicol      |
| d/l-Tryptophan                               | Prednisolone         |
| Uric acid                                    | d/l-Propranolol      |
| Ketoprofen                                   | d-Pseudoephedrine    |
| Loperamide                                   | Quinine              |
| Meprobamate                                  | Ranitidine           |
| Nalidixic acid                               | Serotonin            |
| Niacinamide                                  | Sulindac             |
| Tyramine                                     | Tetrahydrocortisone  |
| Norethindrone                                | 3-acetate            |
| Noscapine                                    | Thiamine             |
| Verapamil                                    | d/l-Tyrosine         |
| Trans-2-phenylcyclopropylamine hydrochloride | Triamterene          |
|                                              | Trimethoprim         |

- Schifano, F.; Albanese, A.; Fergus, S.; Stair, J. L.; Deluca, P.; Corazza, O.; Davey, Z.; Corkery, J.; Siemann, H.; Scherbaum, N.; Farre', M.; Torrens, M.; Demetrovics, Z.; Ghodse, A. H.; Psychonaut Web, M.; Rednet Research, G. (2010). "Mephedrone (4-methylmethcathinone; 'meow meow'): chemical, pharmacological and clinical issues". *Psychopharmacology* 214 (3):593-602. doi:10.1007/s00213-010-2070-x. ISSN 0033-3158. PMID 21072502.

| INDEX OF SYMBOLS                                                                  |                                                                         |
|-----------------------------------------------------------------------------------|-------------------------------------------------------------------------|
|  | In vitro diagnostic medical device                                      |
|  | Temperature limit                                                       |
|  | Do not use if package is damaged and consult instructions for use       |
|  | Catalogue number                                                        |
|  | Contains sufficient for <n> tests                                       |
|  | Use-by date                                                             |
|  | Batch code                                                              |
|  | Manufacturer                                                            |
|  | Do not re-use                                                           |
|  | Consult instructions for use or consult electronic instructions for use |
|  | Caution                                                                 |
|  | Authorized representative in the European Community                     |

REF: DMPE-102  
Number: CT58971  
Rev: 02  
Date: 07/14/2025

**BIBLIOGRAPHY**

- Cumming, E. (22 April 2010). "Mephedrone: Chemistry lessons". London: The Daily Telegraph. Retrieved 2010-09-14.
- "Drugs crackdown hailed a success". BBC News. 8 March 2010. Retrieved 2010-03-31.
- Kihara, Rhiannon; Day, Edward (May 2014). "Transient psychotic episodes following recreational use of NRG-3". *Progress in Neurology and Psychiatry* 18 (3): 14-18. doi:10.1002/pnp.331. Retrieved 22 March 2015.

A rapid test for the qualitative detection of Pregabalin in human urine.  
For medical and other professional *in vitro* diagnostic use only.

### INTENDED USE

The PGB Rapid Test Cassette (Urine) is a rapid chromatographic immunoassay for the detection of Pregabalin in urine at a cut-off concentration of 500ng/mL. This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert. This assay provides only a qualitative, preliminary test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result. The test results can be used to provide evidence and basis for therapy and treatment plans of drug dependence and toxic psychosis. For laboratory professional *in vitro* diagnostic use only. The PGB Rapid Test Cassette (Urine) should only be performed by health professionals in a clinical/hospital setting to aid in screening of drug of abuse to determine the follow-up treatment measures in combination of clinical symptoms.

### SUMMARY

Pregabalin, also known as  $\beta$ -isobutyl- $\gamma$ -amino butyric acid (beta-isobutyl-GABA), is a medication used to treat epilepsy, neuropathic pain, fibromyalgia, and generalized anxiety disorder.<sup>1</sup> Common side effects include: sleepiness, confusion, trouble with memory, poor coordination, dry mouth, problem with vision, and weight gain. Potentially serious side effects include angioedema, drug misuse, and an increased suicide risk.<sup>2</sup>

Pregabalin is eliminated from the systemic circulation primarily by renal excretion as unchanged drug. The Pregabalin is predominantly excreted unchanged in urine ( $\geq 98\%$ )<sup>3</sup>. Pregabalin mean elimination half-life is 6.3 hours.<sup>4</sup> 50% would be expected to have negative urine specimens within 3 days and a total of 5 days would be needed to achieve negative urine specimens in the subject with the maximum urinary concentration measured.<sup>5</sup>

The PGB Rapid Test Cassette (Urine) is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Pregabalin in urine. The PGB Rapid Test Cassette (Urine) yields a positive result when Pregabalin in urine exceed 500ng/mL.

### PRINCIPLE

The PGB Rapid Test Cassette (Urine) is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a urine specimen migrates upward by capillary action. Pregabalin, if present in the urine specimen below the cut-off level, will not saturate the binding sites of the antibody in the test. The antibody coated particles will then be captured by immobilized Pregabalin-protein conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the Pregabalin level exceeds the cut-off level, because it will saturate all the binding sites of anti-Pregabalin antibody.

A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

### PRECAUTIONS

- For medical and other professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.

- The used test should be discarded according to local regulations.

### STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30 °C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

### SPECIMEN COLLECTION AND PREPARATION

#### Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible particles should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

#### Specimen Storage

Urine specimens may be stored at 2-8 °C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20 °C. Frozen specimens should be thawed and mixed before testing.

### MATERIALS

#### Materials Provided

- Test cassettes
- Droppers
- Package insert

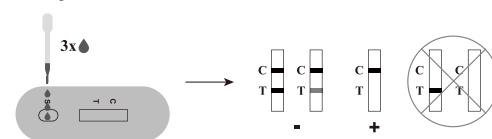
#### Materials Required But Not Provided

- Specimen collection containers
- Timer

### DIRECTIONS FOR USE

Allow the test, urine specimen, and/or controls to reach room temperature (15-30°C) prior to testing.

- Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within one hour.
- Place the test cassette on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 120  $\mu$ L) to the specimen well (S) of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
- Wait for the colored line(s) to appear. **Read results at 5 minutes.** Do not interpret the result after 10 minutes.



### INTERPRETATION OF RESULTS

(Please refer to the illustration above)

**NEGATIVE: Two colored lines appear.** One colored line should be in the control line region (C), and another colored line should be in the test line region (T). This negative result indicates that the Pregabalin concentration is below the detectable cut-off level.

**\*NOTE:** The shade of color in the test line region (T) may vary, but it should be considered negative whenever there is even a faint colored line.

**POSITIVE: One colored line appears in the control line region (C).** No line appears in the test line region (T). This positive result indicates that the Pregabalin concentration exceeds the detectable cut-off level.

**INVALID: Control line fails to appear.** Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

### QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory testing practice to confirm the test procedure and to verify proper test performance.

### LIMITATIONS

- The PGB Rapid Test Cassette (Urine) provides only a qualitative, preliminary result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/ mass spectrometry (GC/MS) is the preferred confirmatory method.
- It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
- A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
- A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
- Test does not distinguish between drugs of abuse and certain medications.
- The PGB Rapid Test Cassette can only be used with urine specimen.

### PERFORMANCE CHARACTERISTICS

A side-by-side comparison was conducted using the PGB Rapid Test Cassette and GC/MS at the cut-off of 500ng/mL. Testing was performed on 75 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

| Method                  | GC/MS    |          | Total Results |
|-------------------------|----------|----------|---------------|
|                         | Positive | Negative |               |
| PGB Rapid Test Cassette | Positive | 20       | 22            |
|                         | Negative | 1        | 53            |
| <b>Total Results</b>    | 21       | 54       | 75            |
| <b>% Agreement</b>      | 95.2%    | 96.3%    | 96.0%         |

#### Analytical Sensitivity

A drug-free urine pool was spiked with Pregabalin at the following concentrations: 0 ng/mL, 250ng/mL, 375ng/mL, 500ng/mL, 625ng/mL, 750ng/mL and 1500ng/mL. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

| Pregabalin Concentration ( $\mu$ g/mL) | Percent of Cut-off | N  | Visual Result |          |
|----------------------------------------|--------------------|----|---------------|----------|
|                                        |                    |    | Negative      | Positive |
| 0                                      | 0                  | 30 | 30            | 0        |
| 250                                    | -50%               | 30 | 30            | 0        |
| 375                                    | -25%               | 30 | 25            | 5        |
| 500                                    | Cut-off            | 30 | 15            | 15       |
| 625                                    | +25%               | 30 | 6             | 24       |
| 750                                    | +50%               | 30 | 0             | 30       |
| 1500                                   | 3X                 | 30 | 0             | 30       |

#### Analytical Specificity

The following table lists compounds that are positively detected in urine by the PGB Rapid Test Cassette (Urine) at 5 minutes.

| Compound   | Concentration ( $\mu$ g/mL) |
|------------|-----------------------------|
| Pregabalin | 500                         |

#### Precision

A study was conducted at three hospitals by laypersons using three different lots of product to demonstrate the within run, between run and between operator precision. An identical cassette of coded specimens containing, according to GC/MS, no Pregabalin, 25% Pregabalin above and below the cut-off, and 50% Pregabalin above and below the 500ng/mL cut-off was provided to each site. The results are given below:

| Pregabalin Concentration ( $\mu$ g/mL) | n per Site | Site A |    | Site B |    | Site C |    |
|----------------------------------------|------------|--------|----|--------|----|--------|----|
|                                        |            | -      | +  | -      | +  | -      | +  |
| 0                                      | 10         | 10     | 0  | 10     | 0  | 10     | 0  |
| 250                                    | 10         | 10     | 0  | 10     | 0  | 10     | 0  |
| 375                                    | 10         | 9      | 1  | 8      | 2  | 8      | 2  |
| 625                                    | 10         | 2      | 8  | 2      | 8  | 2      | 8  |
| 750                                    | 10         | 0      | 10 | 0      | 10 | 0      | 10 |
| 1500                                   | 10         | 0      | 10 | 0      | 10 | 0      | 10 |

#### Effect of Urinary Specific Gravity

Fifteen urine specimens of normal, high, and low specific gravity ranges were spiked with 250ng/mL and 750ng/mL of Pregabalin. The PGB Rapid Test Cassette (Urine) was tested in duplicate using the fifteen neat and spiked urine specimens. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

#### Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with Pregabalin to 250ng/mL and 750ng/mL. The spiked, pH-adjusted urine was tested with the PGB Rapid Test Cassette (Urine) in duplicate. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

#### Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Pregabalin positive urine. The following compounds show no cross-reactivity when tested with the PGB Rapid Test Cassette (Urine) at a concentration of 100  $\mu$ g/mL.

#### Non Cross-Reacting Compounds













|                                                 |                                              |
|-------------------------------------------------|----------------------------------------------|
| Acetaminophen                                   | d/l-Chlorpheniramine                         |
| N-Acetylprocainamide                            | Chloroquine                                  |
| Ampicillin                                      | Tetrahydrocortisone 3-acetate                |
| Tetrahydrocortisone 3 ( $\beta$ -D-glucuronide) | Trans-2-phenylcyclopropylamine hydrochloride |
| Apomorphine                                     | l-Cotinine                                   |
| Atropine                                        | Deoxycorticosterone                          |
| Benzoic acid                                    | Diclofenac                                   |
| d/l-Brompheniramine                             | Digoxin                                      |
| Chloral-hydrate                                 | l- $\Psi$ -Ephedrine                         |
| Chlorothiazide                                  | Estrone-3-sulfate                            |
| Chlorpromazine                                  | l(-)-Ephedrine                               |
| Cholesterol                                     | Fenoprofen                                   |
| Cortisone                                       | Genistic acid                                |
| Creatinine                                      | Hydralazine                                  |
| Dextromethorphan                                | Hydrocortisone                               |
| Diflunisal                                      | p-Hydroxytyramine                            |
| Diphenhydramine                                 | Iproniazid                                   |
| $\beta$ -Estradiol                              | Isoxsuprine                                  |
| Ethyl-p-aminobenzoate                           | Ketamine                                     |
| Erythromycin                                    | Labetalol                                    |
| Furosemide                                      | Meperidine                                   |
| Hemoglobin                                      | Methylphenidate                              |
| Hydrochlorothiazide                             | Naproxen                                     |
| Zomepirac                                       | Nifedipine                                   |
| Ibuprofen                                       | d-Norpropoxyphene                            |
| d/l-Isoproterenol                               | d/l-Octopamine                               |
| Acetophenetidin                                 | Oxolinic acid                                |
| Acetylsalicylic acid                            | Papaverine                                   |
| Amoxicillin                                     | Pentazocine hydrochloride                    |
| l-Ascorbic acid                                 | Phenelzine                                   |
| Aspartame                                       | Phenylpropanolamine                          |
| Benzilic acid                                   | Prednisone                                   |
| Benzphetamine                                   | d-Propoxyphene                               |
| Caffeine                                        | Quinacrine                                   |
| Chloramphenicol                                 | Quindine                                     |

|                        |                   |
|------------------------|-------------------|
| Sulfamethazine         | d/l-Propranolol   |
| Tetracycline           | d-Pseudoephedrine |
| Salicylic acid         | Quinine           |
| o-Hydroxyhippuric acid | Ranitidine        |
| Thioridazine           | Serotonin         |
| Tolbutamide            | Sulindac          |
| Trifluoperazine        | Verapamil         |
| d/l-Tryptophan         | Thiamine          |
| Uric acid              | d/l-Tyrosine      |
| Ketoprofen             | Triamterene       |
| Loperamide             | Trimethoprim      |
| Meprobamate            | Tyramine          |
| Nalidixic acid         | Oxymetazoline     |
| Niacinamide            | Penicillin-G      |
| Norethindrone          | Perphenazine      |
| Noscapine              | Clonidine         |
| Oxalic acid            | Prednisolone      |

**BIBLIOGRAPHY**

1. Frampton, JE (September 2014). "Pregabalin: a review of its use in adults with generalized anxiety disorder." CNS Drugs 28 (9): 835–54.
2. "Pregabalin". The American Society of Health-System Pharmacists. Retrieved Oct 23, 2015.
3. D.R. Guay. Pregabalin in neuropathic pain: a more "pharmaceutically elegant" gabapentin? Am. J. Geriatr. Pharmacother. 3: 274–287 (2005).
4. "Summary of product characteristics" (PDF). European Medicines Agency. 6 March 2013. Retrieved 6 May 2013.
5. "Detection times of Pregabalin in urine after illicit use: when should a positive specimen be considered a new intake?" TherDrugMonit. 2013 Feb;35(1):137-40.

**INDEX OF SYMBOLS**

|                                                                                   |                                                                         |
|-----------------------------------------------------------------------------------|-------------------------------------------------------------------------|
|    | In vitro diagnostic medical device                                      |
|    | Temperature limit                                                       |
|    | Do not use if package is damaged and consult instructions for use       |
|    | Catalogue number                                                        |
|   | Contains sufficient for <n> tests                                       |
|  | Use-by date                                                             |
|  | Batch code                                                              |
|  | Manufacturer                                                            |
|  | Do not re-use                                                           |
|  | Consult instructions for use or consult electronic instructions for use |
|  | Caution                                                                 |
|  | Authorized representative in the European Community                     |