



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.





Lubica Škrovanová
Head of Certification Body



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 (including 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.

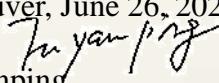
As the Manufacturer we declare that:

- 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:



Fu Yanping

Name:

Fu Yanping

Title:

General Manager

CITEST DIAGNOSTICS INC



Attachment I Product List- Drug of Abuse

Cat.no.	Product Name	Certificate No.	Classification under IVDD
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	α-Pyrrolidinovalerophenone (α-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	Methylenedioxypyrovalerone (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	Methylenedioxypyrovalerone (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 HCI (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	Methadone (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	Desmethylmirtazapine(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/CT102/CT114	Nitazene (NTZ) Rapid Test(Urine)	RPS/1780/2025	Self-declaration Others
DOA-125~1175/ DUA-125-1175	Multi-Drug X Drugs Rapid Test with/Without Adulteration(Urine)	RPS/1190/2025	Self-declaration Others
DOA-124~1204/ DUA-124~1204			
DOA-127~1227/ 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/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 RTARPBCI	Aripiprazole (ARP) Rapid Test (Urine)	RPS/2711/2025	Self-declaration Others
RTDIPCI/RTDIPACI/ RTDIPBCI	Diphenoxylate (DIP) Rapid Test (Urine)	RPS/2711/2025	Self-declaration Others
RTDXMCI/RTDXMA CI/RTDXMBCI	Dextromethorphan (DXM) Rapid Test (Urine)	RPS/2711/2025	Self-declaration Others
RTNTZCI/RTNTZACI /RTNTZBCI	Nitazene (NTZ) Rapid Test (Urine)	RPS/2711/2025	Self-declaration Others



Instruction Sheet for testing of any combination of the following drugs:
 ACE/AMP/BAR/BZO/BUP/CO/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/MCA
 T7-ACL/CAF/CFYL/CAT/TRO/ALP/PGB/ZAL/MPRD/CNB/GAB/TZD/CAR/ABP/OTP/
 FLX/UR-144/KRA/TLD/α-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)	Benzoylgegonine	1,500/300/200/150/100
Marijuana (THC)	11-nor-Δ ⁹ -THC-9 COOH	300/200/150/50/30/25/20
Methadone (MTD)	Methadone	300/200
Methamphetamine (MET)	d-Methamphetamine	1,000/500/300/200
Methylenedioxymethamphetamine (MDMA)	d,l-Methylenedioxymethamphetamine	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
(±) 3,4-Methylenedioxymethamphetamine (MDA)	(±) 3,4-Methylenedioxymethamphetamine	500
Ethyl-β-D-Glucuronide (ETG)	Ethyl-β-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-methylenedioxypyrovalerone (MDPV)	3,4-methylenedioxypyrovalerone	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 (CFY)	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)	AB-PINACA	10
Quetiapine (QTP)	Quetiapine	1,000
Fluoxetine (FLX)	Fluoxetine	500
UR-144	UR-144 5-Pentanoic acid	25
Kratom (KRA)	Mitragynine	300
Tilidine (TLD)	Tilidine	50
Trazodone (TZD)	Trazodone	200
Alpha-Pyrrolidinovalerophenone (α-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(ALK)	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.³ 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.³ 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.³ 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.¹ 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 Cassette
- Alcohol(ALK)
- Droppers
- Adulteration Color Chart (when applicable)
- 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.

- 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.

Positive	90.9%	92.9%	97.1%	95.2%	95.8%	92.3%	95.0%	98.8%	91.9%	97.3%	97.1%
Agreement											
Negative	97.3%	96.1%	98.4%	97.4%	97.6%	98.5%	96.0%	99.4%	95.2%	98.3%	98.3%
Agreement											

Total Results	95.9%	95.2%	98.0%	96.7%	96.9%	96.7%	95.6%	99.2%	94.0%	97.9%	97.9%
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	PAP 500	KRA 300	CAR 2,000	FLX 500	K2 25	CIT 500	FKET 1,000	RPD 150	FYL 100	FYL 200	CFYL 250
Positive	96.9%	95.7%	95.0%	97.1%	97.6%	93.3%	96.7%	93.3%	98.8%	97.5%	94.7%
Agreement											
Negative	98.0%	98.3%	94.2%	96.6%	98.2%	95.5%	97.0%	95.5%	99.4%	99.4%	98.6%

Total Results	97.6%	97.6%	94.4%	96.8%	98.0%	94.8%	96.9%	94.8%	99.2%	98.8%	97.3%
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	PGB 500	MES 300	OZP 1,000	MDPV 300	α -PVP 2,000	α -PVP 300	TAP 1,000	NND 1,000	SCOP 500	MTZ 500	
Positive	95.2%	95.8%	95.8%	93.8%	86.8%	92.1%	94.4%	96.7%	93.5%	93.3%	
Agreement											
Negative	96.3%	97.6%	97.6%	97.1%	96.8%	95.2%	98.2%	97.0%	98.6%	95.6%	

Total Results	96.0%	96.9%	96.9%	96.1%	93.0%	94.0%	96.7%	96.9%	97.0%	94.9%	
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	COT 300	THC 200	THC 30	MEP 500	MPD 150	OPI 1,000	PCP 50	TML 500	TCA 300	CAR 1,000	FYL 300
Positive	97.7%	93.4%	97.9%	95.2%	91.9%	95.9%	92.3%	92.9%	94.9%	90.0%	97.0%
Agreement											
Negative	97.5%	97.5%	98.1%	98.5%	98.4%	93.8%	96.9%	98.1%	92.1%	98.1%	98.9%

Total Results	97.6%	96.0%	98.0%	97.7%	96.0%	94.8%	95.2%	96.9%	93.2%	95.8%	98.6%
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	HMO 250	HMO 300	HMO 500	MET 200	CAR 500	COC 1,500	ETG 1,500	ZOP 300			
Positive	93.8%	91.7%	91.7%	97.6%	90.0%	92.0%	97.7%	90.9%			
Agreement											
Negative	97.5%	98.7%	98.7%	97.0%	92.3%	98.3%	99.4%	97.2%			

Total Results	96.1%	96.1%	96.1%	97.2%	91.7%	95.2%	98.8%	95.7%			
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	ACE 5,000	AMP 1,000	BAR 300/500	BZD 200/300	BUP 10/5	COC 300/100	COC 1,500/100	THC 500/200	THC 300/200	MPD 1,000/200	
Positive	*	>99.9%	>99.9%	>99.9%	>99.9%	*	>99.9%	*	*	*	
Agreement	*										
Negative	*	>99.9%	>99.9%	>99.9%	>99.9%	*	>99.9%	*	*	*	

Total Results	*	>99.9%	>99.9%	>99.9%	>99.9%	*	>99.9%	*	*	*	
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	7-ACL 300/200	MTD 1,000/200	MET 500/100	M DMA 300/500	M DMA 1,000/100	MOP/ OPI 300/200	MOP/ OPI 1,000/500	MQL 100	MEP 500/100	LSD 50/20	
Positive	*	>99.9%	>99.9%	*	>99.9%	*	>99.9%	*	>99.9%	*	
Agreement	*										
Negative	*	>99.9%	>99.9%	*	>99.9%	*	>99.9%	*	>99.9%	*	

Total Results	*	>99.9%	>99.9%	*	>99.9%	*	>99.9%	*	>99.9%	*	
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Flunitrazepam	200	Diazepam	300
(±) Lorazepam	3,000	Estazolam	6,000
RS-Lorazepamglucuronide	200	Triazolam	3,000
Midazolam	6,000		
BENZODIAZEPINES (BZO 200)			
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		
BENZODIAZEPINES (BZO 100)			
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		
BUPRENORPHINE (BUP 10)			
Buprenorphine	10	Norbuprenorphine	50
Buprenorphine 3-D-Glucuronide	50	Norbuprenorphine 3-D-Glucuronide	100
BUPRENORPHINE (BUP 5)			
Buprenorphine	5	Norbuprenorphine	25
Buprenorphine 3-D-Glucuronide	25	Norbuprenorphine 3-D-Glucuronide	50
COCAINE (COC 1,500)			
Benzoyleconine	1,500	Cocaethylene	100,000
Cocaine HCl	1200	Egonine	150,000
COCAINE (COC 300)			
Benzoyleconine	300	Cocaethylene	20,000
Cocaine HCl	200	Egonine	30,000
COCAINE (COC 200)			
Benzoyleconine	200	Cocaethylene	13,500
Cocaine HCl	135	Egonine	20,000
COCAINE (COC 150)			
Benzoyleconine	150	Cocaethylene	1,0000
Cocaine HCl	120	Egonine	15,000
COCAINE (COC 100)			
Benzoyleconine	100	Cocaethylene	7,000
Cocaine HCl	80	Egonine	10,000
MARIJUANA (THC 300)			
Cannabinol	200,000	Δ ⁸ -THC	100,000
11-nor-Δ ⁸ -THC-9-COOH	200	Δ ⁹ -THC	100,000
11-nor-Δ ⁹ -THC-9-COOH	300		
MARIJUANA (THC 200)			
Cannabinol	140,000	Δ ⁸ -THC	68,000
11-nor-Δ ⁸ -THC-9-COOH	120	Δ ⁹ -THC	68,000
11-nor-Δ ⁹ -THC-9-COOH	200		
MARIJUANA (THC 150)			
Cannabinol	100,000	Δ ⁸ -THC	50,000
11-nor-Δ ⁸ -THC-9-COOH	100	Δ ⁹ -THC	50,000
11-nor-Δ ⁹ -THC-9-COOH	150		
MARIJUANA (THC 50)			
Cannabinol	35,000	Δ ⁸ -THC	17,000
11-nor-Δ ⁸ -THC-9-COOH	30	Δ ⁹ -THC	17,000
11-nor-Δ ⁹ -THC-9-COOH	50		
MARIJUANA (THC 30)			
Cannabinol	20,000	Δ ⁸ -THC	10,000
11-nor-Δ ⁸ -THC-9-COOH	20	Δ ⁹ -THC	10,000
11-nor-Δ ⁹ -THC-9-COOH	30		
MARIJUANA (THC 25)			
Cannabinol	17,500	Δ ⁸ -THC	8,500
11-nor-Δ ⁸ -THC-9-COOH	15	Δ ⁹ -THC	8,500
11-nor-Δ ⁹ -THC-9-COOH	25		
MARIJUANA (THC 20)			
Cannabinol	14,000	Δ ⁸ -THC	6,800
11-nor-Δ ⁸ -THC-9-COOH	12	Δ ⁹ -THC	6,800
11-nor-Δ ⁹ -THC-9-COOH	20		
METHADONE (MTD 300)			
Methadone	300	Doxylamine	100,000
METHADONE (MTD 200)			
Methadone	200	Doxylamine	65,000
METHAMPHETAMINE (MET 1,000)			
o-Hydroxymethamphetamine	25,000	(±)-3,4-Methylenedioxy-methamphetamine	12,500
D-Methamphetamine	1,000		
L-Methamphetamine	20,000	Mephentermine	50,000
METHAMPHETAMINE (MET 200)			
o-Hydroxymethamphetamine	5,000	(±)-3,4-Methylenedioxy-methamphetamine	2,500
D-Methamphetamine	200	Mephentermine	10,000
L-Methamphetamine	4,000		
METHAMPHETAMINE (MET 300)			
o-Hydroxymethamphetamine	7,500	(±)-3,4-Methylenedioxy-methamphetamine	3,750
D-Methamphetamine	300	Mephentermine	
L-Methamphetamine	6,000		
METHAMPHETAMINE (MET 500)			
o-Hydroxymethamphetamine	12,500	(±)-3,4-Methylenedioxy-methamphetamine	6,250
D-Methamphetamine	500	Mephentermine	
L-Methamphetamine	10,000		
TRICYCLIC ANTIDEPRESSANTS (TCA 300)			
Nortriptyline	1,000	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	Dithiadien	5,000
TRICYCLIC ANTIDEPRESSANTS (TCA 200)			
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	Dithiadien	3,000
TRAMADOL (TML 100)			
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
TRAMADOL (TML 200)			
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
TRAMADOL (TML 300)			
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
TRAMADOL (TML 500)			
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
KETAMINE (KET 1,000)			
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	d-Methamphetamine	50,000
Mephentermine	25,000	l-Methamphetamine	50,000
(1R, 2S) - (-)-Ephedrine	100,000	3,4-Methylenedioxymethamphetamine (MDMA)	100,000
Disopyramide	25,000	Thioridazine	50,000
KETAMINE (KET 500)			
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	d-Methamphetamine	25,000
Mephentermine	12,500	l-Methamphetamine	25,000
(1R, 2S) - (-)-Ephedrine	50,000	3,4-Methylenedioxymethamphetamine (MDMA)	50,000

CLONAZEPAM (CLO 400)			
Clonazepam	400	Flunitrazepam	300
Alprazolam	200	(±) Lorazepam	1,250
a-hydroxyalprazolam	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		
CLONAZEPAM (CLO 150)			
Clonazepam	150	Flunitrazepam	120
Alprazolam	75	(±) Lorazepam	500
a-hydroxyalprazolam	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		
LYSERGIC ACID DIETHYLAMIDE (LSD 10)			
Lysergic Acid Diethylamide	10		
LYSERGIC ACID DIETHYLAMIDE (LSD 20)			
Lysergic Acid Diethylamide	20		
LYSERGIC ACID DIETHYLAMIDE (LSD 50)			
Lysergic Acid Diethylamide	50		
METHYLPHENIDATE (MPD 300)			
Methylphenidate (Ritalin)	300	Ritalinic Acid	1,000
METHYLPHENIDATE (MPD 150)			
Methylphenidate (Ritalin)	150	Ritalinic Acid	500
METHYLPHENIDATE (MPD 1,000)			
Methylphenidate (Ritalin)	350	Ritalinic Acid	1,000
ZOLPIDEM (ZOL 50)			
Zolpidem	50		
MEPHEDRONE (MEP 500)			
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
MEPHEDRONE (MEP 100)			
Mephedrone HCl	100	R(+)-Methcathinone HCl	1500
S(-)-Methcathinone HCl	500	3-Fluoromethcathinone HCl	1500
4-Fluoromethcathinone HCl	300	Methoxyphenamine	100,000
3, 4-METHYLENEDIOXYPYROVALERONE (MDPV 1,000)			
3, 4-methylenedioxy- pyrovalerone	1,000		
3, 4-METHYLENEDIOXYPYROVALERONE (MDPV 500)			
3, 4-methylenedioxy- pyrovalerone	500		
3, 4-METHYLENEDIOXYPYROVALERONE (MDPV 300)			
3, 4-methylenedioxy- pyrovalerone	300		
DIAZEPAM (DIA 300)			
Diazepam	300	Midazolam	6,000
Clobazam	200	Nitrazepam	200
Clonazepam	500	Norchlordiazepoxide	100
Clorazepatedipotassium	500	Nordiazepam	900
Alprazolam	100	Flunitrazepam	200
a-hydroxyalprazolam	1,500	(±) Lorazepam	3,000
Bromazepam	900	RS-Lorazepam glucuronide	200
Chlordiazepoxide	900	Triazolam	3,000
Estazolam	6,000	Temazepam	100
DIAZEPAM (DIA 200)			
Diazepam	200	Midazolam	4,000
Clobazam	120	Nitrazepam	120
Clonazepam	300	Norchlordiazepoxide	70
Clorazepatedipotassium	300	Nordiazepam	600
Alprazolam	70	Flunitrazepam	120
a-hydroxyalprazolam	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		
ZOPICLONE (ZOP 300)			
Zopiclone-x-oxide	300	Zopiclone	300
ZOPICLONE (ZOP 50)			
Zopiclone-x-oxide	50	Zopiclone	50
METHCATHINONE (MCAT 500)			
S(-)-Methcathinone HCl	500	R(+)-Methcathinone HCl	1,500
Methoxyphenamine	100,000	3-Fluoromethcathinone HCl	1,500
7-AMINOCLONAZEPAM (7-ACL 300)			

a-hydroxyalprazolam	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		
7-AMINOCLONAZEPAM (7-ACL 200)			
a-hydroxyalprazolam	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
7-AMINOCLONAZEPAM (7-ACL 100)			
a-hydroxyalprazolam	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
7-AMINOCLONAZEPAM (7-ACL 50)			
a-hydroxyalprazolam	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
CARFENTANYL (CFYL 500)			
Carfentanyl	500	Fentanyl	100
Sufentanil	50,000	Ramifentanil	10,000
(±)cis-3-Methylfentanyl	20,000	Butyl fentanyl	150
CARFENTANYL (CFYL 250)			
Carfentanyl	250	Fentanyl	50
Sufentanil	25,000	Ramifentanil	5,000
(±)cis-3-Methylfentanyl	10,000	Butyl fentanyl	75
CARFENTANYL (CFYL 100)			
Carfentanyl	2,000	Fentanyl	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
CARFENTANYL (CFYL 50)			
Carfentanyl	500	Fentanyl	100
Sufentanil	50,000	Ramifentanil	10,000
(±)cis-3-Methylfentanyl	20,000	Butyl fentanyl	150
CAFFÉINE (CAF 1,000)			
Caffeine	1,000		
CATHINE (CAT 150)			
(+)-Norpseudoephedrine HCl	150	(+)-3,4-Methylenedioxymethamphetamine (MDA)	100
Cathine	900		
d,l-Amphetamine	100	p-Hydroxyamphetamine	100
Tryptamine	12,500	Methoxyphenamine	12,500
TROPICAMIDE (TRO 350)			
Tropicamide	350		
ALPRAZOLAM (ALP 100)			
Benzodiazepines	300	Flunitrazepam	200
a-hydroxyalprazolam	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
PREGABALIN (PGB 50,000)			
Pregabalin	50,000		
PREGABALIN (PGB 500)			
Pregabalin	500		
ZALEPLON (ZAL 100)			
Zaleplon	100		
CANNABINOL(CNB 500)			
cannabinol	50		

Instruction Sheet for testing of any combination of the following drugs:
AMP/BAR/BZD/COC/THC/MTD/MET/MDMA/MOP/OPI/PPX/TCA/OXY/EDDP/COT/TML/FYL/MDPV/K2/PCP/KET/LSD/MDA
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
Methylenedioxymethamphetamine (MDMA)	d,l-Methylenedioxymethamphetamine	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-methylenedioxypyrovalerone (MDPV)	3,4-methylenedioxypyrovalerone	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-Methylenedioxymethamphetamine (MDA)	3,4-Methylenedioxymethamphetamine	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.

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.¹ 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 days²

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.³ 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 benzoylcegonine.^{4,5} Benzoylcegonine, 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.⁵ The Multi-Drug Rapid Test Cassette yields a positive result when the concentration of benzoylcegonine 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 be prescribed 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.⁶

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, and psychotic behavior.

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.

Methylenedioxymethamphetamine (MDMA)

Methylenedioxymethamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity.⁷ 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 Methylenedioxymethamphetamine 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.⁸

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 70-5% 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 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®, Percocet® and Percocet®. While Tylox®,

Percocet® 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.⁹ 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%.¹⁰ While cotinine is thought to be an inactive metabolite, its 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 parenteral administration.¹¹ 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).

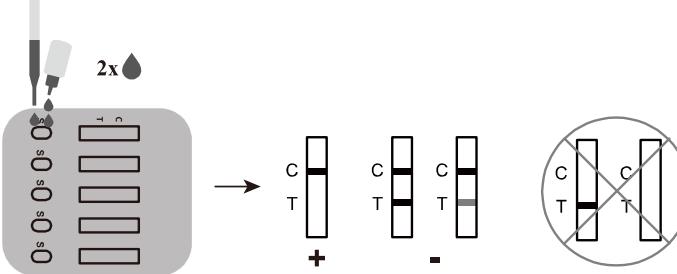
Cotinine (COT100)

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

specimen well of the cassette, and then start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.

3. 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.

40 µl of serum or plasma



For whole blood specimen:

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 cassette on a clean and level surface.

For Venipuncture Whole blood specimen:

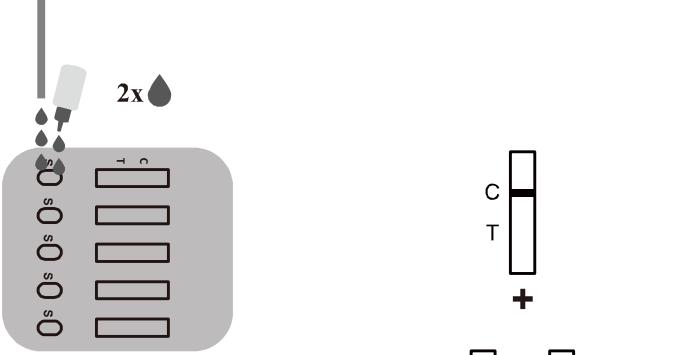
Hold the dropper vertically and transfer **1 drop of whole blood** (approximately 40 µl) to the specimen well, then add **2 drops of buffer** (approximately 80 µl), and start the timer. See illustration below.

For Fingerstick Whole blood specimen:

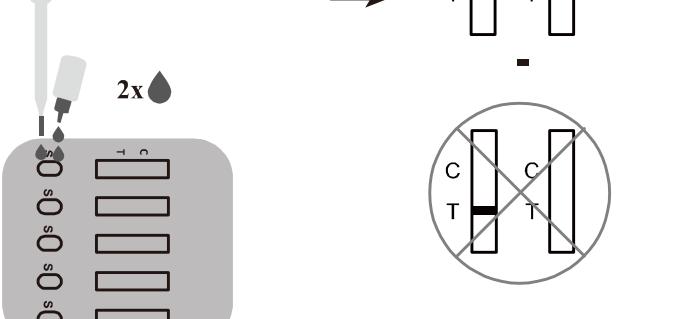
To use a capillary tube: Fill the capillary tube and transfer approximately **40 µl of fingerstick whole blood** specimen to the specimen area of test cassette, then add **2 drops of buffer** (approximately 80 µl) and start the timer. See illustration below.

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

40 µl of Fingerstick Whole Blood



1 Drop of Venipuncture Whole Blood



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

1. 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^{13,14}.
2. 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.
3. 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.
4. 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.

5. 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		% agreement with GC/MS
Multi-Drug Rapid Test Cassette	Positive	Negative	
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%
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	Positive 23	1	92.0%
	Negative 2	64	98.5%
100	Positive 23	2	95.8%
	Negative 1	64	97.0%
10	Positive 18	2	90.0%
	Negative 2	68	97.1%
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	68	98.5%
KET	Positive 23	2	95.8%
	Negative 1	64	97.0%
LSD	Positive 20	1	95.2%
	Negative 1	69	98.6%
MDA	Positive 23	1	95.8%
	Negative 1	68	98.6%
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%
LSD	Positive 19	2	95.0%
	Negative 1	68	97.1%
MDA	Positive 23	1	95.8%
	Negative 1	68	98.6%
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%
LSD	Positive 19	2	95.0%
	Negative 1	68	97.1%
MDA	Positive 23	1	95.8%
	Negative 1	68	98.6%
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%
LSD	Positive 19	2	95.0%
	Negative 1	68	97.1%
MDA	Positive 23	1	95.8%
	Negative 1	68	98.6%
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%
LSD	Positive 19	2	95.0%
	Negative 1	68	97.1%
MDA	Positive 23	1	95.8%
	Negative 1	68	98.6%
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%
LSD	Positive 19	2	95.0%
	Negative 1	68	97.1%
MDA	Positive 23	1	95.8%
	Negative 1	68	98.6%
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%
LSD	Positive 19	2	95.0%
	Negative 1	68	97.1%
MDA	Positive 23	1	95.8%
	Negative 1		

Drug Concentration Cut-off Range	OXY	COT10	COT100	EDDP	TML	K2	PCP	KET
-	+	-	+	-	+	-	+	-
0% Cut-off	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0
Cut-off	15	15	15	15	15	15	15	15
+50% Cut-off	0	30	0	30	0	30	0	30
+300% Cut-off	0	30	0	30	0	30	0	30

For serum or plasma:

Drug Concentration Cut-off Range	AMP	BAR	BZO	BUP	COC	THC	MTD
-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30
-50% Cut-off	30	0	30	0	30	0	30
Cut-off	15	15	16	14	15	15	15
+50% Cut-off	0	30	0	30	0	30	0
+300% Cut-off	0	30	0	30	0	30	0

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

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

Drug Concentration Cut-off Range	LSD	MDA
-	+	+
0% Cut-off	30	0
-50% Cut-off	30	0
Cut-off	15	15
+50% Cut-off	0	30
+300% Cut-off	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.

Analyses	Concentration (ng/ml)	Analyses	Concentration (ng/ml)
AMPHETAMINE (AMP)			
D,L-Amphetamine sulfate	20	Phentermine	150
L-Amphetamine	3,000	Maprotiline	6,000
(±) 3,4-Methylenedioxyamphetamine	40	Methoxyphenamine	1,500
BARBITURATES (BAR)			
Amobarbital	1,500	Alphenol	200
5,5-Diphenylhydantoin	2,500	Aprobarbital	150
Allobarbital	200	Butobarbital	80
Barbital	2,500	Butalbital	2,500
Talbutal	80	Butethal	150
Cyclopentobarbital	10,000	Secobarbital	100
Pentobarbital	2,500		
BENZODIAZEPINES (BZO)			
Alprazolam	40	Bromazepam	300
1-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
BUPRENORPHINE (BUP)			
Buprenorphine	5	Norprenorphine	30
Buprenorphine 3-D-Glucuronide	30	Norprenorphine 3-D-Glucuronide	50
COCAINE (COC)			
Benzoylcegonine	50	Cocaethylene	5,000
Cocaine HCl	60	Egonine	7,500
MARIJUANA (THC)			
Cannabinol	25,000	Δ8-THC	12,000
11-nor-Δ8-THC-9 COOH	25	Δ9-THC	12,000
11-nor-Δ9-THC-9 COOH	35		
METHADONE (MTD)			
Methadone	40	Doxylamine	13,000
METHAMPHETAMINE (MET)			
o-Hydroxymethamphetamine	1,800	(±)-3,4-Methylenedioxy-	900
D-Methamphetamine	70	methamphetamine	
L-Methamphetamine	1,500	Mephentermine	3,500
METHYLENEDIOXYMETHAMPHETAMINE (MDMA) Ecstasy			
(±)3,4-Methylenedioxymethamphetamine HCl	50	3,4-Methylenedioxymethyl-a-mphetamine	40
(±) 3,4-Methylenedioxymethamphetamine HCl	300		
MORPHINE/Opiate (MOP/OPI)			
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

PROPOXYPHENE (PPX)			
D-Propoxyphene	100		
TRICYCLIC ANTIDEPRESSANTS (TCA)			
Nortriptiline	300		
Nordoxepine	150		
Trimipramine	1,300		
Amitriptyline	600		
Promazine	1,300		
Desipramine	80		
Cyclobenzaprine	600		
Oxycodone (OXY)			
Oxycodone	20		
Oxymorphone	60		
Levorphanol	10,000		
Hydrocodone	5,000		
Cotinine (COT 10)			
(-)-Cotinine	10		
Cotinine (COT 100)			
(-)-Cotinine	100		
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)			
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	50		
Tramadol (TML)			
n-Desmethyl-cis-tramadol	100		
Cis-tramadol	50		
Procyclidine	50		
Fentanyl (FYL)			
Alfentanil	450,000		
Fenfluramine	40,000		
Fentanyl	75		
3,4-methylenedioxypyrovalerone (MDPV)			
3,4-methylenedioxypyrovalerone	300		
Synthetic Marijuana (K2)			
JWH-018 5-Pentanoic acid metabolite	100		
JWH-018 4-Hydroxypentyl metabolite	800		
JWH-073 4-Hydroxybutyl metabolite	1,000		
Phencyclidine (PCP)			
Phencyclidine	20		
Ketamine (KET)			
Ketamine	200		
Benzphetamine	5,000		
(+)-Chlorpheniramine	5,000		
Clonidine	2,000		
Dextromethorphan	400		
Disopyramide	5,000		
EDDP	10,000		
Mephentermine	5,000		
(1R, 2S) - (-)-Ephedrine	20,000		
4-Hydroxyphencyclidine	10,000		
Levorphanol	10,000		
MDE	10,000		
Lysergic Acid Diethylamide (LSD)			
Lysergic Acid Diethylamide	20		
3,4-Methylenedioxymphetamine (MDA)			
D,L-Amphetamine sulfate	40		
L-Amphetamine	6,000		
Phentermine	300		
Methoxyphenamine	3,000		
Cross-Reactivity			
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, Methyleneedioxymethamphetamine, 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.			
Non Cross-Reacting Compounds			
Acetophenetidin	Cortisone	Zomepirac	d-Pseudoephedrine
N-Acetylprocainamide	Creatinine	Ketoprofen	Quinidine
Acetylsalicylic acid	Deoxycorticosterone	Labetalol	Quinine
Aminopyrine	Dextromethorphan	Loperamide	Salicylic acid
Amoxicillin	Diclofenac	Meprobamate	Serotonin
Ampicillin	Diflunisal	Methoxyphenamine	Sulfamethazine
l-Ascorbic acid	Digoxin	Methylphenidate	Sulindac
Apomorphine	Diphenhydramine	Nalidixic acid	Tetracycline
Aspartame	Ethyl-p-aminobenzoate	Naproxen	Tetrahydrocortisone
Atropine	β-Estradiol	Niacinamide	3-acetate
Benzilic acid	Estrone-3-sulfate	Nifedipine	Tetrahydrocortisone
Benzoic acid	Erythromycin	Norethindrone	Tetrahydrozoline
Bilirubin	Fenoprofen	Noscapine	Thiamine
d,l-Brompheniramine	Furosemide	d,l-Octopamine	Thioridazine
Caffeine	Gentisic acid	Oxalic acid	d,l-Tyrosine
Cannabidiol	Hemoglobin	Oxolinic acid	Tolbutamide
Chloral hydrate	Hydralazine	Oxymetazoline	Triamterene
Chloramphenicol	Hydrochlorothiazide	Papaverine	Trifluoperazine
Chlorothiazide	Hydrocortisone	Penicillin-G	Trimethoprim
d,l-Chlorpheniramine	o-Hydroxyhippuric acid	Perphenazine	d,l-Tryptophan
Chlorpromazine	3-Hydroxytyramine	Phenelzine	Uric acid
Cholesterol	d,l-Isoproterenol	Prednisone	Verapamil
Clonidine	Isoxsuprine	d,l-Propanolol	

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INDEX OF SYMBOLS

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

Number: 145499703
 Date: 2023-08-07