Date: 15/05/2022

EU Declaration of Conformity

Declaration of Conformity

for Rapid strips & devices

Digitally signed by Dolgopol Iulian
Date: 2025.02.18 10:20:03 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

European Communities Council Directive 98/79/EC concerning In-Vitro Diagnostic Medical Devices as amended by Regulation (EC) 596/2009.

The undersigned declares that the products named in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Rapid Strips & devices
Manufacturer:	Rapid Labs Ltd. Unit 2 & 2a Hall Farm Business Centre, Church road, Little Bentley, Colchester, Essex, CO7 8SD United Kingdom
Variants:	n/a
Intended Use:	These tests are designed to detect the presence or absence of antigens, antibodies, viruses, hormones and drugs, each test is designed to identify a specific analyte or combination of analytes and in the presence of the analyte will induce a colour change reaction on the porous membraneof the rapid device or strip.
Intended User:	Professional use
IVD Directive Category:	General
Notified Body:	n/a
CE Certificate Reference:	n/a
IVD Directive Assessment Route:	Annex III
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Floor, Tower Street, Swatar BKR4013 Malta

Name Rowland King **Position** Managing Director

Signed **Date** 15/05/2022

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under his own name, regardless of whether these operations are carried out by the Manufacturer, or on their behalf by a third party.

Rapid Labs

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Appendix I – Applicable Standards

This present declaration is also in conformity with the following European and International standards:

Standard/Document Name	Description
98/79/EC	In Vitro Diagnostic Medical Devices EU Council Directive as amended by Regulation (EC) 596/2009
EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied bythe manufacturer (labelling) - Part 1: Terms, definitions and general requirements
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019	Medical Devices – Application of Risk Management to MedicalDevices
EN 13612:2002	Performance evaluation of in-vitro medical devices
EN 13641:2002	Elimination or reduction of risk infection related to in-vitro diagnostics
EN ISO 15223-1:2016	Medical devices - Symbols
EN ISO 23640:2015	Evaluation of stability

Appendix II – Product listing / Schedule

Part/Catalogue Number	Description/Name	GMDN Code	IVDR CLA	Rule
D-ADOD25	Adenovirus Rapid Test Device – Feces	49856	B	6
D-ASTD10	Astrovirus Rapid Test Device – Feces	64772	B	6
D-AFPD20	AFP Rapid Test Device – WB/S/P	63981	C	3h
D-CTTD10	Cardiac Troponin T Rapid Test Device – WB/S/P	46989	C	3j
D-CAMD10	Campylobacter Rapid Test Device – Feces	50683	B	6
D-CA125D10	CA125 Rapid Test Device – WB/S/P	64534	C	3h
D-CA153D10	CA15-3 Rapid Test Device – WB/S/P	64535	C	3h
D-CA199D10	CA19-9 Rapid Test Device – WB/S/P	64536	C	3h
D-CRYD10	Cryptosporidium Rapid Test Device – Feces	52163	C	3c
D-CAND10	Candida Albicans Rapid Test Device – Swab	63216	B	6
D-CHIKWBD40	Chikungunya IgG/IgM Rapid Test Device – WB/S/P	63970	B	6
D-CALAD10	Calprotectin & Lactoferrin Combo Rapid test Device- Feces	60775	B	6
D-CRYGLD10	Cryptosporidium & Gardia Lamblia Combo Rapid Test Device –	47358	C	3c
D-ENTD10	Entamoeba Histolytica Rapid Test Device – Feces	47358	B	6
D-EGCD10	Entamoeba/Giardia/Crypto Rapid test Device- Faces	47358	C	3c
D-FABD10	H-FABP Rapid Test Device – WB/S/P	66449	C	3j
D-HCGD20	hCG Pregnancy Rapid Test Device – Urine/S/P	66850	B	6
D-HCGD40	hCG Pregnancy Rapid Test Device – Urine/S/P	66850	B	6
D-HCGS50	hCG Pregnancy Rapid Test Strip – Urine/S/P	66850	B	6
D-HCGS100	hCG Pregnancy Rapid Test Strip – Urine/S/P	66850	B	6
D-HCGUS25	hCG Pregnancy Rapid Test Cannister Strip – Urine	66850	B	6
D-HCGUS50	hCG Pregnancy Rapid Test Strip – Urine	66850	B	6
D-HCGUS100	hCG Pregnancy Rapid Test Strip – Urine	66850	B	6
D-HCGUD40	hCG Pregnancy Rapid Test Device - Urine	66850	B	6
D-IGED10	IgE Rapid Test Device – WB/S/P	65991	C	3e
D-LACFD10	Lactoferrin Rapid test Device- Feces	53910	B	6
D-LYMD10	Lyme IgG/IgM Rapid Test Device -WB/S/P	66392	B	6
D-LPSPD10	Streptococcus pneumoniae and Legionella pneumophila Combo Rapid Test Device -Urine	60765	C	3c
D-LHD20	LH Ovulation Rapid Test Device – Urine	54255	B	6
D-LHS50	LH Ovulation Rapid Test Strip – Urine	54225	B	6
D-HPS50	H.pylori Antibody Rapid Test Strip – WB/S/P	30825	B	6
D-HPAGD20	H.pylori antigen Rapid Test Device – Feces	30825	B	6
D-TBD20	Tuberculosis Rapid Test Device – WB/S/P	51172	C	3e
D-DGMD20	Dengue Rapid Test Device – WB/S/P	63238	B	6
D-DAGMD20	Dengue Combo Rapid Test Device – WB/S/P	62928	C	3b
D-DAGD20	Dengue NS1 Rapid Test Device – WB/S/P	62946	C	3b
D-CHIKMD20	Chikungunya IgG/IgM Rapid Test Device– WB/S/P	60870	B	6
D-NTPD10	NT-proBNP Rapid Test Device - WB/S/P	47041	C	3j
D-FILGMD20	Filariasis IgG/IgM Rapid Test Device – WB/S/P	52508	B	6
D-HEVD20	HEV IgG/IgM Rapid Test Device – S/P	65766	C	3e
D-INFS20	Influenza A Rapid Test Strip - Swab/Nasal Aspirate Influenza A Rapid Test Device - Swab/Nasal Aspirate	49150	B	6
D-LEIGMD20	Leishmania IgG/IgM Rapid Test Device – WB/S/P	52283	B	6
D-LEPGMD20	Leptospira IgG/IgM Rapid Test Device – WB/S/P	63726	B	6
D-MPFD20	Malaria Pf Rapid Test Device – WB	52336	C	3c

D-PNEUD20	Mycoplasma pneumoniae Antigen Rapid Test Device – Swab	65851	B	6
D-NOROD25	Norovirus Rapid Test Device – Feces	48235	B	6
D-COVD25	2019-nCOV IgG/IgM Rapid Test Device – WB/S/P	64756	D	1
D-COVAGD25	COVID-19 Antigen Rapid Test Strip - Nasopharyngeal Swab	64787	D	1
D-COVAGIFD25	COVID-19 and Influenza A+B Antigen Combo Rapid Test Device (Nasopharyngeal Swab)	64770	D	1
D-COVAGD25B	SARS-CoV-2 Antigen Rapid Test Device – Nasal Swab	64787	D	1
D-MPFPVPAND20	Malaria P.f./P.v./Pan Rapid Test Device – WB	52311	C	3c
D-MPFPAND20	Malaria P.f./Pan Rapid Test Device – WB	52311	C	3c
D-MPFPVD20	Malaria P.f./P.v. Rapid Test Device - WB	52311	C	3c
D-MYPMD20	Mycoplasma Pneumoniae IgM Rapid Test Device – WB/S/P	65851	B	6
D-MYPGMD20	Mycoplasma Pneumoniae IgG/Ig M Rapid Test Device – WB/S/P	66460	B	6
D-MONOD25	MONO Rapid Test Device – WB/S/P	49689	C	3e
D-TYPGMD20	Typhoid Rapid Test Strip - WB/S/P Typhoid Rapid Test Device - WB/S/P	51560	C	3e
D-FOBD10	FOB Rapid Test Device – Feces	54532	B	6
D-FOBD20	FOB Rapid Test Device – Feces	54532	B	6
D-FOBS10	FOB Rapid Test Strip – Feces	54532	B	6
D-TROPD20	Cardiac Troponin I Rapid Test Device – WB/S/P	46989	C	3j
D-MCKTMD20	Myoglobin/CK-MB/Troponin I Combo Rapid Test Device – WB/S/P	61295	C	3j
D-CALD10	Calprotectin Rapid Test Device – Feces	60775	B	6
D-DIMERD10	D-Dimer Rapid Test Device – WB/P	47343	C	3k
D-GLD10	Giardia Lamblia Rapid Test Device - Feces	52249	B	6
D-PCTD40	PCT Rapid Test Device – S/P	58305	B	6
D-MYOD10	Myoglobin Rapid Test Device – WB/S/P	46987	C	3j
D-CHABD20	Chagas Rapid Test Device – WB/S/P	52480	B	6
D-SAAD10	SAA Rapid Test Device – WB/S/P	65297	B	6
D-STRAS20	Strep A Rapid Test Strips – Throat Swab	51707	B	6
D-TPSPD40	Syphilis Rapid Test Device – S/P	51788	C	3a
D-TPSPS50	Syphilis Rapid Test Strip – S/P	51788	C	3a
D-TRFOBD20	Transferrin and FOB Combo Rapid Test Device - Feces	65270	B	6
D-RSVD20	RSV Rapid Test Device – Nasopharyngeal swab/Nasal Aspirate	64770	B	6
D-SAACRPD10	SAA & CRP Combo Rapid Test Device – WB/S/P	65297	B	6
D-TPD20	Syphilis Rapid Test Device – WB/S/P	51788	C	3a
D-TPS50	Syphilis Rapid Test Strip – WB/S/P	51788	C	3a
D-TPD40	Syphilis Rapid Test Device – WB/S/P	51788	C	3a
D-TETD40	Tetanus Rapid Test Device – WB/S/P	50867	B	6
D-TSHD20	TSH Rapid Test Device – WB/S/P	65274	B	6
D-STRBS20	Strep B Rapid Test Strip – Swab	51747	C	3b
D-GOND20	Gonorrhea Rapid Test Cassette Device - Swab	51228	C	3a
D-INFAS20	Influenza A Rapid Test Strip – Swab/Nasal Aspirate	49150	B	6
D-RFD20	RF Rapid Test Device– WB/S/P	42230	B	6
D-HSV12D10	HSV 1/2 IgM Rapid Test Device - WB/S/P	49549	C	3a
D-TYGMD20	Typhoid Rapid Test Device – S/P	63976	C	3e
D-TYGMCD20	Typhoid IgG/IgM Rapid Tes Device– WB/S/P	51560	C	3e
D-ROTAGD20	Rotavirus Rapid Test Device – Feces	48235	B	6
D-ROAAGD20	Rotavirus & Adenovirus Combo Rapid Test Device – Feces	48235	B	6

D-TYAGD20	Salmonella typhi Antigen Rapid Test Device – Feces	51512	C	3e
D-VC01D10	Vibrio cholerae O1 (VC O1) Rapid Test Device - Feces	51840	c	3c
D-VC0139D10	Vibrio cholerae O139 (VC O139) Rapid Test Device - Feces	51840	C	3c
D-VCPD10	Vibrio cholerae O1/O139 Combo Rapid Tes tDevice - Feces	51840	C	3c
D-DOA1D20	Amphetamine (AMP) Rapid Test Device – Urine	46994	B	6
D-DOA1S50	Amphetamine (AMP) Rapid Test Strip – Urine	46994	B	6
D-DOA2D20	Methamphetamine (MET) Rapid Test Device – Urine	46994	B	6
D-DOA2S50	Methamphetamine (MET) Rapid Test Strip – Urine	46994	B	6
D-DOA3D20	Opiates (OPI) Rapid Test Device – Urine	46994	B	6
D-DOA4D20	Barbiturates (BAR) Rapid Test Device – Urine	46994	B	6
D-DOA4S50	Barbiturates (BAR) Rapid Test Strip – Urine	46994	B	6
D-DOA5D20	Benzodiazepine (BZO) Rapid Test Device – Urine	46994	B	6
D-DOA5S50	Benzodiazepine (BZO) Rapid Test Strip – Urine	46994	B	6
D-DOA6D20	Cocaine (COC) Rapid Test Device – Urine	46994	B	6
D-DOA6S50	Cocaine (COC) Rapid Test Strip – Urine	46994	B	6
D-DOA37D40	Carisoprodol (CAR) Rapid Test Device – Urine	46994	B	6
D-DOA37S50	Carisoprodol (CAR) Rapid Test Strip – Urine	46994	B	6
D-DOA7D20	Methadone (MTD) Rapid Test Device – Urine	46994	B	6
D-DOA7S50	Methadone (MTD) Rapid Test strip – Urine	30521	B	6
D-DOA8D20	Marijuana (THC) Rapid Test Device – Urine	46994	B	6
D-DOA8S50	Marijuana (THC) Rapid Test Strip – Urine	46994	B	6
D-DOA38D20	Morphine (MOP) Rapid Test Device – Urine	46994	B	6
D-DOA22D20	Meperidine (MPRD) Rapid Test Device – Urine	46994	B	6
D-DOA22S50	Meperidine (MPRD) Rapid Test Strip – Urine	46994	B	6
D-DOA38D40	Pregabalin (PGB) Rapid test Strip- Urine Pregabalin (PGB) Rapid test Device-Urine Pregabalin (PGB) Rapid test Panel- Urine	46994	B	6
D-DOA38S50	Morphine (MOP) Rapid Test Strip – Urine	46994	B	6
D-DOA35D40	Papaverine (PAP) Rapid Test Device – Urine	46994	B	6
D-DOA35S50	Papaverine (PAP) Rapid Test Strip – Urine	46994	B	6
D-DOA24D20	Mescaline (MES) Rapid Test Device – Urine	46994	B	6
D-DOA24S50	Mescaline (MES) Rapid Test Strip – Urine	46994	B	6
D-DOA42D20	Fentanyl (FYL) Rapid Test Device – Urine	46994	B	6
D-DOA42S50	Fentanyl (FYL) Rapid Test Strip – Urine	46994	B	6
D-DOA39D20	Oxycodone (OXY) Rapid Test Device – Urine	46994	B	6
D-DOA39S50	Oxycodone (OXY) Rapid Test Strip – Urine	46994	B	6
D-DOA9D20	Ketamine (KET) Rapid Test Device – Urine	46994	B	6
D-DOA9S50	Ketamine (KET) Rapid Test Strip – Urine	46994	B	6
D-DOA23D20	Mephedrone HCI (MEP) Rapid Test Device – Urine	46994	B	6
D-DOA23S50	Mephedrone HCI (MEP) Rapid Test Strip – Urine	46994	B	6
D-DOA36D40	Kratom (KRA) Rapid Test Device – Urine	46994	B	6
D-DOA36S50	Kratom (KRA) Rapid Test Strip – Urine	46994	B	6
D-DOA10D20	Tricyclic Antidepressants (TCA) Rapid Test Device – Urine	30524	B	6
D-DOA10S50	Tricyclic Antidepressants (TCA) Rapid Test Strip – Urine	30524	B	6
D-DOA34D40	Quetiapine (QTP) Rapid Test Device – Urine	46994	B	6
D-DOA34S50	Quetiapine (QTP) Rapid Test Strip – Urine	46994	B	6
D-DOA33D40	Tilidine (TLD) Rapid Test Device – Urine	46994	B	6
D-DOA25D20	Tropicmide (TRO) Rapid Test Device – Urine	46994	B	6

D-DOA25S50	Tropicmide (TRO) Rapid Test Strip – Urine	46994	B	6
D-DOA26D20	Trazodone (TZD) Rapid Test Device – Urine	46994	B	6
D-DOA26S50	Trazodone (TZD) Rapid Test Strip – Urine	46994	B	6
D-DOA11D20	Buprenorphine (BUP) Rapid Test Device – Urine	46994	B	6
D-DOA11S50	Buprenorphine (BUP) Rapid Test Strip – Urine	46994	B	6
D-DOA21D20	Gabapentin (GAB) Rapid Test Device – Urine	46994	B	6
D-DOA21S50	Gabapentin (GAB) Rapid Test Strip – Urine	46994	B	6
D-DOA43D20	6-Monoacetylmorphine (6-MAM) Rapid Test Device – Urine	46994	B	6
D-DOA43S50	6-Monoacetylmorphine (6-MAM) Rapid Test Strip – Urine	46994	B	6
D-DOA12D20	Ecstasy (MDMA) Rapid Test Device – Urine	46994	B	6
D-DOA12S50	Ecstasy (MDMA) Rapid Test Strip – Urine	46994	B	6
D-DOA13D20	Phencyclidine (PCP) Rapid Test Device - Urine	46994	B	6
D-DOA13S50	Phencyclidine (PCP) Rapid Test Strip – Urine	46994	B	6
D-DOA32D20	Acetaminophen (ACE) Rapid Test Device- Urine	46994	B	6
D-DOA32S50	Acetaminophen (ACE) Rapid Test Strip – Urine	46994	B	6
D-DOA40D20	Alcohol (ALC) Rapid Test Device – Urine	46994	B	6
D-DOA40S50	Alcohol (ALC) Rapid Test Strip – Urine	46994	B	6
D-DOA41D20	Diazepam (DIA)) Rapid Test Device- Urine	46994	B	6
D-DOA41S50	Diazepam (DIA) Rapid Test Strip – Urine	46994	B	6
D-DOA27D20	UR-144 Rapid Test Device - Urine	46994	B	6
D-DOA27S50	UR-144 Rapid Test Strip – Urine	46994	B	6
D-DOA29D20	Lysergic Acid Diethylamide (LSD) Rapid Test Device – Urine	46994	B	6
D-DOA29S50	Lysergic Acid Diethylamide (LSD) Rapid Test Strip – Urine	46994	B	6
D-DOA28D20	Zaleplon (ZAL) Rapid Test Device – Urine	46994	B	6
D-DOA28S50	Zaleplon (ZAL) Rapid Test Strip – Urine	46994	B	6
D-DOA30D20	Tramadol (TML) Rapid Test Device – Urine	46994	B	6
D-DOA30S50	Tramadol (TML) Rapid Test Strip – Urine	46994	B	6
D-DOA16D20	Marijuana (THC) Rapid Test Midstream- Saliva	30519	B	6
D-DOA17D20	Cocaine (COC) Rapid Test Midstream - Saliva Cocaine (COC) Rapid Test Device - Saliva	46994	B	6
D-DOA18D20	Methamphetamine (MET) Rapid Test Midstream- Saliva Methamphetamine (MET) Rapid Test Device- Saliva	55498	B	6
D-DOA19D20	Opiates (OPI) Test Device- Saliva Opiates (OPI) Test Midstream- Saliva	55701	B	6
D-DOA20D20	Ecstasy (MDMA) Rapid Test Midstream - Saliva Ecstasy (MDMA) Rapid Test Device - Saliva	46994	B	6
D-DOAM2U	Multi-drug 2 drugs Rapid Test Device – Urine	46994	B	6
D-DOAM3U	Multi-drug 3 drugs Rapid Test Device – Urine	46994	B	6
D-DOAM4U	Multi-drug 4 drugs Rapid Test Device – Urine	46994	B	6
D-DOAM5U	Multi-drug 5 drugs Rapid Test Device – Urine	46994	B	6
D-DOAM6U	Multi-Drug 6 Drugs Rapid Test Device-Urine	46994	B	6
D-DOAM7U	Multi-drug 7 drugs Rapid Test Device – Urine	46994	B	6
D-DOAM8U	Multi-drug 8 drugs Rapid Test Device – Urine	46994	B	6
D-DOAM9U	Multi-drug 9 drugs Rapid Test Device – Urine	46994	B	6
D-DOAM10U	Multi-drug 10 drugs Rapid Test Device – Urine	46994	B	6
D-DOAM11U	Multi-drug 11 drugs Rapid Test Device – Urine	46994	B	6
D-DOAM12U	Multi-drug 12 drugs Rapid Test Device – Urine	46994	B	6
D-DOAM13U	Multi-drug 13 drugs Rapid Test Device – Urine	46994	B	6

D-DOAM14U	Multi-drug 14 drugs Rapid Test Device – Urine	46994	B	6
D-DOAM15U	Multi-drug 15 drugs Rapid Test Device – Urine	46994	B	6
D-DOAM16U	Multi-drug 16 drugs Rapid Test Device – Urine	46994	B	6
D-DOAM17U	Multi-drug 17 drugs Rapid Test Device – Urine	46994	B	6
D-HCGS25	hCG Pregnancy Rapid Test Strip (Canister Pack) – Urine/S/P	66850	B	6
D-HCGES25	hCG Pregnancy Enhanced Sensitivity Rapid Test Device (Canister Pack) – Urine/S/P	66850	B	6
D-HCGUES50	hCG Pregnancy Enhanced Sensitivity 10mlU/mL Rapid Test Strip –	66850	B	6
D-HCGUES100	hCG Pregnancy Enhanced Sensitivity 10mlU/mL Rapid Test Strip –	66850	B	6
D-HCGES20	hCG Pregnancy Enhanced Sensitivity Rapid Test strip-S/P/U	33819	B	6
D-HCGUM0	hCG Pregnancy Rapid Test Device – Midstream Urine	66850	B	6
D-HCGUEM0	hCG Pregnancy Enhanced Sensitivity 10mlU/mL Rapid Test Device – Midstream Urine	66850	B	6
D-HCGCD40	Pregnancy (hCG) Rapid Test Device-WB/S/P	33819	B	6
D-HCGECD40	hCG Pregnancy Enhanced Sensitivity Rapid Test Device – WB/S/P	66850	B	6
D-HCGED20	hCG Pregnancy Enhanced Sensitivity Rapid Test Device – Urine/S/P	66850	B	6
D-HCGUED40	hCG Pregnancy Enhanced Sensitivity Rapid Test Device – Urine	66850	B	6
D-LHM0	LH Ovulation Rapid Test Midstream -Urine	54255	B	6
D-LHESM0	LH Ovulation Enhanced Sensitivity Rapid Test Midstream -Urine	54255	B	6
D-LHES50	LH Ovulation Enhanced Sensitivity Rapid Test Strip- Urine	54255	B	6
D-LHES25	LH Ovulation Enhanced Sensitivity Rapid Test Strip (Canister Pack) – Urine	54255	B	6
D-FSHS50	FSH Rapid Test Strip – Urine	65840	B	6
D-FSHD20	FSH Rapid Test Device – Urine	65840	B	6
D-FSHM2	FSH Rapid Test Midstream-Urine	65840	B	6
D-AMHD10	AMH Rapid Test Device – WB/S/P	65295	B	6
D-FFD25	Fetal Fibronectin (fFN) Rapid Test Device – Vaginal Secretion	65270	B	6
D-iGFBP1D25	Insulin-like Growth Factor-binding Protein 1 (iGFBP-1) Rapid Test Device – Vaginal Swab	64054	B	6
D-HSV12GD40	HSV 1/2 IgG Rapid Test Device – S/P	49545	C	3a
D-HSV12GCD40	HSV 1/2 IgG Rapid Test Device – WB/S/P	49545	C	3a
D-HSV12CD40	HSV 1/2 IgM Rapid Test Device – WB/S/P	49549	C	3a
D-HSV12GMD40	HSV 1/2 IgG/IgM Rapid Test Device – S/P	49556	C	3a
D-HSV12GMD25	HSV 1/2 IgG/IgM Combo Rapid Test Device – S/P	49556	C	3a
D-HSV12GMCD40	HSV 1/2 IgG/IgM Rapid Test Device – WB/S/P	49556	C	3a
D-HSV12GMCD25	HSV 1/2 IgG/IgM Combo Rapid Test Device – WB/S/P	49556	C	3a
D-TVD10	Trichomonas Vaginalis Rapid Test Device-Vaginal Swab	52471	C	3a
D-STRBD20	Strep B Rapid Test Device – Swab	51747	C	3b
D-NRAD10	Norovirus, Rotavirus and Adenovirus Combo Rapid Test Device -	48235	B	6
D-NRAAD10	Norovirus, Rotavirus, Adenovirus and Astrovirus Combo Rapid Test Device - Feces	48235	B	6
D-CLOSD20	C.difficile GDH Rapid Test Device – Feces	50831	B	6
D-CDTABD10	C.difficile Toxin A +Toxin B Combo Rapid Test Device – Feces	47382	B	6
D-CDGTABD10	C.difficile GDH + Toxin A + Toxin B Combo Rapid Test Device – Feces	47382	B	6
D-HPABD40	H.pylori antibody Rapid Test Device – S/P	65844	B	6
D-HPAGS25	H. pylori Antigen Rapid Test strip-Feces	30825	B	6
D-CHAD40	Chagas Rapid Test Device – S/P	52480	B	6
D-CHIKGMD40	Chikungunya IgG/IgM Rapid Test Device – S/P	63970	B	6

D-ZNSD10	Zika NS1 Rapid Test Device -WB/S/P	66467	C	3b
D-ZGMD10	Zika IgG/IgM Rapid Test Device – WB/S/P	63719	B	6
D-ZGMNSD10	Zika IgG/IgM & NS1 Combo Rapid Test Device – WB/S/P	63767	C	3b
D-FILGMD40	Filariasis IgG/IgM rapid Test Device – WB/S/P	52508	B	6
D-TYGMS50	Typhoid Rapid Test Strip – S/P	63976	C	3e
D-PAAGD25	Salmonella paratyphi Antigen Rapid Test Device -Feces	51543	C	3e
D-TYPAGD20	Salmonella typhi and paratyphi Antigen Combo Rapid Test Device – WB/S/P	51512	C	3e
D-MPFS50	Malaria Pf Rapid Test Strip – WB	52336	C	3c
D-HAVGMD25	HAV IgG/IgM Combo Rapid Test Device – WB/S/P	65737	B	6
D-HAVMWBD20	HAVIgM Rapid Test Device – WB/S/P	48270	B	6
D-STRABD20	Strep A Rapid Test Device – Throat Swab	51707	B	6
D-STRARD20	Strep A Rapid Test Device – Throat Swab	51707	B	6
D-LPD25	Legionella pneumophila Rapid Test Device – Urine	51054	C	3c
D-SPAGD10	Streptococcus pneumoniae antigen Rapid Test Device – Urine	51770	C	3c
D-CRAGD10	Cryptococcus Antigen Rapid Test Device – WB/S/P/CSF	65815	C	3b
D-EVGD10	EBV VCA IgG Rapid Test Device – WB/S/P	64773	C	3e
D-ENGD10	EBNA IgG Rapid Test Device – WB/S/P	49689	C	3e
D-EVENGD10	EBV VCA and EBNA IgG Combo Rapid Test Device – WB/S/P	64773	C	3e
D-ADAGD20	Adenovirus Antigen Rapid Test Device – Swab	49856	B	6
D-INFABS20	Influenza A+B Rapid Test Strip-Swab / Nasal Aspirate	49119	B	6
D-HNAGD20	H1N1 Antigen Rapid Test Device – Swab	49150	D	1
D-IHD10	Influenza A/B + H1N1 Combo Rapid Test Device – Swab	49119	D	1
D-RID10	RSV & Influenza A+B Combo Rapid Test Device – Swab/Nasal	64770	B	6
D-ARD10	Adenovirus & RSV Combo Rapid Test Device – Nasopharyngeal Swab	64770	B	6
D-ARID10	Adenovirus, RSV and Influenza A+B Combo Rapid Test Device - Nasopharyngeal Swab	64770	B	6
D-BRUD20	Brucella Abortus Antigen Rapid Test Device – WB/S/P	50611	C	3b
D-SCTD10	Scrub Typhus IgG/IgM Rapid Test Device – WB/S/P	51333	C	3e
D-TBS50	Tuberculosis Rapid Test Strip – WB/S/P	51172	C	3e
D-DOA52D40	AB-PINACA (ABP) Rapid Test Device – Urine	46994	B	6
D-DOA52P40	AB-PINACA (ABP) Rapid Test Panel – Urine	46994	B	6
D-DOA52S50	AB-PINACA (ABP) Rapid Test Strip – Urine	46994	B	6
D-DOA32P40	Acetaminophen (ACE) Rapid Test Panel – Urine	46994	B	6
D-DOA53D40	7-Aminoclonazepam (7-ACL) Rapid Test Device – Urine	46994	B	6
D-DOA53P40	7-Aminoclonazapam (7-ACL) Rapid Test Panel – Urine	46994	B	6
D-DOA53S50	7-Aminoclonazapam (7-ACL) Rapid Test Strip – Urine	46994	B	6
D-DOA44D20	Alprazolam (ALP) Rapid Test Device – Urine	46994	B	6
D-DOA44P40	Alprazolam (ALP) Rapid Test Panel – Urine	46994	B	6
D-DOA44S50	Alprazolam (ALP) Rapid Test Strip – Urine	46994	B	6
D-DOA1P40	Amphetamine (AMP) Rapid Test Panel – Urine	46994	B	6
D-DOA54D40	α-Pyrrolidinovalerophenone (α-PVP) Rapid Test Device – Urine	46994	B	6
D-DOA54P40	α-PVP Rapid Test Panel – Urine	46994	B	6
D-DOA54S50	α-PVP Rapid Test Strip – Urine	46994	B	6
D-DOA4P40	Barbiturate (BAR) Rapid Test Panel – Urine	46994	B	6
D-DOA11P40	Buprenorphine (BUP) Rapid Test Panel – Urine	46994	B	6
D-DOA5P40	Benzodiazepines (BZO) Rapid Test Panel – Urine	46994	B	6
D-DOA45D20	Cathine (CAT) Rapid Test Device – Urine	46994	B	6

D-DOA45P40	Cathine (CAT) Rapid Test Panel – Urine	46994	B	6
D-DOA45S50	Cathine (CAT) Rapid Test Strip – Urine	46994	B	6
D-DOA46D20	Caffeine (CAF) Rapid Test Device – Urine	46994	B	6
D-DOA46P40	Caffeine (CAF) Rapid Test Panel – Urine	46994	B	6
D-DOA46S50	Caffeine (CAF) Rapid Test Strip – Urine	46994	B	6
D-DOA37P40	Carisoprodol (CAR) Rapid Test Panel – Urine	46994	B	6
D-DOA55D40	Cannabinol (CNB) Rapid Test Device – Urine	46994	B	6
D-DOA55P40	Cannabinol (CNB) Rapid Test Panel – Urine	46994	B	6
D-DOA55S50	Cannabinol (CNB) Rapid Test Strip – Urine	46994	B	6
D-DOA47D20	Carfentanyl (CFYL) Rapid Test Device – Urine	46994	B	6
D-DOA47P40	Carfentanyl (CFYL) Rapid Test Panel – Urine	46994	B	6
D-DOA47S50	Carfentanyl (CFYL) Rapid Test Strip – Urine	46994	B	6
D-DOA56D40	Clonazepam (CLO) Rapid Test Device – Urine	46994	B	6
D-DOA56P40	Clonazepam (CLO) Rapid Test Panel – Urine	46994	B	6
D-DOA56S50	Clonazepam (CLO) Rapid Test Strip – Urine	46994	B	6
D-DOA6P40	Cocaine (COC) Rapid Test Panel – Urine	46994	B	6
D-DOA31D20	Cotinine (COT) Rapid Test Device – Urine	46994	B	6
D-DOA31P40	Cotinine (COT) Rapid Test Panel – Urine	46994	B	6
D-DOA31S50	Cotinine (COT) Rapid Test Strip – Urine	46994	B	6
D-DOA41P40	Diazepam (DIA) Rapid Test Panel – Urine	46994	B	6
D-DOA57D40	Ethylenediamine-dimethylphosphinic acid (EDDP) Rapid Test Device – Urine	46994	B	6
D-DOA57P40	Ethylenediamine-dimethylphosphinic acid (EDDP) Rapid Test Panel – Urine	46994	B	6
D-DOA57S50	Ethylenediamine-dimethylphosphinic acid (EDDP) Rapid Test Strip – Urine	46994	B	6
D-DOA58D40	Ethyl Glucuronide (ETG) Rapid Test Device – Urine	46994	B	6
D-DOA58P40	Ethyl Glucuronide (ETG) Rapid Test Panel – Urine	46994	B	6
D-DOA58S50	Ethyl Glucuronide (ETG) Rapid Test strip-Urine	60669	B	6
D-DOA48D20	Fluoketamine (FKET) Rapid Test Device – Urine	46994	B	6
D-DOA48P40	Fluoketamine (FKET) Rapid Test Panel-Urine	46994	B	6
D-DOA48S50	Fluoketamine (FKET) Rapid Test Strip – Urine	46994	B	6
D-DOA59D40	Fluoxetine (FLX) Rapid Test Device – Urine	46994	B	6
D-DOA59P40	Fluoxetine (FLX) Rapid Test Panel – Urine	46994	B	6
D-DOA59S50	Fluoxetine (FLX) Rapid Test Strip – Urine	46994	B	6
D-DOA42P40	Fentanyl (FYL) Rapid Test Panel – Urine	46994	B	6
D-DOA21P40	Gabapentin (GAB) Rapid Test Panel – Urine	46994	B	6
D-DOA9P40	Ketamine (KET) Rapid Test Panel – Urine	46994	B	6
D-DOA36P40	Kratom (KRA) Rapid Test Panel – Urine	46994	B	6
D-DOA29P40	Lysergic Acid Diethylamide (LSD) Rapid Test Panel – Urine	46994	B	6
D-DOA43P40	6-Monoacetylmorphine (6-MAM) Rapid Test Panel – Urine	46994	B	6
D-DOA60D40	Methcathinone (MCAT) Rapid Test Device – Urine	46994	B	6
D-DOA60P40	Methcathinone (MCAT) Rapid Test Panel – Urine	46994	B	6
D-DOA60S50	Methcathinone (MCAT) Rapid Test Strip – Urine	46994	B	6
D-DOA12P40	Ecstasy (MDMA) Rapid Test Panel – Urine	46994	B	6
D-DOA61D40	Tenamfetamine (MDA) Rapid Test Device – Urine	46994	B	6
D-DOA61P40	Tenamfetamine (MDA) Rapid Test Panel – Urine	46994	B	6
D-DOA61S50	Tenamfetamine (MDA) Rapid Test Strip – Urine	46994	B	6

D-DOA62D40	Methylenedioxypyrovalerone (MDPV) Rapid Test Device – Urine	46994	B	6
D-DOA62P40	Methylenedioxypyrovalerone (MDPV) Rapid Test Panel – Urine	46994	B	6
D-DOA62S50	Methylenedioxypyrovalerone (MDPV) Rapid Test Strip – Urine	46994	B	6
D-DOA2P40	Methamphetamine (MET) Rapid Test Panel – Urine	46994	B	6
D-DOA23P40	Mephedrone HCl (MEP) Rapid Test Panel – Urine	46994	B	6
D-DOA24P40	Mescaline (MES) Rapid Test Panel – Urine	46994	B	6
D-DOA38P40	Morphine (MOP) Rapid Test Panel – Urine	46994	B	6
D-DOA63D40	Methylphenidate (MPD) Rapid Test Device – Urine	46994	B	6
D-DOA63P40	Methylphenidate (MPD) Rapid Test Panel – Urine	46994	B	6
D-DOA63S50	Methylphenidate (MPD) Rapid Test Strip – Urine	46994	B	6
D-DOA22P40	Meperidine (MPRD) Rapid Test Panel – Urine	46994	B	6
D-DOA64D40	Methaqualone (MQL) Rapid Test Device – Urine	46994	B	6
D-DOA64P40	Methaqualone (MQL) Rapid Test Panel – Urine	46994	B	6
D-DOA64S50	Methaqualone (MQL) Rapid Test Strip – Urine	46994	B	6
D-DOA7P40	Methadone (MTD) Rapid Test Panel – Urine	46994	B	6
D-DOA3P40	Opiates (OPI) Rapid Test Panel – Urine	46994	B	6
D-DOA3S50	Opiates (OPI) Rapid Test Strip – Urine	46994	B	6
D-DOA39P40	Oxycodone (OXY) Rapid Test Panel – Urine	46994	B	6
D-DOA49D20	Olanzapine (OZP) Rapid Test Device - Urine	46994	B	6
D-DOA49P40	Olanzapine (OZP) Rapid Test Panel – Urine	46994	B	6
D-DOA49S50	Olanzapine (OZP) Rapid Test Strip – Urine	46994	B	6
D-DOA35P40	Papaverine (PAP) Rapid Test Panel – Urine	46994	B	6
D-DOA13P40	Phencyclidine (PCP) Rapid Test Panel – Urine	46994	B	6
D-DOA50P40	Pregabalin (PGB) Rapid Test Panel – Urine	46994	B	6
D-DOA65D40	Propoxyphene (PPX) Rapid Test Device – Urine	46994	B	6
D-DOA65P40	Propoxyphene (PPX) Rapid Test Panel – Urine	46994	B	6
D-DOA65S50	Propoxyphene (PPX) Rapid Test Strip – Urine	46994	B	6
D-DOA34P40	Quetiapine (QTP) Rapid Test Panel – Urine	46994	B	6
D-DOA66D40	Risperidone (RPD) Rapid Test Device-Urine	46994	B	6
D-DOA66P40	Risperidone (RPD) Rapid Test Panel-Urine	46994	B	6
D-DOA66S50	Risperidone (RPD) Rapid Test strip-Urine	46994	B	6
D-DOA51P40	Synthetic Marijuana (K2) Rapid Test Panel – Urine	46994	B	6
D-DOA10P40	Tricyclic Antidepressants (TCA) Rapid Test Panel – Urine	30524	B	6
D-DOA8P40	Marijuana (THC) Rapid Test Panel – Urine	46994	B	6
D-DOA33P40	Tilidine (TLD) Rapid Test Panel – Urine	46994	B	6
D-DOA33S50	Tilidine (TLD) Rapid Test Strip – Urine	46994	B	6
D-DOA30P40	Tramadol (TML) Rapid Test Panel – Urine	46994	B	6
D-DOA25P40	Tropicmide (TRO) Rapid Test Panel – Urine	46994	B	6
D-DOA26P40	Trazodone (TZD) Rapid Test Panel – Urine	46994	B	6
D-DOA27P40	UR-144 Rapid Test Panel – Urine	46994	B	6
D-DOA28P40	Zaleplon (ZAL) Rapid Test Panel – Urine	46994	B	6
D-DOA68D40	Zolpidem (ZOL) Rapid Test Device – Urine	46994	B	6
D-DOA68P40	Zolpidem (ZOL) Rapid Test Panel – Urine	46994	B	6
D-DOA68S50	Zolpidem (ZOL) Rapid Test Strip – Urine	46994	B	6
D-DOA69D40	Zopiclone (ZOP) Rapid Test Device – Urine	46994	B	6
D-DOA69P40	Zopiclone (ZOP) Rapid Test Panel – Urine	46994	B	6
D-DOA69S50	Zopiclone (ZOP) Rapid Test Strip – Urine	46994	B	6
D-DOAPM2	Multi-drug 2 drugs Rapid Test Panel – Urine	46994	B	6

D-DOAPM3	Multi-drug 3 drugs Rapid Test Panel – Urine	46994	B	6
D-DOAPM4	Multi-drug 4 drugs Rapid Test Panel – Urine	46994	B	6
D-DOAPM5	Multi-drug 5 drugs Rapid Test Panel – Urine	46994	B	6
D-DOAPM6	Multi-drug 6 drugs Rapid Test Panel – Urine	46994	B	6
D-DOAPM7	Multi-drug 7 drugs Rapid Test Panel – Urine	46994	B	6
D-DOAPM8	Multi-drug 8 drugs Rapid Test Panel – Urine	46994	B	6
D-DOAPM9	Multi-drug 9 drugs Rapid Test Panel – Urine	46994	B	6
D-DOAPM10	Multi-drug 10 drugs Rapid Test Panel – Urine	46994	B	6
D-DOAPM11	Multi-drug 11 drugs Rapid Test Panel – Urine	46994	B	6
D-DOAPM12	Multi-drug 12 drugs Rapid Test Panel – Urine	46994	B	6
D-DOAPM13	Multi-drug 13 drugs Rapid Test Panel – Urine	46994	B	6
D-DOAPM14	Multi-drug 14 drugs Rapid Test Panel – Urine	46994	B	6
D-DOAPM15	Multi-drug 15 drugs Rapid Test Panel – Urine	46994	B	6
D-DOAPM16	Multi-drug 16 drugs Rapid Test Panel – Urine	46994	B	6
D-DOAPM17	Multi-drug 17 drugs Rapid Test Panel – Urine	46994	B	6
D-DOAPM18	Multi-drug 18 drugs Rapid Test Panel – Urine	46994	B	6
D-DOAPM19	Multi-drug 19 drugs Rapid Test Panel – Urine	46994	B	6
D-DOAPM20	Multi-drug 20 drugs Rapid Test Panel – Urine	46994	B	6
D-DOACM2	Multi-Drug 2 Drugs Rapid Test 1-Step Cup - Urine	46994	B	6
D-DOACM3	Multi-Drug 3 Drugs Rapid Test 1-Step Cup - Urine	46994	B	6
D-DOACM4	Multi-Drug 4 Drugs Rapid Test 1-Step Cup - Urine	46994	B	6
D-DOACM5	Multi-Drug 5 Drugs Rapid Test 1-Step Cup - Urine	46994	B	6
D-DOACM6	Multi-Drug 6 Drugs Rapid Test 1-Step Cup - Urine	46994	B	6
D-DOACM7	Multi-Drug 7 Drugs Rapid Test 1-Step Cup - Urine	46994	B	6
D-DOACM8	Multi-Drug 8 Drugs Rapid Test 1-Step Cup - Urine	46994	B	6
D-DOACM9	Multi-Drug 9 Drugs Rapid Test 1-Step Cup - Urine	46994	B	6
D-DOACM10	Multi-Drug 10 Drugs Rapid Test 1-Step Cup - Urine	46994	B	6
D-DOACM11	Multi-Drug 11 Drugs Rapid Test 1-Step Cup - Urine	46994	B	6
D-DOACM12	Multi-Drug 12 Drugs Rapid Test 1-Step Cup - Urine	46994	B	6
D-DOACM13	Multi-Drug 13 Drugs Rapid Test 1-Step Cup - Urine	46994	B	6
D-DOACM14	Multi-Drug 14 Drugs Rapid Test 1-Step Cup - Urine	46994	B	6
D-DOACM15	Multi-Drug 15 Drugs Rapid Test 1-Step Cup - Urine	46994	B	6
D-DOACM16	Multi-Drug 16 Drugs Rapid Test 1-Step Cup - Urine	46994	B	6
D-DOACM17	Multi-Drug 17 Drugs Rapid Test 1-Step Cup - Urine	46994	B	6
D-DOACM18	Multi-Drug 18 Drugs Rapid Test 1-Step Cup - Urine	46994	B	6
D-DOACM19	Multi-Drug 19 Drugs Rapid Test 1-Step Cup - Urine	46994	B	6
D-DOACM20	Multi-Drug 20 Drugs Rapid Test 1-Step Cup - Urine	46994	B	6
D-DOACM21	Multi-Drug 21 Drugs Rapid Test 1-Step Cup - Urine	46994	B	6
D-DOACM22	Multi-Drug 22 Drugs Rapid Test 1-Step Cup - Urine	46994	B	6
D-DOACM2K	Multi-Drug 2 Drugs Rapid Test 2-Step Cup - Urine	46994	B	6
D-DOACM3K	Multi-Drug 3 Drugs Rapid Test 2-Step Cup - Urine	46994	B	6
D-DOACM4K	Multi-Drug 4 Drugs Rapid Test 2-Step Cup - Urine	46994	B	6
D-DOACM5K	Multi-Drug 5 Drugs Rapid Test 2-Step Cup - Urine	46994	B	6
D-DOACM6K	Multi-Drug 6 Drugs Rapid Test 2-Step Cup - Urine	46994	B	6
D-DOACM7K	Multi-Drug 7 Drugs Rapid Test 2-Step Cup - Urine	46994	B	6
D-DOACM8K	Multi-Drug 8 Drugs Rapid Test 2-Step Cup - Urine	46994	B	6
D-DOACM9K	Multi-Drug 9 Drugs Rapid Test 2-Step Cup - Urine	46994	B	6
D-DOACM10K	Multi-Drug 10 Drugs Rapid Test 2-Step Cup - Urine	46994	B	6

D-DOACM11K	Multi-Drug 11 Drugs Rapid Test 2-Step Cup - Urine	46994	B	6
D-DOACM12K	Multi-Drug 12 Drugs Rapid Test 2-Step Cup - Urine	46994	B	6
D-DOACM13K	Multi-Drug 13 Drugs Rapid Test 2-Step Cup - Urine	46994	B	6
D-DOACM14K	Multi-Drug 14 Drugs Rapid Test 2-Step Cup - Urine	46994	B	6
D-DOACM15K	Multi-Drug 15 Drugs Rapid Test 2-Step Cup - Urine	46994	B	6
D-DOACM16K	Multi-Drug 16 Drugs Rapid Test 2-Step Cup - Urine	46994	B	6
D-DOACM17K	Multi-Drug 17 Drugs Rapid Test 2-Step Cup - Urine	46994	B	6
D-DOACM18K	Multi-Drug 18 Drugs Rapid Test 2-Step Cup - Urine	46994	B	6
D-DOA1D20S	Amphetamine (AMP) Rapid Test Device – Saliva	46994	B	6
D-DOA1M25S	Amphetamine (AMP) Rapid Test Midstream-Saliva	46994	B	6
D-DOA54D25S	α-Pyrrolidinovalerophenone (α-PVP) Rapid Test Device- Saliva	46994	B	6
D-DOA54M25S	α-Pyrrolidinovalerophenone (α-PVP) Rapid Test Midstream-Saliva	46994	B	6
D-DOA4D20S	Barbiturates (BAR) Rapid Test Device – Salvia	46994	B	6
D-DOA4M25S	Barbiturates (BAR) Rapid Test Midstream-Salvia	46994	B	6
D-DOA11D20S	Buprenorphine (BUP) Rapid Test Device – Saliva	46994	B	6
D-DOA11M25S	Buprenorphine (BUP) Rapid Test Midstream-Saliva	46994	B	6
D-DOA5D20S	Benzodiazepine (BZO) Rapid Test Device – Salvia	46994	B	6
D-DOA5M25S	Benzodiazepine (BZO) Rapid Test Midstream-Salvia	46994	B	6
D-DOA6M25S	Cocaine (COC) Rapid Test Midstream-Saliva	46994	B	6
D-DOA47D25S	Carfentanyl (CFYL) Rapid Test Device – Salvia	46994	B	6
D-DOA47M25S	Carfentanyl (CFYL) Rapid Test Midstream-Salvia	46994	B	6
D-DOA31M25S	Cotinine (COT) Rapid Test Midstream-Salvia	46994	B	6
D-DOA42D20S	Fentanyl (FYL) Rapid Test Device – Salvia	46994	B	6
D-DOA42M25S	Fentanyl (FYL) Rapid Test Midstream-Salvia	46994	B	6
D-DOA9D20S	Ketamine (KET) Rapid Test Device – Saliva	46994	B	6
D-DOA9M25S	Ketamine (KET) Rapid Test Midstream-Salvia	46994	B	6
D-DOA43D20S	6-Monoacetylmorphine(6-MAM) Rapid Test Device-Saliva	64154	B	6
D-DOA43M25S	6-Monoacetylmorphine (6-MAM) Rapid Test Midstream-salvia	46994	B	6
D-DOA12M20S	Ecstasy (MDMA) Rapid Test Midstream-Saliva	46994	B	6
D-DOA62D25S	Methylenedioxypyrovalerone (MDPV) Rapid Test Device-Saliva	46994	B	6
D-DOA62M25S	Methylenedioxypyrovalerone (MDPV) Rapid Test Midstream-Urine	46994	B	6
D-DOA7M20S	Methadone (MTD) Rapid Test Midstream-Saliva	46994	B	6
D-DOA3M20S	Opiates (OPI) Rapid Test Midstream-Saliva	46994	B	6
D-DOA39D20S	Oxycodone (OXY) Rapid Test Device – Saliva	46994	B	6
D-DOA39M25S	Oxycodone (OXY) Rapid Test Midstream-Saliva	46994	B	6
D-DOA13D20S	Phencyclidine (PCP) Rapid Test Device – Saliva	46994	B	6
D-DOA13M25S	Phencyclidine (PCP) Rapid Test Midstream-Saliva	46994	B	6
D-DOA51D20S	Synthetic Marijuana (K2) Rapid Test Device – Salvia	46994	B	6
D-DOA51M25S	Synthetic Marijuana (K2) Rapid Test Midstream-Salvia	46994	B	6
D-DOA8M25S	Marijuana (THC) Rapid Test Midstream-Saliva	46994	B	6
D-DOA30D20S	Tramadol (TML) Rapid Test Device – Saliva	46994	B	6
D-DOA30M25S	Tramadol(TML) Rapid Test Midstream-Saliva	64161	B	6
D-DOAMM2S	Multi-drug 2 Drugs Rapid Test Midstream-Saliva	46994	B	6
D-DOAMM3S	Multi-drug 3 Drugs Rapid Test Midstream-Saliva	46994	B	6
D-DOAMM4S	Multi-drug 4 Drugs Rapid Test Midstream-Saliva	46994	B	6
D-DOAMM5S	Multi-drug 5 Drugs Rapid Test Midstream-Saliva	46994	B	6
D-DOAMM6S	Multi-drug 6 Drugs Rapid Test Midstream-Saliva	46994	B	6
D-DOAMM7S	Multi-drug 7 Drugs Rapid Test Midstream-Saliva	46994	B	6

D-DOAMM8S	Multi-drug 8 Drugs Rapid Test Midstream-Saliva	46994	B	6
D-DOAMM9S	Multi-drug 9 Drugs Rapid Test Midstream-Saliva	46994	B	6
D-DOAMM10S	Multi-drug 10 drugs Rapid Test Midstream-Saliva	46994	B	6
D-DOAMM11S	Multi-drug 11 drugs Rapid Test Midstream-Saliva	46994	B	6
D-DOAMM12S	Multi-drug 12 drugs Rapid Test Midstream-Saliva	46994	B	6
D-DOAM2S	Multi-drug 2 drugs Rapid Test Device – Saliva	46994	B	6
D-DOAM3S	Multi-drug 3 drugs Rapid Test Device – Saliva	46994	B	6
D-DOAM4S	Multi-drug 4 drugs Rapid Test Device – Saliva	46994	B	6
D-DOAM5S	Multi-drug 5 drugs Rapid Test Device – Saliva	46994	B	6
D-DOAM6S	Multi-drug 6 drugs Rapid Test Device – Saliva	46994	B	6
D-DOAM7S	Multi-drug 7 drugs Rapid Test Device – Saliva	46994	B	6
D-DOAM8S	Multi-drug 8 drugs Rapid Test Device – Saliva	46994	B	6
D-DOAM9S	Multi-drug 9 drugs Rapid Test Device – Saliva	46994	B	6
D-DOAM10S	Multi-drug 10 drugs Rapid Test Device – Saliva	46994	B	6
D-DOAM11S	Multi-drug 11 drugs Rapid Test Device – Saliva	46994	B	6
D-DOAM12S	Multi-drug 12 drugs Rapid Test Device – Saliva	46994	B	6
D-DOACM2S	Multi-Drug 2 Drugs Rapid Test Cup – Saliva	46994	B	6
D-DOACM3S	Multi-Drug 3 Drugs Rapid Test Cup – Saliva	46994	B	6
D-DOACM4S	Multi-Drug 4 Drugs Rapid Test Cup – Saliva	46994	B	6
D-DOACM5S	Multi-Drug 5 Drugs Rapid Test Cup – Saliva	46994	B	6
D-DOACM6S	Multi-Drug 6 Drugs Rapid Test Cup – Saliva	46994	B	6
D-DOACM7S	Multi-Drug 7 Drugs Rapid Test Cup – Saliva	46994	B	6
D-DOACM8S	Multi-Drug 8 Drugs Rapid Test Cup – Saliva	46994	B	6
D-DOACM9S	Multi-Drug 9 Drugs Rapid Test Cup – Saliva	46994	B	6
D-DOACM10S	Multi-Drug 10 Drugs Rapid Test Cup – Saliva	46994	B	6
D-DOACM11S	Multi-Drug 11 Drugs Rapid Test Cup – Saliva	46994	B	6
D-DOACM12S	Multi-Drug 12 Drugs Rapid Test Cup – Saliva	46994	B	6
D-DOACM13S	Multi-Drug 13 Drugs Rapid Test Cup – Saliva	46994	B	6
D-DOACM14S	Multi-Drug 14 Drugs Rapid Test Cup – Saliva	46994	B	6
D-DOACM15S	Multi-Drug 15 Drugs Rapid Test Cup – Saliva	46994	B	6
D-DOACM16S	Multi-Drug 16 Drugs Rapid Test Cup – Saliva	46994	B	6
D-DOA1WBD40	AMP Rapid Test Device – WB/S/P	46994	B	6
D-DOA4WBD40	BAR Rapid Test Device – WB/S/P	46994	B	6
D-DOA11WBD40	BUP Rapid Test Device – WB/S/P	46994	B	6
D-DOA5WBD40	BZO Rapid Test Device – WB/S/P	46994	B	6
D-DOA6WBD40	COC Rapid Test Device – WB/S/P	46994	B	6
D-DOA31WBD40	COT Rapid Test Device – WB/S/P	46994	B	6
D-DOA57WBD40	EDDP Rapid Test Device – WB/S/P	46994	B	6
D--DOA42WBD40	FYL Rapid Test Device-WB/S/P	64153	B	6
D-DOA9WBD40	KET Rapid Test Device-WB/S/P	62130	B	6
D-DOA29WBD40	LSD Rapid Test Device-WB/S/P	64156	B	6
D-DOA12WBD40	MDMA Rapid Test Device – WB/S/P	46994	B	6
D-DOA61WBD40	MDA Rapid Test Device-WB/S/P	46994	B	6
D-DOA62WBD40	MDPV Rapid Test Device – WB/S/P/	46994	B	6
D-DOA2WBD40	MET Rapid Test Device – WB/S/P	46994	B	6
D-DOA38WBD40	MOP Rapid Test Device – WB/S/P	46994	B	6
D-DOA7WBD40	MTD Rapid Test Device – WB/S/P	46994	B	6
D-DOA39WBD40	OXY Rapid Test Device – WB/S/P	46994	B	6

D-DOA13WBD40	PCP Rapid Test Device-WB/S/P	30523	B	6
D-DOA65WBD40	PPX Rapid Test Device – WB/S/P	46994	B	6
D-DOA51WBD40	K2 Rapid Test Device-WB/S/P	30519	B	6
D-DOA10WBD40	TCA Rapid Test Device – WB/S/P	30524	B	6
D-DOA67WBD40	THC Rapid Test Device – WB/S/P	46994	B	6
D-DOA30WBD20	TML Rapid Test Device – WB/S/P	46994	B	6
D-DOAWBM2	Multi-drug 2 drugs Rapid Test Device – WB/S/P	46994	B	6
D-DOAWBM3	Multi-drug 3 drugs Rapid Test Device – WB/S/P	46994	B	6
D-DOAWBM4	Multi-drug 4 drugs Rapid Test Device – WB/S/P	46994	B	6
D-DOAWBM5	Multi-drug 5 drugs Rapid Test Device – WB/S/P	46994	B	6
D-DOAWBM6	Multi-drug 6 drugs Rapid Test Device – WB/S/P	46994	B	6
D-DOAWBM7	Multi-drug 7 drugs Rapid Test Device – WB/S/P	46994	B	6
D-DOAWBM8	Multi-drug 8 drugs Rapid Test Device – WB/S/P	46994	B	6
D-DOAWBM9	Multi-drug 9 drugs Rapid Test Device – WB/S/P	46994	B	6
D-DOAWBM10	Multi-drug 10 drugs Rapid Test Device – WB/S/P	46994	B	6
D-DOAWBM11	Multi-drug 11 drugs Rapid Test Device – WB/S/P	46994	B	6
D-DOAWBM12	Multi-drug 12 drugs Rapid Test Device – WB/S/P	46994	B	6
D-DOAWBM13	Multi-drug 13 drugs Rapid Test Device – WB/S/P	46994	B	6
D-DOAWBM14	Multi-drug 14 drugs Rapid Test Device – WB/S/P	46994	B	6
D-DOAWBM15	Multi-drug 15 drugs Rapid Test Device – WB/S/P	46994	B	6
D-DOAWBM16	Multi-drug 16 drugs Rapid Test Device – WB/S/P	46994	B	6
D-DOAWBM17	Multi-drug 17 drugs Rapid Test Device – WB/S/P	46994	B	6
D-DOA1D20H	Amphetamine (AMP) Rapid Test Device – Hair	46994	B	6
D-DOA4D20H	Barbiturates (BAR) Rapid Test Device – Hair	46994	B	6
D-DOA11D20H	Buprenorphine (BUP) Rapid Test Device – Hair	46994	B	6
D-DOA5D20H	Benzodiazepine (BZO) Rapid Test Device – Hair	46994	B	6
D-DOA6D20H	Cocaine (COC) Rapid Test Device – Hair	46994	B	6
D-DOA31D20H	Cotinine (COT) Rapid Test Device – Hair	46994	B	6
D-DOA9D20H	Ketamine (KET) Rapid Test Device – Hair	46994	B	6
D-DOA43D20H	6-Monoacetylmorphine (6-MAM)Rapid Test Device – Hair	46994	B	6
D-DOA12D20H	Ecstasy (MDMA) Rapid Test Device – Hair	46994	B	6
D-DOA2D20H	Methamphetamine (MET) Rapid Test Device – Hair	46994	B	6
D-DOA38D20H	Morphine (MOP) Rapid Test Device -Hair	46994	B	6
D-DOA39D20H	Oxycodone (OXY) Rapid Test Device -Hair	46994	B	6
D-DOA13D20H	Phencyclidine (PCP) Rapid Test Device – Hair	46994	B	6
D-DOAM2H	Multi-drug 2 drugs Rapid Test Device – Hair	46994	B	6
D-DOAM3H	Multi-drug 3 drugs Rapid Test Device – Hair	46994	B	6
D-DOAM4H	Multi-drug 4 drugs Rapid Test Device -Hair	46994	B	6
D-DOAM5H	Multi-drug 5 drugs Rapid Test Device – Hair	46994	B	6
D-DOAM6H	Multi-drug 6 drugs Rapid Test Device – Hair	46994	B	6
D-DOAM7H	Multi-drug 7 drugs Rapid Test Device – Hair	46994	B	6
D-DOAM8H	Multi-drug 8 drugs Rapid Test Device – Hair	46994	B	6
D-DOAM9H	Multi-drug 9 drugs Rapid Test Device – Hair	46994	B	6
D-CEAD20	CEA Rapid Test Device – WB/S/P	54617	C	3h
D-CFOBD10	Calprotectin and FOB Combo Rapid Test Device – Feces	66462	B	6
D-HBHBD20	Hb+Hb-Hp Combo Rapid Test Device – Feces	54557	B	6
D-TRFOBHBD20	Transferrin/FOB and Hb-Hp Combo Rapid Test Device - Feces	65270	B	6
D-CKMBD10	CK-MB Rapid Test Device – WB/S/P	52995	C	3j

D-HFCD25	H-FABP and cTnl Combo Rapid Test Device – WB/S/P	61295	C	3j
D-HMCKCTD10	H-FABP and Myoglobin/CK-MB/Cardiac Troponin I Combo Rapid Test Device – WB/S/P	61295	C	3j
D-CRPS10	CRP Rapid Test Strip – WB/S/P	58395	B	6
D-CRPD10	CRP Rapid Test Device – WB/S/P	58395	B	6
D-CRPSQS10	CRP Semi-Quantitative Rapid Test Device – WB/S/P	58395	B	6
D-CRPSQD10	CRP Semi-Quantitative Rapid Test Device – WB/S/P	58395	B	6
D-PCTD10	PCT Rapid Test Device – S/P	58305	B	6
D-FED10	Ferritin Rapid Test Device – WB/S/P	66124	B	6
D-FESQD10	Ferritin Semi-Quantitative Rapid Test Device – WB/S/P	66124	B	6
D-SP10D1	SP-10 Male Fertility Rapid Test Device-Sperm	61076	B	6
D-SP10D2	SP-10 Male Fertility Rapid Test Device-Sperm	61076	B	6
D-VDD10	Vitamin D Rapid Test Device – WB	60955	B	6
D-HBA1CD10	HbA1c Rapid Test Device-WB	65322	C	3k
D-RFSPD20	Rheumatoid Factor Rapid Test Device – S/P	66486	B	6
D-DMASQS50	Micro-Albumin Semi-Quantitative Rapid Test strip-urine	60471	B	6
D-MASQD25	Micro-Albumin Semi-Quantitative Rapid Test Device – Urine	60471	B	6
D-MAQS50	Micro-Albumin Qualitative Rapid Test Strip – Urine	60471	B	6
D-MAQD25	Micro-Albumin Qualitative Rapid Test Device – Urine	60471	B	6
D-RDOA32D40	Acetaminophen (ACE) Rapid Test Device -Urine	64160	B	6
D-RDOA53D40	7-Aminoclonazepam (7-ACL) Rapid Test Device -Urine	55532	B	6
D-RDOA1D40	Amphetamine (AMP) Rapid Test Device -Urine	46994	B	6
D-RDOA54D40	α-Pyrrolidinovalerophenone (α-PVP) Rapid Test Device -Urine	46994	B	6
D-RDOA4D40	Barbiturate (BAR) Rapid Test Device-urine	46994	B	6
D-RDOA11D40	Buprenorphine (BUP) Rapid Test Device -Urine	65385	B	6
D-RDOA5D40	Benzodiazepines (BZO) Rapid Test Device-urine	46994	B	6
D-RDOA56D40	Clonazepam (CLO) Rapid Test Device -Urine	55532	B	6
D-RDOA6D40	COCAINE (COC) Rapid Test Device-urine	46994	B	6
D-RDOA31D40	Cotinine (COT) Rapid Test Device -Urine	64155	B	6
D-RDOA41D40	Diazepam (DIA) Rapid Test Device -urine	64157	B	6
D-RDOA57D40	Ethylenediamine-dimethylphosphinic acid (EDDP) Rapid Test Device -urine	42656	B	6
D-RDOA58D40	Ethyl Glucuronide (ETG) Rapid Test Device-urine	60669	B	6
D-RDOA42D40	Fentanyl (FYL) Rapid Test Device -urine	64153	B	6
D-RDOA9D40	Ketamine (KET)Rapid Test Device-urine	62130	B	6
D-RDOA43D40	6-Monoacetylmorphine (6-MAM) Rapid Test Device -urine	64154	B	6
D-RDOA12D40	Ecstasy (MDMA) Rapid Test Device-urine	55489	B	6
D-RDOA61D40	Tenamfetamine (MDA) Rapid Test Device -urine	46994	B	6
D-RDOA62D40	Methylenedioxypyrovalerone (MDPV) Rapid Test Device -urine	46994	B	6
D-RDOA63D40	Methylphenidate(MPD) Rapid Test Device -urine	46994	B	6
D-RDOA2D40	Methamphetamine (MET) Rapid Test Device -urine	55498	B	6
D-RDOA38D40	Morphine (MOP) Rapid Test Device -urine	55701	B	6
D-RDOA64D40	Methaqualone (MQL) Rapid Test Device -urine	55696	B	6
D-RDOA7D40	Methadone (MTD) Rapid Test Device -urine	30521	B	6
D-RDOA3D40	Opiates (OPI) Rapid Test Device -urine	55701	B	6
D-RDOA39D40	Oxycodone (OXY) Rapid Test Device -urine	55734	B	6
D-RDOA13D40	Phencyclidine (PCP) Rapid Test Device -urine	30523	B	6
D-RDOA65D40	Propoxyphene (PPX) Rapid Test Device -urine	62324	B	6

D-RDOA51D40	Synthetic Marijuana (K2) Rapid Test Device-urine	30519	B	6
D-RDOA10D40	Tricyclic Antidepressants (TCA) Rapid Test Device -urine	55712	B	6
D-RDOA8D40	Marijuana (THC) Rapid Test Device-urine	30519	B	6
D-RDTMLD40	Tramadol (TML) Rapid Test Device -urine	64161	B	6
D-RDOA29D40	Lysergic Acid Diethylamide (LSD) Rapid Test Device -urine	64156	B	6
D-RDOA68D40	Zolpidem(ZOL) Rapid Test Device -urine	46994	B	6
D-RDOA1D25S	Amphetamine (AMP) Rapid Test Device -Saliva	46994	B	6
D-RDOA4D25S	Barbiturate (BAR) Rapid Test Device -Saliva	46994	B	6
D-RDOA11D25S	Buprenorphine (BUP) Rapid Test Device -Saliva	65385	B	6
D-RDOA5D20S	Benzodiazepines (BZO) Rapid Test Device -Saliva	46994	B	6
D-RDOA6D25S	COCAINE (COC) Rapid Test Device -Saliva	46994	B	6
D-RDOA2D25S	Methamphetamine (MET) Rapid Test Device -Saliva	55498	B	6
D-RDOA7D25S	Methadone (MTD) Rapid Test Device -Saliva	30521	B	6
D-RDOA3D25S	Opiates (OPI) Rapid Test Device -Saliva	55701	B	6
D-RDOA13D25S	Phencyclidine (PCP) Rapid Test Device -Saliva	30523	B	6
D-RDOA51D25S	Synthetic Marijuana (K2) Rapid Test Device -Saliva	30523	B	6
D-RDOAPM3	Multi-Drug 3 Drugs Rapid Test Panel-urine	46994	B	6
D-RDOAPM4	Multi-Drug 4 Drugs Rapid Test Panel-urine	46994	B	6
D-RDOAPM5	Multi-Drug 5 Drugs Rapid Test Panel-urine	46994	B	6
D-RDOAPM6	Multi-Drug 6 Drugs Rapid Test Panel-urine	46994	B	6
D-RDOAPM7	Multi-Drug 7 Drugs Rapid Test Panel-urine	46994	B	6
D-RDOAPM8	Multi-Drug 8 Drugs Rapid Test Panel-urine	46994	B	6
D-RDOAPM9	Multi-Drug 9 Drugs Rapid Test Panel-urine	46994	B	6
D-RDOAPM10	Multi-Drug 10 Drugs Rapid Test Panel-urine	46994	B	6
D-RDOAPM12	Multi-Drug 12 Drugs Rapid Test Panel-urine	46994	B	6
D-RDOAPM3A	Multi-Drug 3 Drugs Rapid Test Panel with Adulteration-urine	46994	B	6
D-RDOAPM4A	Multi-Drug 4 Drugs Rapid Test Panel with Adulteration-urine	46994	B	6
D-RDOAPM5A	Multi-Drug 5 Drugs Rapid Test Panel withAdulteration-urine	46994	B	6
D-RDOAPM6A	Multi-Drug 6 Drugs Rapid Test Pane with Adulteration-urine	46994	B	6
D-RDOAPM7A	Multi-Drug 7 Drugs Rapid Test Panel with Adulteration-urine	46994	B	6
D-RDOAPM8A	Multi-Drug 8 Drugs Rapid Test Panel with Adulteration-urine	46994	B	6
D-RDOAPM9A	Multi-Drug 9 Drugs Rapid Test Panel with Adulteration-urine	46994	B	6
D-RDOAPM10A	Multi-Drug 10 Drugs Rapid Test Panel with Adulteration-urine	46994	B	6
D-RDOAPM12A	Multi-Drug 12 Drugs Rapid Test Panel with Adulteration-urine	46994	B	6
D-RDOAM3U	Multi-Drug 3 Drugs Rapid Test Device-urine	46994	B	6
D-RDOAM5U	Multi-Drug 5 Drugs Rapid Test Device-urine	46994	B	6
D-RDOAM6U	Multi-Drug 6 Drugs Rapid Test Device-urine	46994	B	6
D-RDOAM7U	Multi-Drug 7 Drugs Rapid Test Device-urine	46994	B	6
D-RDOAM12U	Multi-Drug 12 Drugs Rapid Test Device-urine	46994	B	6
D-RDOAM3S	Multi-Drug 3 Drugs Rapid Test Device -Saliva	46994	B	6
D-RDOAM4S	Multi-Drug 4 Drugs Rapid Test Device -Saliva	46994	B	6
D-RDOAM5S	Multi-Drug 5 Drugs Rapid Test Device -Saliva	46994	B	6
D-RDOAM6S	Multi-Drug 6 Drugs Rapid Test Device -Saliva	46994	B	6
D-RDOAM7S	Multi-Drug 7 Drugs Rapid Test Device -Saliva	46994	B	6
D-RDOAM8S	Multi-Drug 8 Drugs Rapid Test Device -Saliva	46994	B	6
D-RCFOB10	FOB Rapid Test Device -Feces	54532	B	6
D-RHCGUD40	hCG Pregnancy Rapid Test Device -urine	33819	B	6
D-RCTID10	Cardiac Troponin I Rapid Test Device -WB/S/P	46989	C	3j

D-RNGALD10	NGAL（neutrophil gelatinase-associated lipocalin）Rapid Test Device -WB/S/P	47430	C	3j
D-RCKMBD10	CK-MB Rapid Test Device -WB/S/P	52995	C	3j
D-RMYOD10	Myoglobin Rapid Test Device -WB/S/P	46987	C	3j
D-INFABD20	Influenza A+B Rapid Test Device – Swab/Nasal Aspirate	49119	B	6
D-RHPAGD25	H. pylori Antigen Rapid Test Device -Feces	30825	B	6
D-RMONOD25	MONO Rapid Test Device -WB/S/P	49689	C	3e
D-RINFAD20	Influenza A Rapid Test Device -Swab/Nasal Aspirate	49119	B	6
D-RSTRAS20	Strep A Rapid Test Device -Throat Swab	51707	B	6
D-RTPD40	Syphilis Rapid Test Device -S/P	63969	C	3a
D-RDGMD20	Dengue IgG/IgM Rapid Test Device -WB/S/P	63238	B	6
D-RDAGD20	Dengue NS1 Rapid Test Device-WB/S/P	62946	C	3b
D-RFFD25	Fetal Fibronectin (fFN) Rapid Test Device -Vaginal Discharge	53721	B	6
D-RFSHD20	Follicle Stimulating Hormone (FSH) Rapid Test Device -Urine	54188	B	6
D-RTSHD20	TSH Rapid Test Device -WB/S/P	65274	B	6
D-RFED10	Ferritin Rapid test Device -WB/S/P	66124	B	6
D-RTSHSQD20	Thyroid Stimulating Hormone (TSH) Rapid Test Device -WB/S/P	65274	B	6
D-RVDD10	Vitamin D Rapid Test Device -WB/S/P	60955	B	6
D-RPCTCD10	Procalcitonin (PCT) Rapid Test Device -WB/S/P	58305	B	6
D-RCALD10	Calprotectin Rapid Test Device -Feces	60775	B	6
D-RCRD10	CRP Rapid Test Device -WB/S/P	58768	B	6
D-FICEAD20	CEA Test Device -S/P	54616	C	3h
D-FIAFPD20	AFP Test Device -S/P	54060	C	3h
D-FIDIMERD10	D-Dimer Test Device -WB/P	61389	C	3k
D-FICKMBD10	CK-MB Test Device -WB/S/P	61385	C	3j
D-FITROPID20	cTnI Test Device -WB/S/P	54010	C	3j
D-FIMYOD25	Myoglobin Rapid Test Device —WB/S/P	61390	C	3j
D-FIFABD10	H-FABP Test Device -WB/S/P	53365	C	3j
D-FINTPD10	NT-proBNP Test Device -WB/S/P	47352	C	3j
D-FITIMCKD20	Troponin I/Myoglobin/CK-MB (3 in 1) Test Device -WB/S/P	47384	C	3j
D-FITTMCKD20	Troponin T/Myoglobin/CK-MB (3 in 1) Test Device -WB/S/P	47384	C	3j
D-FILHD20	LH Test Device -WB/S/P	65959	B	6
D-FISTRAS20	Strep A Test Device -Swab	63770	B	6
D-FIIABD20	Influenza A+B Test Device -Swab	49117	B	6
D-FIDGMD20	Dengue IgG/IgM Test Device -WB/S/P	48915	B	6
D-FIDAGD25	Dengue NS1 Test Device -WB/S/P	48915	C	3b
D-FIRSVD20	RSV Test Device -Swab	62587	B	6
D-FICDTABD10	Clostridium difficile Toxin A/Toxin B Combo Test Device -Feces	65995	B	6
D-FICDGD10	Clostridium difficile GDH Test Device -Feces	65995	B	6
D-FIADED25	Adenovirus antigen Test Device -Feces	49854	B	6
D-FISPD10	Streptococcus pneumoniae Test Device -urine	63796	C	3c
D-FILPD25	Legionella pneumophila Test Device -urine	63781	C	3c
D-FITPSPD40	Syphilis Test Device -WB/S/P	51814	C	3a
D-FIZAGD10	Zika antigen Test Device -WB/S/P	65994	B	6
D-FIZMD10	Zika IgM Test Device -WB/S/P	66015	B	6
D-FIAMHD10	AMH Test Device -WB/S/P	58410	B	6
D-FIFFD25	Fetal Fibronectin (fFN) Test Device-Swab	53721	B	6
D-FIFSHD20	FSH Test Device -WB/S/P	54188	B	6

D-FIRFSPD20	Rheumatoid Factor IgM Test Device -WB/S/P	55109	B	6
D-FICRPD25	CRP Test Device-WB/S/P	58768	B	6
D-FIPCTD25	PCT Test Device-WB/S/P	54313	B	6
D-FIFOBD25	FOB Test Device-Feces	66044	B	6
D-FIT4D25	T4 Test Device-S/P	63072	B	6
D-FIHCG D25	β-HCG Test Device-S/P	58789	B	6
D-FITSHD25	TSH Test Device-S/P	54384	B	6
D-FIT3D25	T3 Test Device-S/P	63082	B	6
D-FITESD25	Testosterone Test Device-S/P	54184	B	6
D-FIP4D25	Progesterone(P4) Test Device-S/P	54327	B	6
D-FICYSCD25	CysC Test Device-WB/S/P	48177	B	6
D-FI2MGD25	β2MG Test Device-WB/S/P	53930	B	6
D-FINGALD25	N-GAL Test Device-Urine	47426	C	3j
D-FIHBA1CD25	HbA1c Test Device-WB	65958	C	3k
D-FIIGED25	IgE Test Device-WB/S/P	60380	C	3e
D-FIFED25	Ferritin Test Device-S/P	58769	B	6
D-CAND20	Candida Albicans Rapid Test Device – Swab	63216	B	6
D-CHAGBD20	Cholera Ag O139 Rapid Test Device – Feces	51840	c	3c
D-COVAGD20B	SARS-CoV-2 Antigen Rapid Test Device – swab	64787	D	1
D-COVAGD20H	COVID-19 Antigen Rapid Test Device – Oral Fluid	64787	D	1
D-COVGD25	COVID-19 IgG Rapid Test Device – WB/S/P	64831	D	1
D-COVID1	SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test Device – Nasal Swab	64770	D	1
D-COVID20	SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test Device – Nasal Swab	64770	D	1
D-DOA12D20S	Ecstasy (MDMA) Rapid Test Device – Saliva	46994	B	6
D-DOA2D20S	Methamphetamine (MET) Rapid Test Device - Saliva	46994	B	6
D-DOA31D20S	Cotinine (COT) Rapid Test Device – Salvia	46994	B	6
D-DOA3D20S	Opiates (OPI) Rapid Test Device – Saliva	46994	B	6
D-DOA43D20D	6-Monoacetylmorphine (6-MAM) Rapid Test Device – Salvia	46994	B	6
D-DOA50D40	Pregabaline (PGB) Rapid Test Device – Urine	46994	B	6
D-DOA50S50	Pregabaline (PGB) Rapid Test Strip – Urine	46994	B	6
D-DOA51D20	Synthetic Marijuana (K2) Rapid Test Device – Urine	46994	B	6
D-DOA51S50	Synthetic Marijuana (K2) Rapid Test Strip – Urine	46994	B	6
D-DOA58S40	Ethyl Glucuronide (ETG) Rapid Test Strip – Urine	46994	B	6
D-DOA62S25S	Methylenedioxypyrovalerone (MDPV) Rapid Test Device – Saliva	46994	B	6
D-DOA6D20S	Cocaine (COC) Rapid Test Device – Saliva	46994	B	6
D-DOA7D20S	Methadone (MTD) Rapid Test Device – Saliva	46994	B	6
D-DOAS50	Methadone (MTD) Rapid Test Strip – Urine	46994	B	6
D-DOA8D20S	Marijuana (THC) Rapid Test Device – Saliva	46994	B	6
D-DOAM10UT	Multi- Drug 10 drugs inc. T ramadol Rapid Test Device – Urine	46994	B	6
D-GL10D	Giardia Lamblia Rapid Test Device – Feces	52249	B	6
D-GONOD20	Gonorrhea Rapid Test Device – Swab	51228	C	3a
D-HBAC1CD10	HbA1c Rapid Test Device – WB	65322	C	3k
D-HCGS0	(hCG) Rapid Test Device plain/no box – Urine/S/P	66850	B	6
D-HPD20	H.pylori Rapid Test Device – WB/S/P	30825	B	6
D-HPD40	H.pylori Antibody Rapid Test Device – WB/S/P	30825	B	6
D-HPVD20	HPV Antigen Rapid Test Device – Cervical Swab	63733	B	6

D-INFABS50	Influenza A+B Rapid Test Strip – Swab/Nasal Aspirate	49119	B	6
D-LACFD20	Lactoferrin Rapid Test Device – Feces	53910	B	6
D-MASQS50	Micro-Albumin Semi-Quantitative Rapid Test Strip – Urine	60471	B	6
D-MCKTMD40	Myoglobin/CK-MB/Troponin I Combo Rapid Test Device – WB/S/P	61295	C	3j
D-TETD20	Tetanus Rapid Test Device – WB/S/P	50867	B	6
D-TPS100	Syphilis Rapid Test Strip – WB/S/P	51788	C	3a
D-TRFOBHB	Transferrin, FOB, Hb+Hb+Hp Rapid Test Device – Feces	65270	B	6
D-TROPQD20	Troponin I (cTNI) Semi Quantitative Test Rapid Test Device –	46989	C	3j
D-TRVAD10	Trichomonas Vaginalis Rapid Test Device – Swab	52471	C	3a
D-TYGMCD40	Typhoid Rapid Test Device – WB/S/P	63976	C	3e
D-TYGMD40	Typhoid Rapid Test Device – S/P	63976	C	3e
D-COVAGD25H	SARS-CoV-2 Antigen Rapid Test Device – Oral Fluid	64787	D	1
D-DOA30DM25S	Tramadol (TML) Rapid Test Device – Midstream Saliva	46994	B	6
D-SHID20	Shigella Rapid Test Device – Faeces	64874	C	3b
D-FICOVID10	COVID-19 Antigen Rapid Test Device – Nasopharyngeal Swab	64787	D	1
D-HAVMD20	HAV IgM Rapid Test S/P	48270	B	6
D-NGALD10	NGAL Rapid test WB/S/P	47427	C	3j
D-COVD25B	SARS-CoV-2 IgG/ IgM Rapid Test Device (WB/S/P)	64756	D	1
D-CHAGS50	Cholera Ag Rapid test - Faeces	51840	C	3c
D-RDOA40D40	Alcohol(ALC) Rapid Test Casette (for Reader)-Urine	64159	B	6
D-RDOA6725S	Marijuana (THC) Rapid Test device (for Reader)-Saliva	30519	B	6
D-RDOA1M25S	Amphetamine (AMP) Rapid Test Midstream (for Reader)-Saliva	46994	B	6
D-RDOA4M25S	Barbiturate (BAR) Rapid Test Midstream (for Reader)-Saliva	46994	B	6
D-RDOA11M25S	Buprenorphine (BUP) Rapid Test Midstream (for Reader)-Saliva	65385	B	6
D-RDOA5M20S	Benzodiazepines (BZO) Rapid Test Midstream (for Reader)-Saliva	46994	B	6
D-RDOA6M25S	COCAINE (COC) Rapid Test Midstream (for Reader)-Saliva	46994	B	6
D-RDOA2M25S	Methamphetamine (MET) Rapid Test Midstream (for Reader)-Saliva	55498	B	6
D-RDOA7M25S	Methadone (MTD) Rapid Test Midstream (for Reader)-Saliva	30521	B	6
D-RDOA3M25S	Opiates (OPI) Rapid Test Midstream (for Reader)-Saliva	55701	B	6
D-RDOA13M25S	Phencyclidine (PCP) Rapid Test Midstream (for Reader)-Saliva	30523	B	6
D-RDOA51M25S	Synthetic Marijuana (K2) Rapid Test Midstream (for Reader)-Saliva	30519	B	6
D-FIMAD25	Micro-albumin Test device(for Analyzer)-urine	53479	B	6
D-LEIGID20	Legionella Antigen Rapid Test Device – T hroat Swab	51054	C	3c
D-RUBMD10	Rubella Ig M Rapid Test Device – Serum/Plasma	65734	C	3d
D-TOXOWBS50	Toxoplasmosis IgG/ Ig M Rapid Test Strip – WB/S/ P	65735	C	3d
D-TBSPD20	Tuberculosis (TB) Rapid Test Device – WB/S/P	65814	C	3e
D-MPFPVBD20	Malaria P.f./P.v. Rapid Test Device -WB/S/P	63331	C	3c
D-DGMCMD20	Dengue + Chik (IgG/IgM-Chik IgM) Test – WB/S/P	63970	B	6

Annex

The below updates aren't stipulated as a significant change under the IVDR.

Date of Update	Update made	Signature		
15/12/2023	Added new GMDN codes			
Part/Catalogue Number	Description/Name	GMDN Code	IVDR CLA	Rule
D-HPVCSD25	HPV Antigen Rapid Test -Cervical Swab	49993	C	3a
D-HEMS50	HB Hemoglobin Strip	63089	B	6
D-COVIRCS20	COVID-19,Flu A+B &RSV Combo Rapid Test -Nasopharyngeal swab	64770	D	1
D-SCIABRSVAPNS20	SARS-CoV-2 & Influenza A+B & RSV & Adenovirus & M.pneumoniae Antigen Combo Rapid Test -Nasopharyngeal swab	64770	D	1
D-DOA70D40	Tapentadol (TAP) Rapid Test -Urine	46994	B	6
D-DOA70P40	Tapentadol (TAP) Rapid Test -Urine	46994	B	6
D-DOA70S50	Tapentadol (TAP) Rapid Test -Urine	46994	B	6
D-DOA40SS50	Alcohol Rapid Test Dipstick(Saliva)	64159	B	6
D-DOA40D25	Alcohol (ALC) Oral Fluid Cassette	64159	B	6
D-DOA40BBD15	Breath Alcohol Test (With Blow bag) Cassette	64159	B	6
D-DOA40BBD20	Breath Alcohol Test (Without Blow bag) Cassette	64159	B	6
D-LPD25	Legionella pneumophila Rapid Test -Urine	51054	C	3c
D-LPSPD10	Legionella pneumophilla & Streptococcus pneumoniae Rapid Test -Urine	63143	C	3c
D-U12100	Urinalysis Strips 12 Parameter	63695	B	6
D-U13100	Urinalysis Strips 13 Parameter	63695	B	6
D-U14100	Urinalysis Strips 14 Parameter	63695	B	6
D-HSV1D20	HSV-1 IgG/IgM Rapid Test -WB/S/P	49556	C	3a
D-HSV2D20	HSV-2 IgG/IgM Rapid Test -WB/S/P	49556	C	3a
D-CLOSGTD10	C. difficile GDH+ Toxin A +Toxin B Combo Rapid Test -Faeces	50831	B	6

Certificate of Registration

This certificate has been awarded to

Rapid Labs Limited

Unit 2 & 2A Hall Farm, Business Centre, Church Road, Little Bentley, Colchester, Essex, CO7 8SD, United Kingdom

in recognition of the organization's Quality Management System which complies with

ISO 13485:2016

The scope of activities covered by this certificate is defined below

Please refer to the Appendix

Certificate Number **55321/A/0001/UK/En**

A certificate number of 0001, confirms the Client has a single site Certified & the site is their Head Office or Main site in relation to the Certified scope with URS. A certificate number of 0002, or greater (e.g.: xxxx/B/0002/UK/En) refers to a client that has more than one site certified with URS, as such, the following statement shall apply - 'The validity of this certificate depends on the validity of the main certificate'.

Date of Issue of Certification Cycle	Issue Number	Certificate Expiry Date	Certification Cycle
16 October 2024	**10**	**15 October 2027**	**5**
Revision Date	Revision Number	Original Certificate Issue Date	Scheme Number
11 July 2024	**0**	**09 November 2012**	**n/a**

For detailed explanation for the data fields above, refer to http://www.urs-holdings.com/logos-and-regulations

Issued by Mukesh Singhal - On behalf of the Schemes Manager

Appendix to Certificate

Design, Development, Manufacture and Supply of In-Vitro Diagnostic Products for the Blood Grouping products, Detection of Hormones, Drug of Abuse, Infectious Disease, Tumour Markers and Cardiac Markers, and the related POCT Analyzer. Supply of Glass Vials and Bottles

Certificate Number **55321/A/0001/UK/En**

A certificate number of 0001, confirms the Client has a single site Certified & the site is their Head Office or Main site in relation to the Certified scope with URS. A certificate number of 0002, or greater (e.g.: xxxx/B/0002/UK/En) refers to a client that has more than one site certified with URS, as such, the following statement shall apply - 'The validity of this certificate depends on the validity of the main certificate'.

Date of Issue of Certification Cycle	Issue Number	Certificate Expiry Date	Certification Cycle
16 October 2024	**10**	**15 October 2027**	**5**
Revision Date	Revision Number	Original Certificate Issue Date	Scheme Number
11 July 2024	**0**	**09 November 2012**	**n/a**

For detailed explanation for the data fields above, refer to http://www.urs-holdings.com/logos-and-regulations

Issued by

Mukesh Singhal - On behalf of the Schemes Manager

RAPID BIOTEC™ CE IVD

AMP Rapid Test Device (Whole Blood/Serum/Plasma)

CATALOGUE NUMBER

D-DOA1WBD40

A rapid test for the qualitative detection of Amphetamine in human whole blood or serum or plasma. For medical and other professional in vitro diagnostic use only.

INTENDED USE

The AMP Rapid Test Device (Whole Blood/Serum/Plasma) is a lateral flow chromatographic immunoassay for the detection of Amphetamine in whole blood or serum or plasma at a cut-off concentration of 80ng/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 confirmedanalytical result. Gas chromatographymass 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.

SUMMARY

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.[1]

PRINCIPLE

The AMP Rapid Test Device (Whole Blood/Serum/Plasma) is an immunoassay based on the principle of competitive binding. Drugs that may be present in the whole blood/serum/plasma specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a whole blood/serum/plasma specimen migrates upward by capillary action. Amphetamine, if present in the whole blood/serum/plasma 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 Amphetamine-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 Amphetamine level exceeds the cut-off level because it will saturate all the binding sites of anti- Amphetamine antibodies.

A drug-positive whole blood/serum/plasma specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative whole blood/serum/plasma 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 controlline region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

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

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 whenspecimens 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 stablethrough the expiration date printed on the sealed pouch. The test must remain in the sealed pouch untiluse. **DO NOT FREEZE**. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The AMP Rapid Test Device can be performed using whole blood (from venipuncture or fingerstick) or serum or plasma.
- 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 FingerstickWhole blood specimen to the test by using **a capillary tube**:
    - Touch the end of the capillary tube to the blood until filled to approximately 40 μL. 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 well of the test Device.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days, 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 Devices
- Droppers
- Buffer
- Package insert

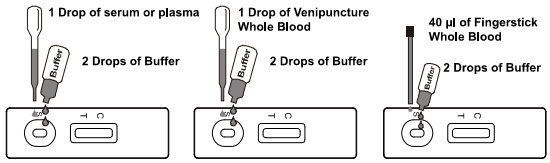
Materials Required But Not Provided

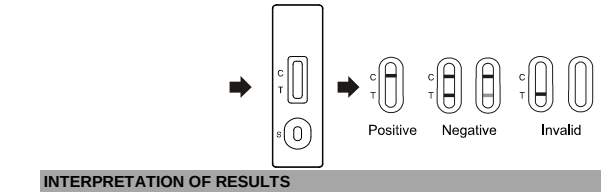
- Specimen collection containers
- Centrifuge
- Lancets (for fingerstick whole blood only)
- Timer
- Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

DIRECTIONS FOR USE

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

1. Bring the pouch to room temperature before opening it. Remove the test Device from the sealed pouch and use it within one hour.
2. Place the Device on a clean and level surface.
   For serum or plasma specimen:
   Hold the dropper vertically and transfer **1 full drop of serum or plasma** (approximately 40μL), then add **2 drops of buffer** (approximately 80μL) to the specimen well of the Device, and then start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.
   For Venipuncture Whole Blood specimen:
   Hold the dropper vertically and transfer **1 drop of whole blood** (approximately 40μL) to the specimen well, then add **2 drops of buffer** (approximately 80μL), 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 well of test Device, then add **2 drops of buffer** (approximately 80μL) and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. **Read the result 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 controlline region (C) and another colored line should be in the test line region (T). This negative result indicates that the Amphetamine 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 controlline region (C). No line appears in the test line region (T). This positive result indicates that the Amphetamine concentration exceeds the detectable cut-off level.

INVALID: Controlline fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for controlline 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 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 AMP Rapid Test Device (Whole Blood/Serum/Plasma) 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.[2]
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 AMP Rapid Test Device and GC/MS at the cut-off of 80ng/mL. Testing was performed on 90 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Clinic Result of Whole Blood

Method		GC/MS		Total Results
AMP Rapid Test Device	Results	Positive	Negative	
	Positive	20	1	21
	Negative	1	68	69
Total Results		21	69	90
% Agreement		95.2%	98.6%	97.8%

Clinic Result of Serum or Plasma

Method		GC/MS		Total Results
AMP Rapid Test Device	Results	Positive	Negative	
	Positive	20	1	21
	Negative	1	68	69
Total Results		21	69	90
% Agreement		95.2%	98.6%	97.8%

Analytical Sensitivity

A drug-free whole blood/serum/plasma pool was spiked with Amphetamine at the following concentrations of ±50% cutoff and 3x cutoff, the data are summarized below:

For whole blood:

AMP Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
40	-50%	30	30	0
80	Cut-off	30	15	15

120	+50%	30	0	30
240	3X	30	0	30

For serum or plasma:

AMP Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
40	-50%	30	30	0
80	Cut-off	30	15	15
120	+50%	30	0	30
240	3X	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in Whole blood/Serum/Plasma by the AMP Rapid Test Device (Whole Blood/Serum/Plasma) at 5 minutes.

Compound	Concentration (ng/mL)
D,L-Amphetamine sulfate	20
L-Amphetamine	3,000
(±) 3,4-Methylenedioxyamphetamine	40
Phentermine	150
Maprotiline	6,000
Methoxyphenamine	1,500
D-Amphetamine	80

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 no Amphetamine, and 50% Amphetamine above and below the 80ng/mL cut-off was provided to each site. The following results were tabulated:

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

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 Amphetamine positive whole blood/serum/plasma. The following compounds show no cross-reactivity when tested with the AMP Rapid Test Device (Whole Blood/Serum/Plasma) at a concentration of 100 μg/mL.

Non Cross-Reacting Compounds

4-Acetamidophenol	Creatinine	Ketoprofen	Procaine
Acetophenetidin	Deoxycorticosterone	labetalol	Promazine
N-Acetylprocainamide	Dextromethorphan	levorphanol	Promethazine
Acetylsalicylic acid	Diazepam	loperamide	D,l-Propanolol
Aminopyrine	Diclofenac	Maprotiline	D-Propoxyphene
Amitryptyline	Diflunisal	Meperidine	D-Pseudoephedrine
Amobarbital	Digoxin	Meprobamate	Quinidine
Amoxicillin	Diphenhydramine	Methadone	Quinine
Ampicillin	Doxylamine	D-Methamphetamine	Ranitidine
l-Ascorbic acid	Ecgonine hydrochloride	l-Methamphetamine	Salicylic acid
Apomorphine	Ecgoninemethylester	Methoxyphenamine	Secobarbital
Aspartame	(IR,2S)-(-)-Ephedrine	3,4-Methylenedioxyethyl-	Serotonin
Atropine	l-Ephedrine	amphetamine	(5-Hydroxytyramine)
Benzilic acid	(-)-ψ-Ephedrine	(±) 3,4-Methylenedioxy-	Sulfamethazine
Benzoic acid	Erythromycin	methamphetamine	Sulindac
Benzoylecgonine	β-Estradiol	Methylphenidate	Temazepam
Benzphetamine	Estrone-3-sulfate	Morphine-3-β-D-	Tetracycline
Bilirubin	Ethyl-p-aminobenzoate	glucuronide	Tetrahydrocortisone,
(±)-Brompheniramine	Fenfluramine	Nalidixic acid	3-Acetate
Caffeine	Fenoprofen	Naloxone	Tetrahydrocortisone
Cannabidiol	Furosemide	Oxolinic acid	3-(β-D glucuronide)
Cannabinol	Gentisic acid	Oxycodone	Tetrahydrozoline
Chloralhydrate	Hemoglobin	Oxymetazoline	Thebaine
Chloramphenicol	Hydralazine	Papaverine	Thiamine
Chlordiazepoxide	Hydrochlorothiazide	Penicillin-G	Thioridazine
Chlorothiazide	Hydrocodone	Pentazocine	Tolbutamine
(±) Chlorpheniramine	Hydrocortisone	Pentobarbital	Triamterene
Chlorpromazine	p-Hydroxyamphetamine	Perphenazine	Trifluoperazine
Chlorquine	O-Hydroxyhippuric acid	Phencyclidine	Trimethoprim
Cholesterol	p-Hydroxymethamphetamine	Phenelzine	Trimipramine
Clomipramine	3-Hydroxytyramine	Phenobarbital	D, l-Tryptophan
Clonidine	Ibuprofen	l-Phenylephrine	Tyramine
Cocaine hydrochloride	Imipramine	β-Phenylethlamine	D, l-Tyrosine
Codeine	(±)-Isoproterenol	Phenylpropanolamine	Uric acid
Cortisone	Isoxsuprine	Prednisolone	Verapamil
(-) Cotinine	Ketamine	Prednisone	Zomepirac
4-Acetamidophenol	Creatinine	Ketoprofen	Procaine

Interfering Substances

The AMP Rapid Test Device (Whole Blood/Serum/Plasma) has been tested for possible interference from visibly hemolyzed and lipemic specimens. In addition, no interference was observed in specimens containing up to 100 mg/dL hemoglobin; up to 100 mg/dL bilirubin and up to 200 mg/dL human serum albumin.

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

Index of Symbols

	Consult instructions for use	Σ	Contains sufficient for <*n*> test	EC REP	Authorized representative in the European Community/European Union
IVD	*In vitro* diagnostic medical device		Use-by date		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Batch code	REF	Catalogue number
	Do not use if package is damaged and consult instructions for use		Manufacturer		Date of manufacture

EC REP Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta

Rapid Labs Ltd
Unit 2 & 2A Hall Farm Business
Centre Church Road Little Bentley Colchester
Essex CO7 8SD
United Kingdom

Revision 1 24/06/2024

RAPID BIOTEC™

CE IVD

MET Rapid Test Device
(Whole Blood/Serum/Plasma)

CATALOGUE NUMBER
D-DOA2WBD40

A rapid test for the qualitative detection of Methamphetamine in human whole blood or serum or plasma.
For medical and other professional in vitro diagnostic use only.

INTENDED USE

The MET Rapid Test Device (Whole Blood/Serum/Plasma) is a lateral flow chromatographic immunoassay for the detection of Methamphetamine in whole blood/serum/plasma at a cut-off concentration of 70ng/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.

SUMMARY

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 or serum or 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 or serum or plasma indicates Methamphetamine use. Methamphetamine is generally detectable in the whole blood or serum or plasma for 3-5 days, depending on whole blood or serum or plasma pH level.[1]

PRINCIPLE

The MET Rapid Test Device (Whole Blood/Serum/Plasma) is an immunoassay based on the principle of competitive binding. Drugs that may be present in the whole blood/serum/plasma specimen compete against the drug conjugate for binding sites on the antibody.
During testing, a whole blood/serum/plasma specimen migrates upward by capillary action. Methamphetamine, if present in the whole blood/serum/plasma 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 Methamphetamine-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 Methamphetamine level exceeds the cut-off level because it will saturate all the binding sites of anti-Methamphetamineantibodies.
A drug-positive whole blood/serum/plasma specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative whole blood/serum/plasma 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-Methamphetamineantibody coupled particles and Methamphetamine-protein conjugate. A goat antibody is employed in the control line system.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Do not use test if pouch is damaged
4. 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 ofspecimens.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection whenspecimens are being tested.
6. The used test should be discarded according to local regulations.
7. 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 stablethrough the expiration date printed on the sealed pouch. The test must remain in the sealed pouch untiluse. **DO NOT FREEZE**. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The MET Rapid Test Device can be performed using whole blood (from venipuncture or fingerstick)/serum/plasma.
- 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 40 μL. 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 well of the test device.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days, 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 devices • Droppers • Buffer • Package insert

Materials Required But Not Provided

• Specimen collection containers • Centrifuge
• Lancets (for fingerstick whole blood only) • Timer
• Heparinized 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.

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

For serum or plasma specimen:

•Hold the dropper vertically and transfer **1 full drop of serum or plasma** (approximately 40μL), then add **2 drops of buffer** (approximately 80μL) to the specimen well(S) of the device, and then start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.

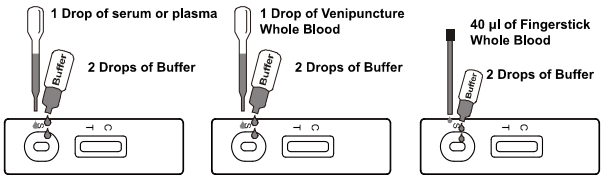
For Venipuncture Whole blood specimen:

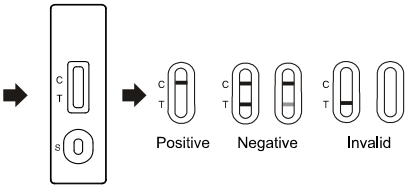
•Hold the dropper vertically and transfer **1 drop of whole blood** (approximately 40μL) to the specimen well(S), then **add 2 drops of buffer** (approximately 80μL), and start the timer. See illustration below.

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 well(S) of test device, then add **2 drops of buffer** (approximately 80μL) and start the timer. See illustration below.

3. Wait for the colored line(s) to appear. **Read the result 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 Methamphetamine 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 Methamphetamine 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 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 MET Rapid Test Device (Whole Blood/Serum/Plasma) 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.[2]
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 MET Rapid Test Device and GC/MS at the cut-off of 70ng/mL. Testing was performed on 90 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Clinic Result of Whole Blood

Method		GC/MS		Total Results
MET Rapid Test Device	Results	Positive	Negative	
	Positive	25	2	27
	Negative	2	61	63
Total Results		27	63	90
% Agreement		92.6%	96.8%	95.6%

Clinic Result of Serum or Plasma

Method		GC/MS		Total Results
MET Rapid Test Device	Results	Positive	Negative	
	Positive	25	2	27
	Negative	2	61	63
Total Results		27	63	90
% Agreement		92.6%	96.8%	95.6%

Analytical Sensitivity

A drug-free whole blood/serum/plasma was spiked with MET at the following concentrations of ±50% cutoff and 3x cutoff, the data are summarized below:

For whole blood:

MET Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
35	-50%	30	30	0
70	Cut-off	30	14	16
105	+50%	30	0	30
210	3X	30	0	30

For serum or plasma:

MET Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
35	-50%	30	30	0
70	Cut-off	30	14	16
105	+50%	30	0	30
210	3X	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in whole blood/serum/plasma by the MET Rapid Test Device (Whole Blood/Serum/Plasma) at 5 minutes.

Compound	Concentration (ng/mL)
ρ-Hydroxymethamphetamine	1,800
D-Methamphetamine	70
L-Methamphetamine	1,500
(±)-3,4-Methylenedioxy-methamphetamine	900
Mephentermine	3,500

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 no Methamphetamine and 50% Methamphetamine above and below the 70ng/mL cut-off was provided to each site. The following results were tabulated:

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

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free whole blood or determine positive whole blood/serum/plasma. The following compounds show no cross-reactivity when tested with the MET Rapid Test Device (Whole Blood/Serum/Plasma) at a concentration of 100 μg/mL.

Non Cross-Reacting Compounds

4-Acetamidophenol	Creatinine	Loperamide	Prednisone
Acetophenetidin	Deoxycorticosterone	Maprotiline	Procaine
N-Acetylprocainamide	Dextromethorphan	Meperidine	Promazine
Acetylsalicylic acid	Diazepam	Meprobamate	Promethazine
Aminopyrine	Diclofenac	Methadone	D,L-Propanolol
Amitryptyline	Diflunisal	Methoxyphenamine	D-Propoxyphene
Amobarbital	Digoxin	(+) 3,4-Methylenedioxy-	D-Pseudoephedrine
Amoxicillin	Diphenhydramine	amphetamine	Quinacrine
Ampicillin	Doxylamine	3,4-Methylenedioxyethyl-	Quinidine
L-Ascorbic acid	Ecgonine hydrochloride	amphetamine	Quinine
D-Amphetamine	Ecgoninemethylester	Methylphenidate	Ranitidine
D,L-Amphetamine	(1R,2S)-(-)-Ephedrine	Morphine-3-β-D-	Salicylic acid
L-Amphetamine	L-Epinephrine	glucuronide	Secobarbital
Apomorphine	(-)-ψ-Ephedrine	Nalidixic acid	Serotonin
Aspartame	Erythromycin	Naloxone	(5-Hydroxytyramine)
Atropine	β-Estradiol	Naltrexone	Sulfamethazine
Benzilic acid	Estrone-3-sulfate	Naproxen	Sulindac
Benzoic acid	Ethyl-p-aminobenzoate	Niacinamide	Temazepam
Benzoylecgonine	Fenfluramine	Nifedipine	Tetracycline
Benzphetamine	Fenoprofen	Norethindrone	Tetrahydrocortisone,
Bilirubin	Furosemide	D-Norpropoxyphene	3-Acetate
(±)-Brompheniramine	Gentisic acid	Noscapine	Tetrahydrocortisone
Caffeine	Hemoglobin	D,L-Octopamine	3-(β-D glucuronide)
Cannabidiol	Hydralazine	Oxalic acid	Tetrahydrozoline
Chloralhydrate	Hydrochlorothiazide	Oxazepam	Thiamine
Chloramphenicol	Hydrocodone	Oxolinic acid	Thioridazine
Chlordiazepoxide	Hydrocortisone	Oxycodone	D, L-Tyrosine
Chlorothiazide	p-Hydroxyamphetamine	Oxymetazoline	Tolbutamine
(±) Chlorpheniramine	O-Hydroxyhippuric acid	Papaverine	Trans-2- phenyl
Chlorpromazine	3-Hydroxytyramine	Penicillin-G	cyclopropylamine
Chlorquine	Ibuprofen	Pentobarbital	Triamterene
Cholesterol	Imipramine	Perphenazine	Trifluoperazine
Clomipramine	Iproniazid	Phencyclidine	Trimethoprim
Clonidine	(±)-Isoproterenol	Phenelzine	Trimipramine
Cocaethylene	Isoxsuprine	Phenobarbital	Tryptamine
Cocaine hydrochloride	Ketamine	Phentermine	D, L-Tryptophan
Codeine	Ketoprofen	L-Phenylephrine	Tyramine

Interfering Substances

The MET Rapid Test Device (Whole Blood/Serum/Plasma) has been tested for possible interference from visibly hemolyzed and lipemic specimens. In addition, no interference was observed in specimens containing up to 100 mg/dL hemoglobin; up to 100 mg/dL bilirubin and up to 200 mg/dL human serum albumin.

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

Index of Symbols

	Consult instructions for use	Σ	Contains sufficient for <*n*> test	EC REP	Authorized representative in the European Community/European Union
IVD	*In vitro* diagnostic medical device		Use-by date		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Batch code	REF	Catalogue number
	Do not use if package is damaged and consult instructions for use		Manufacturer		Date of manufacture

EC REP Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta

Rapid Labs Ltd
Unit 2 & 2A Hall Farm Business
Centre Church Road Little Bentley Colchester
Essex CO7 8SD
United Kingdom

Revision 1 24/06/2024

RAPID BIOTEC™

CE IVD

BAR Rapid Test Device
(Whole Blood/Serum/Plasma)

CATALOGUE NUMBER
D-DOA4WBD40

A rapid test for the qualitative detection of Barbiturates in human whole blood or serum or plasma.
For medical and other professional in vitro diagnostic use only.

INTENDED USE

The BAR Rapid Test Device (Whole Blood/Serum/Plasma) is a lateral flow chromatographic immunoassay for the detection of Barbiturates in whole blood or serum or plasma 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.

SUMMARY

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[1].

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[2]

PRINCIPLE

The BAR Rapid Test Device (Whole Blood/Serum/Plasma) is an immunoassay based on the principle of competitive binding. Drugs that may be present in the whole blood/serum/plasma specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a whole blood/serum/plasma specimen migrates upward by capillary action. Barbiturates, if present in the whole blood/serum/plasma 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 Barbiturates-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 Barbiturates level exceeds the cut-off level because it will saturate all the binding sites of anti-Barbiturates antibodies.

A drug-positive whole blood/serum/plasma specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative whole blood/serum/plasma 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-Barbiturates antibody coupled particles and Barbiturates -protein conjugate. A goat antibody is employed in the control line system.

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 BAR Rapid Test Device can be performed using whole blood (from venipuncture or fingerstick)/serum/plasma.
- 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 40 μL. 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 well of the test Device.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days, 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 Devices • Droppers • Buffer • Package insert

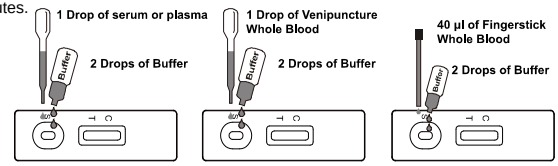
Materials Required But Not Provided

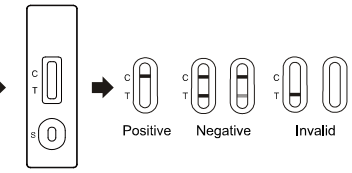
• Specimen collection containers • Centrifuge
• Lancets (for fingerstick whole blood only) • Timer
• Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

DIRECTIONS FOR USE

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

1. Bring the pouch to room temperature before opening it. Remove the Device from the sealed pouch and use it within one hour.
2. Place the Device on a clean and level surface.
   For serum or plasma specimen:
   Hold the dropper vertically and transfer **1 full drop of serum or plasma** (approximately 40μL), then add **2 drops of buffer** (approximately 80μL) to the specimen well of the Device, and then start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.
   For Venipuncture Whole Blood specimen:
   Hold the dropper vertically and transfer **1 drop of whole blood** (approximately 40μL) to the specimen well, then add **2 drops of buffer** (approximately 80μL), 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 well of test Device, then add **2 drops of buffer** (approximately 80μL) and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. **Read the result 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 Barbiturates 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 Barbiturates 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 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 BAR Rapid Test Device (Whole Blood/Serum/Plasma) 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.[2]
2. It is possible that technical or procedural errors, as well as other interfering substances in the whole blood/serum/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/serum/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 BAR Rapid Test Device and GC/MS at the cut-off of 100ng/mL. Testing was performed on 90 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Clinic Result of Whole Blood

Method		GC/MS		Total Results
BAR Rapid Test Device	Results	Positive	Negative	
	Positive	20	2	22
	Negative	2	66	68
Total Results		22	68	90
% Agreement		90.9%	97.1%	95.6%

Clinic Result of Serum or Plasma

Method		GC/MS		Total Results
BAR Rapid Test Device	Results	Positive	Negative	
	Positive	20	2	22
	Negative	2	66	68
Total Results		22	68	90
% Agreement		90.9%	97.1%	95.6%

Analytical Sensitivity

A drug-free whole blood/serum/plasma pool was spiked with Barbiturates at the following concentrations of ±50% cutoff and 3x cutoff, the data are summarized below:

For whole blood:

BAR Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
50	-50%	30	30	0
100	Cut-off	30	16	14
150	+50%	30	0	30
300	3X	30	0	30

For serum or plasma:

BAR Concentration	Percent of	n	Visual Result

(ng/mL)	Cut-off		Negative	Positive
0	0	30	30	0
50	-50%	30	30	0
100	Cut-off	30	16	14
150	+50%	30	0	30
300	3X	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in whole blood/serum/plasma by the BAR Rapid Test Device (Whole Blood/Serum/Plasma) at 5 minutes.

Compound	Concentration (ng/mL)
Amobarbital	1,500
5,5-Diphenylhydantoin	2,500
Allobarbital	200
Barbital	2,500
Talbutal	80
Cyclopentobarbital	10,000
Pentobarbital	2,500
Alphenol	200
Aprobarbital	150
Butabarbital	80
Butalbital	2,500
Butethal	150
Secobarbital	100

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 no Barbiturates, and 50% Barbiturates above and below the 100ng/mL cut-off was provided to each site. The following results were tabulated:

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

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 Barbiturates positive whole blood/serum/plasma. The following compounds show no cross-reactivity when tested with the BAR Rapid Test Device (Whole Blood/Serum/Plasma) at a concentration of 100 μg/mL.

Non Cross-Reacting Compounds

Acetaminophenol	Diazepam	MDE	Phenylpropanolamine
Acetophenetidin	Diclofenac	Meperidine	Prednisolone
N-Acetylprocainamide	Diflunisal	Meprobamate	Prednisone
Acetylsalicylic acid	Digoxin	Methadone	Procaine
Aminopyrine	Diphenhydramine	l-Methamphetamine	Promazine
Amitryptyline	Doxylamine	Methoxyphenamine	Promethazine
Amoxicillin	Ecgonine hydrochloride	(±) - 3,4-Methylenedioxy-	D,l-Propranolol
Ampicillin	Ecgoninemethylester	amphetamine	D-Propoxyphene
l-Ascorbic acid	(-) -ψ-Ephedrine	(±) - 3,4-Methylenedioxy	D-Pseudoephedrine
D,l-Amphetamine sulfate	[1R,2S] (-) Ephedrine	methmphetamine	Quinacrine
Apomorphine	l - Epinephrine	Morphine-3-β-D glucuronide	Quinidine
Aspartame	Erythromycin	Morphine Sulfate	Quinine
Atropine	β-Estradiol	Nalidixic acid	Ranitidine
Benzilic acid	Estrone-3-sulfate	Naloxone	Salicylic acid
Benzoic acid	Ethyl-p-aminobenzoate	Naltrexone	Serotonin
Benzoylecgonine	Fenoprofen	Naproxen	Sulfamethazine
Benzphetamine	Furosemide	Niacinamide	Sulindac
Bilirubin	Gentisic acid	Nifedipine	Temazepam
(±) - Brompheniramine	Hemoglobin	Norcodein	Tetracycline
Caffeine	Hydralazine	Norethindrone	Tetrahydrocortisone,
Cannabidiol	Hydrochlorothiazide	D-Norpropoxyphene	3-Acetate
Cannabinol	Hydrocodone	Noscapine	Tetrahydrocortisone
Chloralhydrate	Hydrocortisone	D,l-Octopamine	3-(β-D-glucuronide)
Chloramphenicol	O-Hydroxyhippuric acid	Oxalic acid	Tetrahydrozoline
Chlorothiazide	p-Hydroxyamphetamine	Oxazepam	Thiamine
(±) - Chlorpheniramine	p-Hydroxy-	Oxolinic acid	Thioridazine
Chlorpromazine	methamphetamine	Oxycodone	D,l-Tyrosine
Chlorquine	3-Hydroxytyramine	Oxymetazoline	Tolbutamide
Cholesterol	Ibuprofen	Papaverine	Triamterene
Clomipramine	Imipramine	Penicillin-G	Trifluoperazine
Clonidine	Iproniazid	Pentazocine hydrochloride	Trimethoprim
Cocaethylene	(±) - Isoproterenol	Perphenazine	Trimipramine
Cocaine hydrochloride	Isoxsuprine	Phencyclidine	Tryptamine
Codeine	Ketamine	Phenelzine	D,l-Tryptophan
Cortisone	Ketoprofen	Phentermine	Tyramine
(-) Cotinine	labetalol	Trans-2-phenylcyclo-	Uric acid
Creatinine	levorphanol	propylamine hydrochloride	Verapamil

Interfering Substances

The BAR Rapid Test Device (Whole Blood/Serum/Plasma) has been tested for possible interference from visibly hemolyzed and lipemic specimens. In addition, no interference was observed in specimens containing up to 100 mg/dL hemoglobin;up to 100 mg/dL bilirubin; and up to 200 mg/dL human serum albumin.

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

Index of Symbols

	Consult instructions for use		Contains sufficient for <*n*> test	EC REP	Authorized representative in the European Community/European Union
IVD	*In vitro* diagnostic medical device		Use-by date		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Batch code	REF	Catalogue number
	Do not use if package is damaged and consult instructions for use		Manufacturer		Date of manufacture

EC REP Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta

Rapid Labs Ltd
Unit 2 & 2A Hall Farm Business
Centre Church Road Little Bentley Colchester
Essex CO7 8SD
United Kingdom

Revision 1 24/06/2024

RAPID BIOTEC™ CE IVD

BZO Rapid Test Device (Whole Blood/Serum/Plasma)

CATALOGUE NUMBER
D-DOA5WBD40

A rapid test for the qualitative detection of Benzodiazepines in human whole blood or serum or plasma.
For medical and other professional in vitro diagnostic use only.

INTENDED USE

The BZO Rapid Test Device (Whole Blood/Serum/Plasma) is a lateral flow chromatographic immunoassay for the detection of Benzodiazepines in whole blood or serum or plasma 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.

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 whole blood or serum or plasma; most of the concentration in whole blood or serum or plasma is conjugated drug. The detection period for benzodiazepines in whole blood or serum or plasma is 3-7 days.

PRINCIPLE

The BZO Rapid Test Device (Whole Blood/Serum/Plasma) is an immunoassay based on the principle of competitive binding. Drugs that may be present in the whole blood/serum/plasma specimen compete against the drug conjugate for binding sites on the antibody.
During testing, a whole blood/serum/plasma specimen migrates upward by capillary action. Benzodiazepines, if present in the whole blood/serum/plasma 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 antibodies.
A drug-positive whole blood/serum/plasma specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative whole blood/serum/plasma 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 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 BZO Rapid Test Device can be performed using whole blood (from venipuncture or fingerstick) /serum/plasma.
- 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 40 µL. 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 well of the test Device.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days, 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 Devices • Droppers • Buffer • Package insert

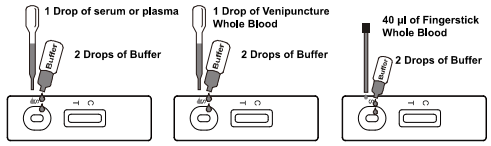
Materials Required But Not Provided

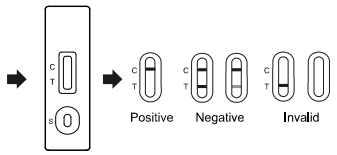
• Specimen collection containers • Centrifuge
• Lancets (for fingerstick whole blood only) • Timer
• Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

DIRECTIONS FOR USE

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

1. Bring the pouch to room temperature before opening it. Remove the Device from the sealed pouch and use it within one hour.
2. Place the Device on a clean and level surface.
   For serum or plasma specimen:
   Hold the dropper vertically and transfer **1 full drop of serum or plasma** (approximately 40µL), then add **2 drops of buffer** (approximately 80µL) to the specimen well of the Device, and then start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.
   For Venipuncture Whole Blood specimen:
   Hold the dropper vertically and transfer **1 drop of whole blood** (approximately 40µL) to the specimen well, then add **2 drops of buffer** (approximately 80µL), 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 well of test Device, then add **2 drops of buffer** (approximately 80µL) and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. **Read the result 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 Benzodiazepines 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 Benzodiazepines 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 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 BZO Rapid Test Device (Whole Blood/Serum/Plasma) 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.[2]
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 BZO Rapid Test Device and GC/MS at the cut-off of 100ng/mL. Testing was performed on 90 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Clinic Result of Whole Blood

Method		GC/MS		Total Results
BZO Rapid Test Device	Results	Positive	Negative	
	Positive	19	2	21
	Negative	2	67	69
Total Results		21	69	90
% Agreement		90.5%	97.1%	95.6%

Clinic Result of Serum or Plasma

Method		GC/MS		Total Results
BZO Rapid Test Device	Results	Positive	Negative	
	Positive	19	2	21
	Negative	2	67	69
Total Results		21	69	90
% Agreement		90.5%	97.1%	95.6%

Analytical Sensitivity

A drug-free whole blood/serum/plasma pool was spiked with Benzodiazepines at the following concentrations of ±50% cutoff and 3x cutoff, the data are summarized below:

For whole blood:

BZO Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
50	-50%	30	30	0

100	Cut-off	30	15	15
150	+50%	30	0	30
300	3X	30	0	30

For serum or plasma:

BZO Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
50	-50%	30	30	0
100	Cut-off	30	15	15
150	+50%	30	0	30
300	3X	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in whole blood/serum/plasma by the BZO Rapid Test Device (Whole Blood/Serum/Plasma) at 5 minutes.

Compound	Concentration (ng/mL)
Alprazolam	40
a-hydroxyalprazolam	500
Clobazam	60
Clonazepam	150
Clorazepatedipotassium	150
Delorazepam	300
Desalkylflurazepam	60
Flunitrazepam	60
(±) lorazepam	1,000
RS-lorazepamglucuronide	60
Midazolam	2,000
Alprazolam	40
Bromazepam	300
Chlordiazepoxide	300
Nitrazepam	60
Norchlordiazepoxide	40
Nordiazepam	300
Oxazepam	100
Temazepam	40
Diazepam	100
Estazolam	2,000
Triazolam	1,000

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 no Benzodiazepines, and 50% Benzodiazepines above and below the 100ng/mL cut-off was provided to each site. The following results were tabulated:

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

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 Benzodiazepines positive whole blood/serum/plasma. The following compounds show no cross-reactivity when tested with the BZO Rapid Test Device (Whole Blood/Serum/Plasma) at a concentration of 100 μg/mL.

Non Cross-Reacting Compounds

Acetaminophen	Deoxycorticosterone	MDE	β-Phenylethylamine
Acetophenetidin	Dextromethorphan	Meperidine	Phenylpropanolamine
N-Acetylprocainamide	Diclofenac	Meprobamate	Prednisolone
Acetylsalicylic acid	Diflunisal	Methadone	Prednisone
Aminopyrine	Digoxin	l-Methamphetamine	Procaine
Amitryptyline	Diphenhydramine	Methoxyphenamine	Promazine
Amobarbital	Doxylamine	(±) - 3,4-Methylenedioxy-	Promethazine
Amoxicillin	Ecgonine	amphetamine	D,l-Propranolol
Ampicillin	Ecgoninemethylester	(±) - 3,4-Methylenedioxy-	D-Propoxyphene
l-Ascorbic acid	(-)-ψ-Ephedrine	methamphetamine	D-Pseudoephedrine
D,l-Amphetamine sulfate	[1R,2S] (-) Ephedrine	Morphine-3-β-D glucuronide	Quinacrine
Apomorphine	(l) - Epinephrine	Morphine Sulfate	Quinidine
Aspartame	Erythromycin	Nalidixic acid	Quinine
Atropine	β-Estradiol	Naloxone	Ranitidine
Benzilic acid	Estrone-3-sulfate	Naltrexone	Salicylic acid
Benzoic acid	Ethyl-p-aminobenzoate	Naproxen	Secobarbital
Benzoylecgonine	Fenoprofen	Niacinamide	Serotonin
Benzphetamine	Furosemide	Nifedipine	Sulfamethazine
Bilirubin	Gentisic acid	Norcodein	Sulindac
(±) – Brompheniramine	Hemoglobin	Norethindrone	Tetracycline
Caffeine	Hydralazine	D-Norpropoxyphene	Tetrahydrocortisone,
Cannabidiol	Hydrochlorothiazide	Noscapine	3-Acetate
Cannabinol	Hydrocodone	D,l-Octopamine	Tetrahydrocortisone
Chloralhydrate	Hydrocortisone	Oxalic acid	3-(β-D-glucuronide)
Chloramphenicol	O-Hydroxyhippuric acid	Oxolinic acid	Tetrahydrozoline
Chlorothiazide	p-Hydroxyamphetamine	Oxycodone	Thiamine
(±) – Chlorpheniramine	p-Hydroxy-	Oxymetazoline	Thioridazine
Chlorpromazine	methamphetamine	Papaverine	D,l-Tyrosine
Chlorquine	3-Hydroxytyramine	Penicillin-G	Tolbutamide
Cholesterol	Ibuprofen	Pentazocine	Triamterene
Clomipramine	Imipramine	Pentobarbital	Trifluoperazine
Clonidine	Iproniazid	Perphenazine	Trimethoprim
Cocaethylene	(±) - Isoproterenol	Phencyclidine	Trimipramine
Cocaine	Isoxsuprine	Phenelzine	Tryptamine
Codeine	Ketamine	Phenobarbital	D,l-Tryptophan
Cortisone	Ketoprofen	Phentermine	Tyramine
(-) Cotinine	labetalol	Trans-2-phenylcyclo-	Uric acid

Interfering Substances

The BZO Rapid Test Device (Whole Blood/Serum/Plasma) has been tested for possible interferencefrom visibly hemolyzed and lipemic specimens. In addition, no interference was observed in specimens containing up to 100 mg/dL hemoglobin; up to 100 mg/dL bilirubin and up to 200 mg/dL human serum albumin.

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

Index of Symbols

	Consult instructions for use		Contains sufficient for <*n*> test	EC REP	Authorized representative in the European Community/European Union
IVD	*In vitro* diagnostic medical device		Use-by date		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Batch code	REF	Catalogue number
	Do not use if package is damaged and consult instructions for use		Manufacturer		Date of manufacture

EC REP Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta

Rapid Labs Ltd
Unit 2 & 2A Hall Farm Business
Centre Church Road Little Bentley Colchester
Essex CO7 8SD
United Kingdom

Revision 1 24/06/2024

RAPID BIOTEC™

CE IVD

COC Rapid Test Device
(Whole Blood/Serum/Plasma)

CATALOGUE NUMBER
D-DOA6WBD40

A rapid test for the qualitative detection of Cocaine in human whole blood or serum or plasma.
For medical and other professional in vitro diagnostic use only.

INTENDED USE

The COC Rapid Test Device (Whole Blood/Serum/Plasma) is a lateral flow chromatographic immunoassay for the detection of Cocaine inwhole blood or serum or plasma at a cut-off concentration of 50ng/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.

SUMMARY

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 or serum or plasma in a short time primarily as benzoylecgonine.[1,2] 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.[2]

PRINCIPLE

The COC Rapid Test Device (Whole Blood/Serum/Plasma) is an immunoassay based on the principle of competitive binding. Drugs that may be present in the whole blood/serum/plasma specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a whole blood/serum/plasma specimen migrates upward by capillary action. Cocaine, if present in the whole blood/serum/plasma 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 immobilizedCocaine-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 Cocaine level exceeds the cut-off level because it will saturate all the binding sites of anti-Cocaine antibodies.

A drug-positive whole blood/serum/plasma specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative whole blood/serum/plasma 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-Cocaine antibody coupled particles and Cocaine-protein conjugate. A goat antibody is employed in the control line system.

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 ofspecimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection whenspecimens 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 stablethrough 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 COC Rapid Test Device can be performed using whole blood (from venipuncture or fingerstick)/serum/plasma.
- 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 40 µL. 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 well of the test Device.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days, 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 Devices • Droppers • Buffer • Package insert

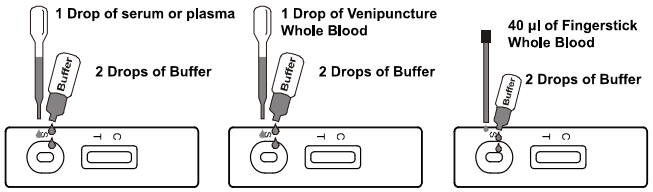
Materials Required But Not Provided

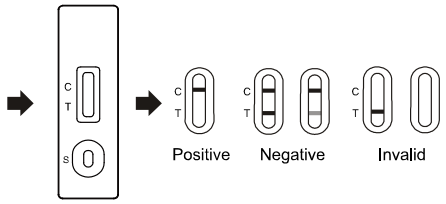
• Specimen collection containers • Centrifuge
• Lancets (for fingerstick whole blood only) • Timer
• Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

DIRECTIONS FOR USE

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

1. Bring the pouch to room temperature before opening it. Remove the Device from the sealed pouch and use it within one hour.
2. Place the Device on a clean and level surface.
   For serum or plasma specimen:
   Hold the dropper vertically and transfer **1 full drop of serum or plasma** (approximately 40µL), then add **2 drops of buffer** (approximately 80µL) to the specimen well of the Device, and then start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.
   For Venipuncture Whole Blood specimen:
   Hold the dropper vertically and transfer **1 drop of whole blood** (approximately 40µL) to the specimen well, then add **2 drops of buffer** (approximately 80µL), 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 well of test Device, then add **2 drops of buffer** (approximately 80µL) and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. **Read the result 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 Cocaine 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 Cocaineconcentration 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 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 COC Rapid Test Device (Whole Blood/Serum/Plasma) 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.[3]
2. It is possible that technical or procedural errors, as well as other interfering substances in theWhole 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 COC Rapid Test Device and GC/MS at the cut-off of 50ng/mL. Testing was performed on 90 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Clinic Result of Whole Blood

Method		GC/MS		Total Results
COC Rapid Test Device	Results	Positive	Negative	
	Positive	25	1	26
	Negative	1	63	64
Total Results		26	64	90
% Agreement		96.2%	98.4%	97.8%

Clinic Result of Serum or Plasma

Method		GC/MS		Total Results
COC Rapid Test Device	Results	Positive	Negative	
	Positive	25	1	26
	Negative	1	63	64
Total Results		26	64	90
% Agreement		96.2%	98.4%	97.8%

Analytical Sensitivity

A drug-free whole blood/serum/plasma pool was spiked with Cocaine at the following concentrations of ±50% cutoff and 3x cutoff, the data are summarized below:

For whole blood:

COC Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
25	-50%	30	30	1
50	Cut-off	30	13	17
75	+50%	30	0	30

150	3X	30	0	30

For serum or plasma:

COC Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
25	-50%	30	30	1
50	Cut-off	30	13	17
75	+50%	30	0	30
150	3X	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in whole blood/serum/plasma by the COC Rapid Test Device (Whole Blood/Serum/Plasma) at 5 minutes.

Compound	Concentration (ng/mL)
Benzoylecgonine	50
Cocaethylene	5,000
Cocaine HCl	60
Ecgonine	7,500

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 no Cocaine, and 50% Cocaine above and below the 50ng/mL cut-off was provided to each site. The following results were tabulated:

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

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free whole blood or Cocaine positive whole blood/serum/plasma. The following compounds show no cross-reactivity when tested with the COC Rapid Test Device (Whole Blood/Serum/Plasma) at a concentration of 100 μg/mL.

Non Cross-Reacting Compounds

Acetominophen	Diazepam	Methadone	Prednisone
Acetophenetidin	Diclofenac	Methoxyphenamine	Procaine
N-Acetylprocainamide	Diflunisal	(±)-3,4-Methylenedioxy-	Promazine
Acetylsalicylic acid	Digoxin	amphetamine	Promethazine
Aminopyrine	Diphenhydramine	(±)-3,4-Methylenedioxy-	D,l-Propranolol
Amitryptyline	Doxylamine	methamphetamine	D-Propoxyphene
Amobarbital	Ecgoninemethylester	Morphine-3-β-D	D-Pseudoephedrine
Amoxicillin	(-)-ψ-Ephedrine	glucuronide	Quinidine
Ampicillin	Erythromycin	Morphine Sulfate	Quinine
l-Ascorbic acid	β-Estradiol	Nalidixic acid	Ranitidine
D,l-Amphetamine sulfate	Estrone-3-sulfate	Naloxone	Salicylic acid
Apomorphine	Ethyl-p-aminobenzoate	Naltrexone	Secobarbital
Aspartame	Fenoprofen	Naproxen	Serotonin
Atropine	Furosemide	Niacinamide	Sulfamethazine
Benzilic acid	Gentisic acid	Nifedipine	Sulindac
Benzoic acid	Hemoglobin	Norcodein	Temazepam
Benzphetamine	Hydralazine	Norethindrone	Tetracycline
Bilirubin	Hydrochlorothiazide	D-Norpropoxyphene	Tetrahydrocortisone,
(±) -Brompheniramine	Hydrocodone	Noscapine	3-Acetate
Caffeine	Hydrocortisone	D,l-Octopamine	Tetrahydrocortisone
Cannabidiol	O-Hydroxyhippuric acid	Oxalic acid	3-(β-D glucuronide)
Cannabinol	p-Hydroxy-	Oxazepam	Tetrahydrozoline
Chloralhydrate	methamphetamine	Oxolinic acid	Thebaine
Chloramphenicol	3-Hydroxytyramine	Oxycodone	Thiamine
Chlordiazepoxide	Ibuprofen	Oxymetazoline	Thioridazine
Chlorothiazide	Imipramine	Papaverine	D,l-Tyrosine
(±) -Chlorpheniramine	Iproniazid	Penicillin-G	Tolbutamide
Chlorpromazine	(±) - Isoproterenol	Pentobarbital	Triamterene
Chlorquine	Isoxsuprine	Perphenazine	Trifluoperazine
Cholesterol	Ketamine	Phencyclidine	Trimethoprim
Clomipramine	Ketoprofen	Phenelzine	Trimipramine
Clonidine	labetalol	Phenobarbital	Tryptamine
Codeine	levorphanol	Phentermine	D,l-Tryptophan
Cortisone	loperamide	l-Phenylephrine	Tyramine
(-) Cotinine	Maprotiline	l-Phenylethylamine	Uric acid
Creatinine	Meperidine	Phenylpropanolamine	Verapamil
Deoxycorticosterone	Meprobamate	Prednisolone	Zomepirac

Interfering Substances

The COC Rapid Test Device (Whole Blood/Serum/Plasma) has been tested for possible interferencefrom visibly hemolyzed and lipemic specimens. In addition, no interference was observed in specimens containing up to 100 mg/dL hemoglobin; up to 100 mg/dL bilirubin and up to 200 mg/dL human serum albumin.

BIBIIOGRAPHY

1. Stewart DJ, Inaba T, lucassen M, Kalow W. Clin. Pharmacol. Ther. April 1979; 25 ed: 464, 264-8.
2. *Ambre J. J. Anal. Toxicol.1985; 9:241.*
3. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man.2nd Ed. Biomedical Publ., Davis, CA. 1982; 488

Index of Symbols

	Consult instructions for use		Contains sufficient for <*n*> test	EC REP	Authorized representative in the European Community/European Union
IVD	*In vitro* diagnostic medical device		Use-by date		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Batch code	REF	Catalogue number
	Do not use if package is damaged and consult instructions for use		Manufacturer		Date of manufacture

EC REP Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta

Rapid Labs Ltd
Unit 2 & 2A Hall Farm Business
Centre Church Road Little Bentley Colchester
Essex CO7 8SD
United Kingdom

Revision 1 24/06/2024

RAPID BIOTEC™ CE IVD

MTD Rapid Test Device (Whole Blood/Serum/Plasma)

CATALOGUE NUMBER
D-DOA7WBD40

A rapid test for the qualitative detection of Methadone in human whole blood or serum or plasma. For medical and other professional in vitro diagnostic use only.

INTENDED USE

The MTD Rapid Test Device (Whole Blood/Serum/Plasma) is a lateral flow chromatographic immunoassay for the detection of Methadone in whole blood or serum or plasma at a cut-off concentration of 40ng/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.

SUMMARY

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[1].

PRINCIPLE

The MTD Rapid Test Device (Whole Blood/Serum/Plasma) is an immunoassay based on the principle of competitive binding. Drugs that may be present in the whole blood/serum/plasma specimen compete against the drug conjugate for binding sites on the antibody.
During testing, a whole blood/serum/plasma specimen migrates upward by capillary action. Methadone, if present in the whole blood/serum/plasma 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 Methadone-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 Methadone level exceeds the cut-off level because it will saturate all the binding sites of anti-Methadone antibodies.
A drug-positive whole blood/serum/plasma specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative whole blood/serum/plasma 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-Methadoneantibody coupled particles and Methadone-protein conjugate. A goat antibody is employed in the control line system.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Do not use test if pouch is damaged
4. 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.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
6. The used test should be discarded according to local regulations.
7. 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 MTD Rapid Test Device can be performed using whole blood (from venipuncture or fingerstick)/serum/plasma.
- 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 40 μL. 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 well of the test device.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days, 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 devices • Droppers • Buffer • Package insert

Materials Required But Not Provided

• Specimen collection containers • Centrifuge
• Lancets (for fingerstick whole blood only) • Timer
• Heparinized 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.

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

For serum or plasma specimen:

•Hold the dropper vertically and transfer **1 full drop of serum or plasma** (approximately 40μL), then add **2 drops of buffer** (approximately 80μL) to the specimen well(S) of the device, and then start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.

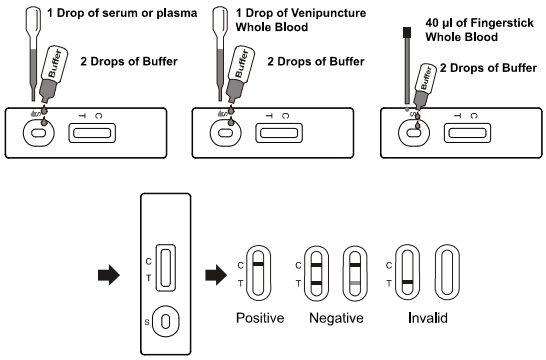
For Venipuncture Whole blood specimen:

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

3. Wait for the colored line(s) to appear. **Read the result 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 Methadone 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 Methadone 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 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 MTD Rapid Test Device (Whole Blood/Serum/Plasma) 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.[2]
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 MTD Rapid Test Device and GC/MS at the cut-off of 40ng/mL. Testing was performed on 90 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Clinic Result of Whole Blood

Method		GC/MS		Total Results
MTD Rapid Test Device	Results	Positive	Negative	
	Positive	19	2	21
	Negative	1	68	69
Total Results		20	70	90
% Agreement		95.0%	97.1%	96.7%

Clinic Result of Serum or Plasma

Method		GC/MS		Total Results
MTD Rapid Test Device	Results	Positive	Negative	
	Positive	19	2	21
	Negative	1	68	69
Total Results		20	70	90
% Agreement		95.0%	97.1%	96.7%

Analytical Sensitivity

A drug-free whole blood/serum/plasma pool was spiked with MTD at the following concentrations of ±50% cutoff and 3x cutoff. The data are summarized below:

For whole blood:

MTD Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
20	-50%	30	30	0
40	Cut-off	30	15	15
60	+50%	30	0	30
120	3X	30	0	30

For serum or plasma:

MTD Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
20	-50%	30	30	0
40	Cut-off	30	15	15
60	+50%	30	0	30
120	3X	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in whole blood/serum/plasma by the MTD Rapid Test Device (Whole Blood/Serum/Plasma) at 5 minutes.

Compound	Concentration (ng/mL)
Methadone	40
Doxylamine	13,000

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 no Methadone, and 50% Methadone above and below the 40ng/mL cut-off was provided to each site. The following results were tabulated:

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

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 Methadone positive whole blood/serum/plasma. The following compounds show no cross-reactivity when tested with the MTD Rapid Test Device (Whole Blood/Serum/Plasma) at a concentration of 100 μg/mL.

Non Cross-Reacting Compounds

Acetaminophen	Diazepam	Maprotiline	β-Phenylethylamine
Acetophenetidin	Diclofenac	Meperidine	Phenylpropanolamine
N-Acetylprocainamide	Diflunisal	Meprobamate	Prednisolone
Acetylsalicylic acid	Digoxin	Methamphetamine	Prednisone
Aminopyrine	Diphenhydramine	Methoxyphenamine	Procaine
Amitryptyline	EDDP	(±) - 3,4-Methylenedioxy-amphetamine	Promazine
Amobarbital	EMDP	(±) -3,4-Methylenedioxymeth-Amphetamine	Promethazine
Amoxicillin	Ecgonine hydrochloride	Morphine-3-β-D glucuronide	D,l-Propranolol
Ampicillin	Ecgoninemethylester	Morphine Sulfate	D-Propoxyphene
l-Ascorbic acid	(-) -ψ-Ephedrine	Nalidixic acid	D-Pseudoephedrine
D,l-Amphetamine sulfate	[1R,2S] (-) Ephedrine	Naloxone	Quinacrine
Apomorphine	l - Epinephrine	Naltrexone	Quinidine
Aspartame	Erythromycin	Naproxen	Quinine
Atropine	β-Estradiol	Niacinamide	Ranitidine
Benzilic acid	Estrone-3-sulfate	Nifedipine	Salicylic acid
Benzoic acid	Ethyl-p-aminobenzoate	Norcodein	Secobarbital
Benzoylecgonine	Fenoprofen	Norethindrone	Serotonin
Benzphetamine	Furosemide	D-Norpropoxyphene	Sulfamethazine
Bilirubin	Gentisic acid	Noscapine	Sulindac
(±) - Brompheniramine	Hemoglobin	D,l-Octopamine	Temazepam
Caffeine	Hydralazine	Oxalic acid	Tetracycline
Cannabidiol	Hydrochlorothiazide	Oxazepam	Tetrahydrocortisone,
Cannabinol	Hydrocodone	Oxolinic acid	3-Acetate
Chloralhydrate	Hydrocortisone	Oxycodone	Tetrahydrocortisone
Chloramphenicol	O-Hydroxyhippuric acid	Oxymetazoline	3-(β-D-glucuronide)
Chlorothiazide	p-Hydroxyamphetamine	Papaverine	Tetrahydrozoline
(±) - Chlorpheniramine	p-Hydroxy-methamphetamine	Penicillin-G	Thebaine
Chlorpromazine	3-Hydroxytyramine	Pentazocine hydrochloride	Thiamine
Chlorquine	Ibuprofen	Pentobarbital	Thioridazine
Cholesterol	Imipramine	Perphenazine	D,l-Tyrosine
Clomipramine	Iproniazid	Phencyclidine	Tolbutamide
Clonidine	(±) - Isoproterenol	Phenelzine	Triamterene
Cocaethylene	Isoxsuprine	Phenobarbital	Trifluoperazine
Cocaine hydrochloride	Ketamine	Phentermine	Trimethoprim
Codeine	Ketoprofen	D,l-Tryptophan	Trimipramine
Cortisone	labetalol	(-) Cotinine	Tryptamine

Interfering Substances

The MTD Rapid Test Device (Whole Blood/Serum/Plasma) has been tested for possible interference from visibly hemolyzed and lipemic specimens. In addition, no interference was observed in specimens containing up to 100 mg/dL hemoglobin; up to 100 mg/dL bilirubin and up to 200 mg/dL human serum albumin.

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.

Index of Symbols

	Consult instructions for use		Contains sufficient for <*n*> test	EC REP	Authorized representative in the European Community/European Union
IVD	*In vitro* diagnostic medical device		Use-by date		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Batch code	REF	Catalogue number
	Do not use if package is damaged and consult instructions for use		Manufacturer		Date of manufacture

EC REP Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta

Rapid Labs Ltd
Unit 2 & 2A Hall Farm Business
Centre Church Road Little Bentley Colchester
Essex CO7 8SD
United Kingdom

Revision 1 24/06/2024

RAPID BIOTEC™

CE IVD

TCA Rapid Test Device
(Whole Blood/Serum/Plasma)

CATALOGUE NUMBER
D-DOA10WBD40

A rapid test for the qualitative detection of Tricyclic Antidepressants in human whole blood or serum or plasma.
For medical and other professional in vitro diagnostic use only.

INTENDED USE
The TCA Rapid Test Device (Whole Blood/Serum/Plasma) is a lateral flow chromatographic immunoassay for the detection of TCA in whole blood or serum or plasma at a cut-off concentration of 300ng/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.

SUMMARY
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. TCA are taken orally or sometimes by injection. TCA are metabolized in the liver. Both TCA and their metabolites are excreted in whole blood or serum or plasma mostly in the form of metabolites for up to ten days.[1]

PRINCIPLE
The TCA Rapid Test Device (Whole Blood/Serum/Plasma) is an immunoassay based on the principle of competitive binding. Drugs that may be present in the whole blood/serum/plasma specimen compete against the drug conjugate for binding sites on the antibody.
During testing, a whole blood/serum/plasma specimen migrates upward by capillary action. TCA, if present in the whole blood/serum/plasma 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 TCA-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 TCA level exceeds the cut-off level because it will saturate all the binding sites of anti-TCA antibodies.
A drug-positive whole blood/serum/plasma specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative whole blood/serum/plasma 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-TCA antibody coupled particles and TCA-protein conjugate. A goat antibody is employed in the control line system.

PRECAUTIONS
1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Do not use test if pouch is damaged
4. 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.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
6. The used test should be discarded according to local regulations.
7. 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 TCA Rapid Test Device can be performed using whole blood (from venipuncture or fingerstick) or serum or plasma.
- 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 40 μL. 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 well of the test device.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days, 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 devices • Droppers • Buffer • Package insert

Materials Required But Not Provided
• Specimen collection containers • Centrifuge
• Lancets (for fingerstick whole blood only) • Timer
• Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

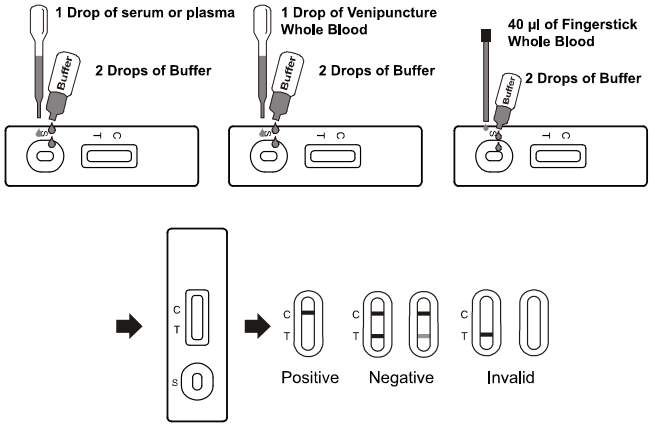
DIRECTIONS FOR USE
Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.
1. Bring the pouch to room temperature before opening it. Remove the device from the sealed pouch and use it within one hour.
2. Place the device on a clean and level surface.

For serum or plasma specimen:
•Hold the dropper vertically and transfer **1 full drop of serum or plasma** (approximately 40μL), then add **2 drops of buffer** (approximately 80μL) to the specimen well(S) of the device, and then start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.

For Venipuncture Whole blood specimen:
•Hold the dropper vertically and transfer **1 drop of whole blood** (approximately 40μL) to the specimen well(S), then **add 2 drops of buffer** (approximately 80μL), 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 well(S) of test device, then add **2 drops of buffer**(approximately 80μL) and start the timer. See illustration below.

3. Wait for the colored line(s) to appear. **Read the result 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 TCA 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 TCA 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 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 TCA Rapid Test Device (Whole blood /Serum/Plasma) 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.[2]
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-freeWhole 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 TCA Rapid Test Device and GC/MS at the cut-off of 300ng/mL. Testing was performed on 90 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Clinic Result of Whole Blood

Method		GC/MS		Total Results
TCA Rapid Test Device	Results	Positive	Negative	
	Positive	23	2	25
	Negative	2	63	65
Total Results		25	65	90
% Agreement		92.0%	96.9%	95.6%

Clinic Result of Serum or Plasma

Method		GC/MS		Total Results
TCA Rapid Test Device	Results	Positive	Negative	
	Positive	23	2	25
	Negative	2	63	65
Total Results		25	65	90
% Agreement		92.0%	96.9%	95.6%

Analytical Sensitivity
A drug-free whole blood/serum/plasma pool was spiked with TCA at the following concentrations of ±50% cutoff and 3x cutoff, the data are summarized below:

For whole blood:

TCA Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
150	-50%	30	30	0
300	Cut-off	30	15	15
450	+50%	30	0	30
900	3X	30	0	30

For serum or plasma:

TCA Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
150	-50%	30	30	0
300	Cut-off	30	15	15
450	+50%	30	0	30
900	3X	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in Whole blood/Serum/Plasma by the TCA Rapid Test Device (Whole Blood/Serum/Plasma) at 5 minutes.

Compound	Concentration (ng/mL)
Nortriptyline	300
Nordoxepine	150
Trimipramine	1,300
Amitriptyline	600
Promazine	1,300
Desipramine	80
Cyclobenzaprine	600
Imipramine	140
Clomipramine	18,000
Doxepine	600
Maprotiline	600
Promethazine	18,000
Perphenazine	18,000

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 no TCA and 50% TCA above and below the 300ng/mL cut-off was provided to each site. The following results were tabulated:

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

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 determine positive whole blood/serum/plasma. The following compounds show no cross-reactivity when tested with the TCA Rapid Test Device (Whole Blood /Serum/Plasma) at a concentration of 100 μg/mL.

Non Cross-Reacting Compounds

Acetophenetidin	Dextromethorphan	Methadone	Phenylpropanolamine
N-Acetylprocainamide	Diazepam	D-methamphetamine	Prednisolone
Acetylsalicylic acid	Diclofenac	(l)-methamphetamine	Prednisone
Aminopyrine	Diflunisal	Methoxyphenamine	Procaine
Amobarbital	Digoxin	3,4-Methylenedioxyethyl-	D,l-Propanolol
Amoxicillin	Diphenhydramine	amphetamine	D-Propoxyphene
Ampicillin	Doxylamine	(±) 3,4-Methylenedioxy-	D-Pseudoephedrine
l-Ascorbic acid	Ecgonine hydrochloride	methamphetamine	Quinidine
Apomorphine	Ecgoninemethylester	Methylphenidate	Quinine
Aspartame	(IR,2S)-(-)-Ephedrine	Morphine-3-β-D-	Ranitidine
Atropine	l-Ephedrine	glucuronide	Salicylic acid
D,l -Amphetamine	Erythromycin	Nalidixic acid	Secobarbital
l-Amphetamine	Ethyl-p-aminobenzoate	Naloxone	Serotonin
Benzilic acid	Fenfluramine	Naltrexone	(5-Hydroxytyramine)
Benzoic acid	Fenoprofen	Naproxen	Sulfamethazine
Benzoylecgonine	Furosemide	Niacinamide	Sulindac
Benzphetamine	Gentisic acid	Nifedipine	Temazepam
Bilirubin	Hemoglobin	Norcodein	Tetracycline
(±)-Brompheniramine	Hydralazine	(-)-ψ- Ephedrine	Tetrahydrocortisone,
Caffeine	Hydrochlorothiazide	Norethindrone	3 Acetate
Cannabidiol	Hydrocodone	D-Norpropoxyphene	Tetrahydrocortisone
Cannabinol	Hydrocortisone	Noscapine	3 (β-D glucuronide)
Chloralhydrate	p-Hydroxyamphetamine	D,l-Octopamine	Tetrahydrozoline
Chloramphenicol	O-Hydroxyhippuric acid	Oxalic acid	Thebaine
Chlordiazepoxide	3-Hydroxytyramine	β-Estradiol	Thiamine
Chlorothiazide	p-Hydroxy-	Oxycodone	Thioridazine
(±) Chlorpheniramine	methamphetamine	Oxymetazoline	Tolbutamine
Chlorpromazine	Ibuprofen	Papaverine	Triamterene
Chlorquine	(±)-Isoproterenol	Penicillin-G	Trifluoperazine
Cholesterol	Isoxsuprine	Pentazocine	Trimethoprim
Clonidine	Ketamine	Pentobarbital	D, l-Tryptophan
Cocaine hydrochloride	Ketoprofen	Phencyclidine	Tyramine
Codeine	labetalol	Phenelzine	D, l-Tyrosine
Cortisone	levorphanol	Phenobarbital	Uric acid
(-) Cotinine	loperamide	Phentermine	Verapamil
Creatinine	Meperidine	l-Phenylephrine	Oxazepam
Deoxycorticosterone	Meprobamate	β-Phenylethlamine	Zomepirac

Interfering Substances

The TCA Rapid Test Device (Whole Blood/Serum/Plasma) has been tested for possible interference from visibly hemolyzed and lipemic specimens. In addition, no interference was observed in specimens containing up to 100 mg/dL hemoglobin; up to 100 mg/dL bilirubin and up to 200 mg/dL human serum albumin.

BIBLIOGRAPHY

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

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	Consult instructions for use	Σ	Contains sufficient for <*n*> test	EC REP	Authorized representative in the European Community/European Union
IVD	*In vitro* diagnostic medical device		Use-by date		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Batch code	REF	Catalogue number
	Do not use if package is damaged and consult instructions for use		Manufacturer		Date of manufacture

EC REP Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta

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Revision 1 24/06/2024

RAPID BIOTEC™

CE IVD

Ecstasy (MDMA) Rapid Test Device

(Urine)

CATALOGUE NUMBER
D-DOA12D20

A rapid test for the qualitative detection of Methylenedioxy-methamphetamine (MDMA) in human urine. For medical and other professional in vitro diagnostic use only.

INTENDED USE

The Ecstasy (MDMA) Rapid Test Device (Urine) is a rapid chromatographic immunoassay for the detection of Methylenedioxy-methamphetamine (primary ingredient of Ecstasy) in human 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.

SUMMARY

Methylenedioxy-methamphetamine (Ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity.[1] 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 Oberlender, 1990). The most pervasive effect of MDMA, occurring in virtually all people who have taken a reasonable dose of the drug, is to produce a clenching of the jaws. The Ecstasy (MDMA) Rapid Test Device (Urine) yields a positive result when Methylenedioxy-methamphetamine in urine exceeds 500 ng/mL.

PRINCIPLE

The Ecstasy (MDMA) Rapid Test Device (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. Methylenedioxy-methamphetamine, if present in the urine specimen below 500 ng/mL, will not saturate the binding sites of antibody coated particles in the test. The antibody coated particles will then be captured by immobilized Methylenedioxy-methamphetamine 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 Methylenedioxy- methamphetamine level exceeds 500 ng/mL because it will saturate all the binding sites of anti-Methylenedioxy-methamphetamine 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-Methylenedioxy-methamphetamine antibody-coupled particles and Methylenedioxy-methamphetamine-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 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 devices
- Droppers
- Package insert

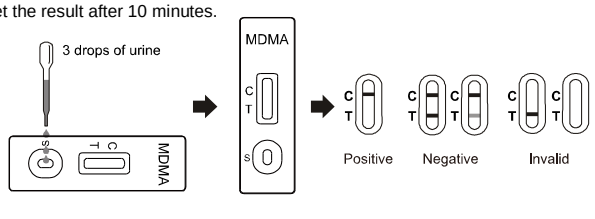
Materials Required But Not Provided

- Specimen collection containers
- Timer

DIRECTIONS FOR USE

Allow 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 device from the sealed pouch and use it within one hour.
2. Place the device on a clean and level surface. Hold the dropper vertically and **transfer 3 full drops of urine** (approx. 120µL) to the specimen well of the device, and then start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.
3. 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 line region (C) and another colored line should be in the test line region (T). This negative result indicates that the Methylenedioxy-methamphetamine concentration is below the detectable level (500 ng/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). This positive result indicates that the Methylenedioxy-methamphetamine concentration exceeds the detectable level (500 ng/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 practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The Ecstasy (MDMA) Rapid Test Device (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.[2,3]
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.
7. A positive test result might be obtained from certain foods or food supplements.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the Ecstasy (MDMA) Rapid Test Device and a commercially available MDMA rapid test. Testing was performed on 110 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Method		Other MDMA Rapid Test		Total Results
Ecstasy (MDMA) Rapid Test Device	Results	Positive	Negative	
	Positive	48	0	48
	Negative	0	62	62
Total Results		48	62	110
% Agreement		>99.9%	>99.9%	>99.9%

A side-by-side comparison was conducted using the Ecstasy (MDMA) Rapid Test Device and GC/MS at the cut-off of 500ng/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
MDMA Rapid Test Device	Results	Positive	Negative	
	Positive	102	1	103
	Negative	2	145	147
Total Results		104	146	250
% Agreement		98.1%	99.3%	98.8%

Analytical Sensitivity

A drug-free urine pool was spiked with Methylenedioxy-methamphetamine 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 result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

Methylenedioxy-methamphetamine 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	25	5
500	Cut-off	30	14	16
625	+25%	30	4	26
750	+50%	30	0	30
1,500	3X	30	0	30

Analytical Specificity

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

Compound	Concentration (ng/mL)
(±) 3,4-Methylenedioxymethamphetamine HCl (MDMA)	500
(±) 3,4-Methylenedioxyamphetamine HCl (MDA)	3,000
3,4-Methylenedioxyethyl-amphetamine (MDE)	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 no Methylenedioxy-methamphetamine, 25% Methylenedioxymethamphetamine above and below the cut-off and 50% Methylenedioxy-methamphetamine above and below the 500 ng/mL cut-off were provided to each site. The results are given below:

Methylenedioxy-methamphetamine 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	8	2	9	1	9	1
625	10	1	9	1	9	1	9
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 Methylenedioxy-methamphetamine. The Ecstasy (MDMA) Rapid Test Device (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 Methylenedioxymethamphetamine to 250 ng/mL and 750 ng/mL. The spiked, pH-adjusted urine was tested with the Ecstasy (MDMA) Rapid Test Device (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 Methylenedioxy-methamphetamine positive urine. The following compounds show no cross-reactivity when tested with the Ecstasy (MDMA) Rapid Test Device (Urine) at a concentration of 100µg/mL.

Non Cross-Reacting Compounds

4-Acetamidophenol	Dextromethorphan	Meprobamate	Procaine
Acetophenetidin	Diclofenac	Methamphetamine	Promazine
N-Acetylprocainamide	Diazepam	Methadone	Promethazine
Acetylsalicylic acid	Diflunisal	Methoxyphenamine	D,L-Propranolol
Aminopyrine	Digoxin	Methylphenidate	D-Propoxyphene
Amitryptyline	Dicylomine	Morphine-	D-Pseudoephedrine
Amobarbital	Diphenhydramine	3-β-D-glucuronide	Quinacrine
Amoxicillin	5,5 - Diphenylhydantoin	Morphine sulfate	Quinidine
Ampicillin	Doxylamine	Nalidixic acid	Quinine
L-Ascorbic acid	Ecgonine hydrochloride	Naloxone	Ranitidine
D-Amphetamine	Ecgonine methylester	Naltrexone	Salicylic acid
D,L-Amphetamine sulfate	(-) -ψ-Ephedrine	Naproxen	Secobarbital
L-Amphetamine	[1R,2S](-) Ephedrine	Niacinamide	Serotonin
Apomorphine	L – Epinephrine	Nifedipine	(5-Hydroxytyramine)
Aspartame	Erythromycin	Nimesulidate	Sulfamethazine
Atropine	β-Estradiol	Norcodein	Sulindac
Benzilic acid	Estrone-3-sulfate	Norethindrone	Sustiva
Benzoic acid	Ethyl-p-aminobenzoate	D-Norpropoxyphene	Temazepam
Benzoylecgonine	Fenoprofen	Noscapine	Tetracycline
Benzphetamine	Furosemide	D,L-Octopamine	Tetrahydrocortisone,
Bilirubin	Gentisic acid	Oxalic acid	3- Acetate
(±) - Brompheniramine	Hemoglobin	Oxazepam	Tetrahydrocortisone
Buspiron	Hydralazine	Oxolinic acid	3-(β-D glucuronide)
Caffeine	Hydrochlorothiazide	Oxycodone	Tetrahydrozoline
Cannabidiol	Hydrocodone	Oxymetazoline	Thebaine
Cannabinol	Hydrocortisone	Papaverine	Theophynine
Chloralhydrate	O-Hydroxyhippuric acid	Penicillin-G	Thiamine
Chloramphenicol	p-Hydroxyamphetamine	Pentazocine	Trans-2-
Chlordiazepoxide	p-Hydroxy-	hydrochloride	phenylcyclopropylamine
Chlorothiazide	methamphetamine	Pentobarbital	Thioridazine
(±) - Chlorpheniramine	3-Hydroxytyramine	Perphenazine	Tolbutamide
Chlorpromazine	Imipramine	Phencyclidine	Trazodone
Chlorquine	Iproniazid	Phenelzine	D,L-Tyrosine
Cholesterol	(±) - Isoproterenol	Phenobarbital	Triamterene
Clomipramine	Isoxsuprine	Phentermine	Trifluoperazine
Clonidine	Ketamine	Trans-2-phenyl	Trimethoprim
Cocaethylene	Ketoprofen	cyclopropylamine	Trimipramine
Cocaine hydrochloride	Labetalol	hydrochloride	Tryptamine
Codeine	Levorphanol	L-Phenylephrine	D,L-Tryptophan
Cortisone	Loperamide	β-Phenylethylamine	Tyramine
(-) Cotinine	Maprotiline	Phenylpropanolamine	Uric acid
Creatinine	Meperidine	Prednisolone	Verapamil
Deoxycorticosterone	Mephentermine	Prednisone	Zomepirac

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1. Winger G. A Handbook of Drug and Alcohol Abuse. Third Edition, Oxford Press. 1992; 146
2. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd Ed. Biomedical Publ., Davis, CA. 1982; 488
3. Hawks RL, Chiang CN. *Urine Testing for Drugs of Abuse*. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986

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	Consult instructions for use		Contains sufficient for <*n*> test	EC REP	Authorized representative in the European Community/European Union
IVD	*In vitro* diagnostic medical device		Use-by date		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Batch code	REF	Catalogue number
	Do not use if package is damaged and consult instructions for use		Manufacturer		Date of manufacture

EC REP Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta

Rapid Labs Ltd
Unit 2 & 2A Hall Farm Business
Centre Church Road Little Bentley Colchester
Essex CO7 8SD
United Kingdom

Revision 1 24/06/2024

RAPID BIOTEC™

CE IVD

MDMA Rapid Test Device (Whole Blood/Serum/Plasma)

CATALOGUE NUMBER
D-DOA12WBD40

A rapid test for the qualitative detection of MDMA in human whole blood or serum or plasma.
For medical and other professional in vitro diagnostic use only.

INTENDED USE

The MDMA Rapid Test Device (Whole Blood/Serum/Plasma) is a lateral flow chromatographic immunoassay for the detection of Methylenedioxymethamphetamine in whole blood or serum or plasma at a cut-off concentration of 50ng/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.

SUMMARY

Methylenedioxymethamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity.[1] 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 Oberlender, 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.

PRINCIPLE

The MDMA Rapid Test Device (Whole Blood/Serum/Plasma) is an immunoassay based on the principle of competitive binding. Drugs that may be present in the whole blood/serum/plasma specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a whole blood/serum/plasma specimen migrates upward by capillary action. MDMA, if present in the whole bloodwhole blood/serum/plasma 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 MDMA-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 MDMA level exceeds the cut-off level because it will saturate all the binding sites of anti-MDMA antibodies.

A drug-positive whole blood/serum/plasma specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative whole blood/serum/plasma 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-MDMA antibody coupled particles and MDMA-protein conjugate. A goat antibody is employed in the control line system.

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 MDMA Rapid Test Device can be performed using whole blood (from venipuncture or fingerstick)/serum/plasma.
- 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 40 μL. 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 well of the test Device.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days, 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 Devices • Droppers • Buffer • Package insert

Materials Required But Not Provided

• Specimen collection containers • Centrifuge
• Lancets (for fingerstick whole blood only) • Timer
• Heparinized 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.

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

For serum or plasma specimen:

•Hold the dropper vertically and transfer **1 full drop of serum or plasma** (approximately 40μL), then add **2 drops of buffer** (approximately 80μL) to the specimen well(S) of the Device, and then start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.

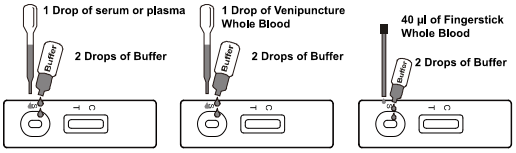
For Venipuncture Whole blood specimen:

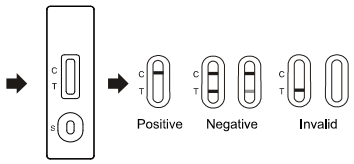
•Hold the dropper vertically and transfer **1 drop of whole blood** (approximately 40μL) to the specimen well(S), then **add 2 drops of buffer** (approximately 80μL), and start the timer. See illustration below.

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 well(S) of test Device, then add **2 drops of buffer**(approximately 80μL) and start the timer. See illustration below.

3. Wait for the colored line(s) to appear. **Read the result 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 MDMA 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 MDMA 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 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 MDMA Rapid Test Device (Whole Blood/Serum/Plasma) 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.[2]
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 inwhole 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 MDMA Rapid Test Device and GC/MS at the cut-off of 50ng/mL. Testing was performed on 90 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Clinic Result of Whole Blood

Method		GC/MS		Total Results
MDMA Rapid Test Device	Results	Positive	Negative	
	Positive	20	2	22
	Negative	2	66	68
Total Results		22	68	90
% Agreement		90.9%	97.1%	95.6%

Clinic Result of Serum or Plasma

Method		GC/MS		Total Results
MDMA Rapid Test Device	Results	Positive	Negative	
	Positive	20	2	22
	Negative	2	66	68
Total Results		22	68	90
% Agreement		90.9%	97.1%	95.6%

Analytical Sensitivity

A drug-free whole blood/serum/plasma pool was spiked with MDMA at the following concentrations of ±50% cutoff and 3x cutoff, the data are summarized below:

For whole blood:

MDMA Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
25	-50%	30	30	0
50	Cut-off	30	15	15
75	+50%	30	0	30
150	3X	30	0	30

For serum or plasma:

MDMA	Percent of	n	Visual Result

Concentration (ng/mL)	Cut-off		Negative	Positive
0	0	30	30	0
25	-50%	30	30	0
50	Cut-off	30	15	15
75	+50%	30	0	30
150	3X	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in whole blood/serum/plasma by the MDMA Rapid Test Device (Whole Blood/Serum/Plasma) at 5 minutes.

Compound	Concentration (ng/mL)
(±)3,4-Methylenedioxymetha-mphetamine HCl	50
(±) 3,4-Methylenedioxyamphetamine HCl	300
3,4-Methylenedioxyethyl-amphetamine	40

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 no MDMA and 50% MDMA above and below the 50ng/mL cut-off was provided to each site. The following results were tabulated:

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

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 determine positive whole blood/serum/plasma. The following compounds show no cross-reactivity when tested with the MDMA Rapid Test Device (Whole Blood/Serum/Plasma) at a concentration of 100 μg/mL.

Non Cross-Reacting Compounds

4-Acetamidophenol	Dextromethorphan	Meprobamate	Procaine
Acetophenetidin	Diclofenac	Methamphetamine	Promazine
N-Acetylprocainamide	Diazepam	Methadone	Promethazine
Acetylsalicylic acid	Diflunisal	Methoxyphenamine	D,l-Propranolol
Aminopyrine	Digoxin	Methylphenidate	D-Propoxyphene
Amitryptyline	Dicylomine	Morphine-	D-Pseudoephedrine
Amobarbital	Diphenhydramine	3-β-D-glucuronide	Quinacrine
Amoxicillin	5,5 - Diphenylhydantoin	Morphine sulfate	Quinidine
Ampicillin	Doxylamine	Nalidixic acid	Quinine
l-Ascorbic acid	Ecgonine hydrochloride	Naloxone	Ranitidine
D-Amphetamine	Ecgoninemethylester	Naltrexone	Salicylic acid
D,l-Amphetamine sulfate	(-) -ψ-Ephedrine	Naproxen	Secobarbital
l-Amphetamine	[1R,2S](-) Ephedrine	Niacinamide	Serotonin
Apomorphine	l – Epinephrine	Nifedipine	(5-Hydroxytyramine)
Aspartame	Erythromycin	Nimesulidate	Sulfamethazine
Atropine	β-Estradiol	Norcodein	Sulindac
Benzilic acid	Estrone-3-sulfate	Norethindrone	Sustiva
Benzoic acid	Ethyl-p-aminobenzoate	D-Norpropoxyphene	Temazepam
Benzoylecgonine	Fenoprofen	Noscapine	Tetracycline
Benzphetamine	Furosemide	D,l-Octopamine	Tetrahydrocortisone,
Bilirubin	Gentisic acid	Oxalic acid	3- Acetate
(±) - Brompheniramine	Hemoglobin	Oxazepam	Tetrahydrocortisone
Buspiron	Hydralazine	Oxolinic acid	3-(β-D glucuronide)
Caffeine	Hydrochlorothiazide	Oxycodone	Tetrahydrozoline
Cannabidiol	Hydrocodone	Oxymetazoline	Thebaine
Cannabinol	Hydrocortisone	Papaverine	Theophynine
Chloralhydrate	O-Hydroxyhippuric acid	Penicillin-G	Thiamine
Chloramphenicol	p-Hydroxyamphetamine	Pentazocine	Trans-2-
Chlordiazepoxide	p-Hydroxy-	hydrochloride	phenylcyclopropylamine
Chlorothiazide	methamphetamine	Pentobarbital	Thioridazine
(±) - Chlorpheniramine	3-Hydroxytyramine	Perphenazine	Tolbutamide
Chlorpromazine	Imipramine	Phencyclidine	Trazodone
Chlorquine	Iproniazid	Phenelzine	D,l-Tyrosine
Cholesterol	(±) - Isoproterenol	Phenobarbital	Triamterene
Clomipramine	Isoxsuprine	Phentermine	Trifluoperazine
Clonidine	Ketamine	Trans-2-phenyl	Trimethoprim
Cocaethylene	Ketoprofen	cyclopropylamine	Trimipramine

Interfering Substances

The MDMA Rapid Test Device (Whole Blood/Serum/Plasma) has been tested for possible interferencefrom visibly hemolyzed and lipemic specimens. In addition, no interference was observed in specimens containing up to 100 mg/dL hemoglobin; up to 100 mg/dL bilirubin and up to 200 mg/dL human serum albumin.

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

Index of Symbols

	Consult instructions for use		Contains sufficient for <*n*> test	EC REP	Authorized representative in the European Community/European Union
IVD	*In vitro* diagnostic medical device		Use-by date		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Batch code	REF	Catalogue number
	Do not use if package is damaged and consult instructions for use		Manufacturer		Date of manufacture

EC REP Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta

Rapid Labs Ltd
Unit 2 & 2A Hall Farm Business
Centre Church Road Little Bentley Colchester
Essex CO7 8SD
United Kingdom

Revision 1 24/06/2024

RAPID BIOTEC™

CE IVD

PCP Rapid Test Device (Whole Blood/Serum/Plasma)

CATALOGUE NUMBER
D-DOA13WBD40

A rapid test for the qualitative detection of Phencyclidine in human whole blood or serum or plasma. For medical and other professional in vitro diagnostic use only.

INTENDED USE

The PCP Rapid Test Device (Whole Blood/Serum/Plasma) is a lateral flow chromatographic immunoassay for the detection of Phencyclidine in whole blood or serum or plasma at a cut-off concentration of 20ng/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.

SUMMARY

Phencyclidine, also known as PCP, is a hallucinogen that was first marketed as a surgical anesthetic in the 1950's. It was removed from the market because patients receiving it became delirious and experienced hallucinations.

Phencyclidine is used in powder, capsule, and tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. PCP is most commonly administered by inhalation but can be used intravenously, intra-nasally, and orally. After low doses, the user thinks and acts swiftly and experiences mood swings from euphoria to depression. Self-injurious behavior is one of the devastating effects of PCP.

PRINCIPLE

The PCP Rapid Test Device (Whole Blood/Serum/Plasma) is an immunoassay based on the principle of competitive binding. Drugs that may be present in thewhole blood/serum/plasma specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a whole blood/serum/plasma specimen migrates upward by capillary action. Phencyclidine, if present in the whole blood/serum/plasma 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 Phencyclidine-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 Phencyclidine level exceeds the cut-off level because it will saturate all the binding sites of anti-Phencyclidineantibodies.

A drug-positive whole blood/serum/plasma specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative whole blood/serum/plasma 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-Phencyclidineantibody coupled particles and Phencyclidine-protein conjugate. A goat antibody is employed in the control line system.

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 PCP Rapid Test Device can be performed using whole blood/serum/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 40 μL. 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 well of the test device.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days, 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 devices • Droppers • Buffer • Package insert

Materials Required But Not Provided

• Specimen collection containers • Centrifuge
• Lancets (for fingerstick whole blood only) • Timer
• Heparinized 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.

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

For serum or plasma specimen:

•Hold the dropper vertically and transfer **1 full drop of serum or plasma** (approximately 40μL), then add **2 drops of buffer** (approximately 80μL) to the specimen well(S) of the device, and then start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.

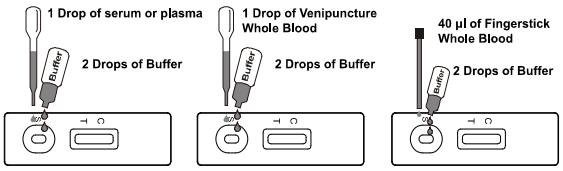
For Venipuncture Whole blood specimen:

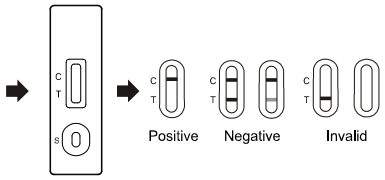
•Hold the dropper vertically and transfer **1 drop of whole blood** (approximately 40μL) to the specimen well(S), then **add 2 drops of buffer** (approximately 80μL), and start the timer. See illustration below.

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 well(S) of test device, then add **2 drops of buffer** (approximately 80μL) and start the timer. See illustration below.

3. Wait for the colored line(s) to appear. **Read the result 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 Phencyclidine 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 Phencyclidine 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 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 PCP Rapid Test Device (Whole Blood/Serum/Plasma) 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.[1,2]
2. It is possible that technical or procedural errors, as well as other interfering substances in thewhole 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. 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 PCP Rapid Test Device and GC/MS at the cut-off of 20ng/mL. Testing was performed on 90 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Clinic Result of Whole Blood

Method		GC/MS		Total Results
PCP Rapid Test Device	Results	Positive	Negative	
	Positive	21	1	22
	Negative	1	67	68
Total Results		22	68	90
% Agreement		95.5%	98.5%	97.8%

Clinic Result of Serum or Plasma

Method		GC/MS		Total Results
PCP Rapid Test Device	Results	Positive	Negative	
	Positive	21	1	22
	Negative	1	67	68
Total Results		22	68	90
% Agreement		95.5%	98.5%	97.8%

Analytical Sensitivity

A drug-free whole blood/serum/plasma pool was spiked with Phencyclidine at the following concentrations of ±50% cutoff and 3x cutoff, the data are summarized below:

For whole blood:

PCP Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
10	-50%	30	30	0
20	Cut-off	30	15	15
30	+50%	30	0	30
60	3X	30	0	30

For serum or plasma:

PCP Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
10	-50%	30	30	0

20	Cut-off	30	15	15
30	+50%	30	0	30
60	3X	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in whole blood/serum/plasma by the PCP Rapid Test Device (Whole Blood/Serum/Plasma) at 5 minutes.

Compound	**Concentration (ng/mL)**
4-Hydroxyphencyclidine	5,000
Phencyclidine	20

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 no PCP and 50% PCP above and below the 20ng/mL cut-off was provided to each site. The following results were tabulated:

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

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 determine positive whole blood. The following compounds show no cross-reactivity when tested with the PCP Rapid Test Device (Whole Blood/Serum/Plasma) at a concentration of 100 μg/mL.

Non Cross-Reacting Compounds

Acetaminophen	Creatinine	Meperidine	Prednisolone
Acetophenetidin	Deoxycorticosterone	Meprobamate	Prednisone
N-Acetylprocainamide	Dextromethorphan	Methadone	Procaine
Acetylsalicylic acid	Diazepam	Methoxyphenamine	Promazine
Aminopyrine	Diclofenac	(+) 3,4-Methylenedioxy-	Promethazine
Amitryptyline	Diflunisal	Amphetamine	D,L-Propanolol
Amobarbital	Digoxin	(+) 3,4-Methylenedioxy-	D-Propoxyphene
Amoxicillin	Diphenhydramine	methamphetamine	D-Pseudoephedrine
Ampicillin	Doxylamine	Morphine-3-	Quinidine
L-Ascorbic acid	Ecgonine hydrochloride	β-D glucuronide	Quinine
D,L-Amphetamine	Ecgoninemethylester	Morphine Sulfate	Ranitidine
Apomorphine	(-)-ψ-Ephedrine	Nalidixic acid	Salicylic acid
Aspartame	Erythromycin	Naloxone	Secobarbital
Atropine	β-Estradiol	Naltrexone	Serotonin
Benzilic acid	Estrone-3-sulfate	Naproxen	(5-Hydroxytyramine)
Benzoic acid	Ethyl-p-aminobenzoate	Niacinamide	Sulfamethazine
Benzoylecgonine	Fenoprofen	Nifedipine	Sulindac
Benzphetamine	Furosemide	Norcodein	Temazepam
Bilirubin	Gentisic acid	Norethindrone	Tetracycline
(±) – Brompheniramine	Hemoglobin	D-Norpropoxyphene	Tetrahydrocortisone,
Caffeine	Hydralazine	Noscapine	3-Aacetate
Cannabidiol	Hydrochlorothiazide	D,L-Octopamine	Tetrahydrocortisone
Cannabinol	Hydrocodone	Oxalic acid	3-(β-D glucuronide)
Chloralhydrate	Hydrocortisone	Oxazepam	Tetrahydrozoline
Chloramphenicol	O-Hydroxyhippuric acid	Oxolinic acid	Thiamine
Chlordiazepoxide	p-Hydroxy-	Oxycodone	Thioridazine
Chlorothiazide	Methamphetamine	Oxymetazoline	D, L-Tyrosine
(±) Chlorpheniramine	3-Hydroxytyramine	Papaverine	Tolbutamide
Chlorpromazine	Ibuprofen	Penicillin-G	Triamterene
Chlorquine	Imipramine	Pentazocine hydrochloride	Trifluoperazine
Cholesterol	Iproniazid	Pentobarbital	Trimethoprim
Clomipramine	(±) - Isoproterenol	Perphenazine	Trimipramine
Clonidine	Isoxsuprine	Phenelzine	Tryptamine
Cocaine hydrochloride	Ketamine	Phenobarbital	D, L-Tryptophan
Codeine	Ketoprofen	Phentermine	Tyramine
Cortisone	Labetalol	L-Phenylephrine	Uric acid
(-) Cotinine	Loperamide	β-Phenylethylamine	Verapamil
	Maprotiline	Phenylpropanolamine	Zomepirac

Interfering Substances

The PCP Rapid Test Device (Whole Blood/Serum/Plasma) has been tested for possible interference from visibly hemolyzed and lipemic specimens. In addition, no interference was observed in specimens containing up to 100 mg/dL hemoglobin; up to 100 mg/dL bilirubin and up to 200 mg/dL human serum albumin.

BIBLIOGRAPHY

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

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	Consult instructions for use		Contains sufficient for <*n*> test	EC REP	Authorized representative in the European Community/European Union
IVD	*In vitro* diagnostic medical device		Use-by date		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Batch code	REF	Catalogue number
	Do not use if package is damaged and consult instructions for use		Manufacturer		Date of manufacture

EC REP Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta

Rapid Labs Ltd
Unit 2 & 2A Hall Farm Business
Centre Church Road Little Bentley Colchester
Essex CO7 8SD
United Kingdom

Revision 1 24/06/2024

RAPID BIOTEC™

CE IVD

Lysergic Acid Diethylamide (LSD) Rapid Test Device (Urine)

CATALOGUE NUMBER
D-DOA29D20

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

INTENDED USE

The Lysergic Acid Diethylamide (LSD) Rapid Test Device (Urine) is a rapid chromatographic immunoassay for the detection of Lysergic Acid Diethylamide in human urine at a cut-off concentration of 20 ng/mL.

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) 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.

SUMMARY

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 2Areceptors 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. LSD use can typically be detected in urine for periods of 2-5 days.

The Lysergic Acid Diethylamide (LSD) Rapid Test Device (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 Lysergic Acid Diethylamide in urine. The Lysergic Acid Diethylamide (LSD) Rapid Test Device (Urine) yields a positive result when Lysergic Acid Diethylamide in urine exceeds 20 ng/mL.

PRINCIPLE

The Lysergic Acid Diethylamide (LSD) Rapid Test Device (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. Lysergic Acid Diethylamide, if present in the urine specimen below 20 ng/mL, will not saturate the binding sites of antibody-coated particles in the test. The antibody-coated particles will then be captured by immobilized Lysergic Acid Diethylamide 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 Lysergic Acid Diethylamide level exceeds 20 ng/mL because it will saturate all the binding sites of anti-Lysergic Acid Diethylamide 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 anti-Lysergic Acid Diethylamide antibody-coupled particles and Lysergic Acid Diethylamide-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 Devices
- Droppers
- Package insert

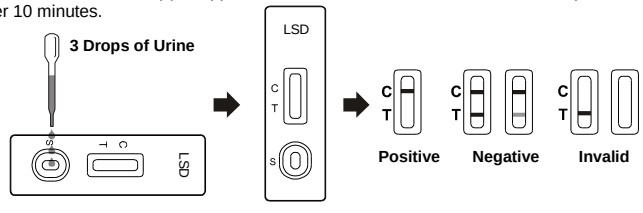
Materials Required But Not Provided

- 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.

1. Bring the pouch to room temperature before opening it. Remove the test Device 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 Device, 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 Lysergic Acid Diethylamide concentration is below the detectable level (20 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 Lysergic Acid Diethylamide concentration exceeds the detectable level (20 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

1. The Lysergic Acid Diethylamide (LSD) Rapid Test Device (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.[2,3]
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 Lysergic Acid Diethylamide (LSD) Rapid Test Device and GC/MS at the cut-off of 20 ng/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
Lysergic Acid Diethylamide (LSD) Rapid Test Device	Results	Positive	Negative	
	Positive	33	1	34
	Negative	2	64	66
Total Results		35	65	100
% Agreement		94.3%	98.5%	97.0%

Analytical Sensitivity

A drug-free urine pool was spiked with Lysergic Acid Diethylamide at the following concentrations: 0 ng/mL, 10 ng/mL, 15 ng/mL, 20 ng/mL, 25 ng/mL, 30 ng/mL and 60 ng/mL. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

Lysergic Acid Diethylamide Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0%	30	30	0
10	-50%	30	30	0
15	-25%	30	27	3
20	Cut-off	30	14	16
25	+25%	30	3	27
30	+50%	30	0	30
60	3X	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in urine by the Lysergic Acid Diethylamide (LSD) Rapid Test Device (Urine) at 5 minutes.

Compound	Concentration(ng/mL)
Lysergic Acid Diethylamide	20

Precision

A study was conducted at 3 hospitals 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 Lysergic Acid Diethylamide, 25% Lysergic Acid Diethylamide above and below the cutoff and 50% Lysergic Acid Diethylamide above and below the 20 ng/mL cutoff were provided to each site. The following results were tabulated:

Lysergic Acid Diethylamide Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
10	10	10	0	10	0	10	0
15	10	9	1	9	1	9	1
25	10	1	9	1	9	1	9
30	10	0	10	0	10	0	10

Effect of Urinary Specific Gravity

Fifteen urine samples with specific gravities ranging from 1.004 to 1.034 were spiked with Lysergic Acid Diethylamide to the concentrations of 10 ng/mL and 30 ng/mL. The Lysergic Acid Diethylamide (LSD) Rapid Test Device (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 Lysergic Acid Diethylamide to 10 ng/mL and 30 ng/mL. The spiked, pH-adjusted urine was tested with the Lysergic Acid Diethylamide (LSD) Rapid Test Device (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 Lysergic Acid Diethylamide positive urine. The following compounds show no cross-reactivity when tested with the Lysergic Acid Diethylamide (LSD) Rapid Test Device (Urine) at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

Acetone	Dopamine	Oxalic Acid
Albumin	(+/-)-Epinephrine	Penicillin-G
Ampicillin	Erythromycin	Pheniramine
Ascorbic	Acid Ethanol	Phenothiazine
Aspartame	Furosemide	L-Phenylephrine
Aspirin	Glucose	β-Phenylethylamine
Atropine	Guaiacol Glyceryl Ether	Procaine
Benzocaine	Hemoglobin	Quinidine
Bilirubin	Ibuprofen	Ranitidine
Caffeine	(+/-)-Isoproterenol	Riboflavin
Chloroquine	Ketamine	Sodium Chloride
(+)-Chlorpheniramine	Levorphanol	Sulindac
(+/-)-Chlorpheniramine	Lidocaine	Tyramine
Creatine	(+)-Naproxen	4-Dimethylaminoantipyrine
Dexbrompheniramine	Niacinamide	(1R,2S)-(-)-N-Methyl-Ephedrine
Dextromethorphan	Nicotine	
Diphenhydramine	(+/-)-Norephedrine	

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1. Glass, IB. The International Handbook of Addiction Behavior. Routledge Publishing, New York, NY. 1991, 216
2. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 6th Ed. Biomedical Publ., Davis, CA.,129, 2002
3. Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.

Index of Symbols

	Consult instructions for use		Contains sufficient for <*n*> test	EC REP	Authorized representative in the European Community/European Union
IVD	*In vitro* diagnostic medical device		Use-by date		Do not reuse
	Store between 2-30 °C	LOT	Batch code	REF	Catalogue number
	Do not use if package is damaged and consult instructions for use		Manufacturer		Date of manufacture

EC REP Advena Ltd. Tower Business Centre, 2nd Flr.,
Tower Street, Swatar, BKR 4013 Malta

Rapid Labs Ltd
Unit 2 & 2A Hall Farm Business
Centre Church Road Little Bentley Colchester
Essex CO7 8SD
United Kingdom

Revision 1 27/06/2024

RAPID BIOTEC™

CE IVD

LSD Rapid Test Device
(Whole Blood/Serum/Plasma)

CATALOGUE NUMBER
D-DOA29WBD40

A rapid test for the qualitative detection of Lysergic Acid Diethylamide in human whole blood or serum or plasma.
For medical and other professional in vitro diagnostic use only.

INTENDED USE

The LSD Rapid Test Device (Whole Blood/Serum/Plasma) is a lateral flow chromatographic immunoassay for the detection of Lysergic Acid Diethylamide in whole blood or serum or plasma at a cut-off concentration of 20ng/mL.

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.

SUMMARY

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 2Areceptors 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 Device (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 Device (Whole Blood/Serum/Plasma) yields a positive result when Lysergic Acid Diethylamide in whole blood/serum/plasma exceeds 20ng/mL.

PRINCIPLE

The LSD Rapid Test Device (Whole Blood/Serum/Plasma) is an immunoassay based on the principle of competitive binding. Drugs which may be present in the whole blood/serum/plasma specimen compete against the drug conjugate for binding sites on the antibody. During testing, a whole blood/serum/plasma specimen migrates upward by capillary action. Lysergic Acid Diethylamide, if present in the specimen below 20ng/mL, will not saturate the binding sites of antibody-coated particles in the test. The antibody-coated particles will then be captured by immobilized Lysergic Acid Diethylamide 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 Lysergic Acid Diethylamide level exceeds 20ng/mL because it will saturate all the binding sites of anti-Lysergic Acid Diethylamide antibodies.

A drug-positive specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative 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 anti- Lysergic acid diethylamide antibody coupled particles and Lysergic acid diethylamide -protein conjugate. A goat antibody is employed in the control line system.

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 LSD Rapid Test Device can be performed using whole blood (from venipuncture or fingerstick) or serum or plasma.
- 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 40 µL. 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 well of the test Device.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days, 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 Devices • Droppers • Buffer • Package insert

Materials Required But Not Provided

• Specimen collection containers • Centrifuge
• Lancets (for fingerstick whole blood only) • Timer
• Heparinized 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.

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

For serum or plasma specimen:

•Hold the dropper vertically and transfer **1 full drop of serum or plasma** (approximately 40µL), then add **2 drops of buffer** (approximately 80µL) to the specimen well(S) of the Device, and then start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.

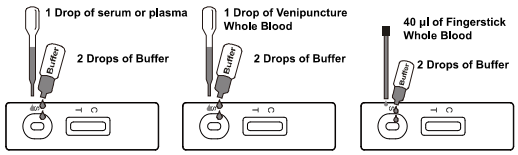
For Venipuncture Whole blood specimen:

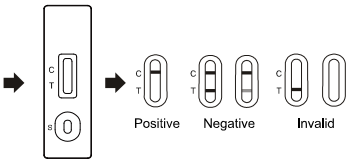
•Hold the dropper vertically and transfer **1 drop of whole blood** (approximately 40µL) to the specimen well(S), then **add 2 drops of buffer** (approximately 80µL), and start the timer. See illustration below.

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 well(S) of test Device, then add **2 drops of buffer**(approximately 80µL) and start the timer. See illustration below.

3. Wait for the colored line(s) to appear. **Read the result 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 Lysergic acid diethylamide 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 Lysergic acid diethylamide 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 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 LSD Rapid Test Device (Whole Blood/Serum/Plasma) 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.[2]
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 LSD Rapid Test Device and GC/MS at the cut-off of 20ng/mL. Testing was performed on 91 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Clinic Result of Whole Blood

Method		GC/MS		Total Results
LSD Rapid Test Device	Results	Positive	Negative	
	Positive	20	1	21
	Negative	1	69	70
Total Results		21	70	91
% Agreement		95.2%	98.6%	97.8%

Clinic Result of Serum or Plasma

Method		GC/MS		Total Results
LSD Rapid Test Device	Results	Positive	Negative	
	Positive	20	1	21
	Negative	1	69	70
Total Results		21	70	91
% Agreement		95.2%	98.6%	97.8%

Analytical Sensitivity

A drug-free whole blood/serum/plasma pool was spiked with Lysergic acid diethylamide at the following concentrations of ±50% cutoff and 3x cutoff, the data are summarized below:

For whole blood:

LSD Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
10	-50%	30	30	0

20	Cut-off	30	15	15
30	+50%	30	0	30
60	3X	30	0	30

For serum or plasma:

LSD Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
10	-50%	30	30	0
20	Cut-off	30	15	15
30	+50%	30	0	30
60	3X	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in whole blood/serum/plasma by the LSD Rapid Test Device (Whole Blood/Serum/Plasma) at 5 minutes.

Compound	Concentration (ng/mL)
Lysergic Acid Diethylamide	20

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 no Lysergic acid diethylamide, and 50% Lysergic acid diethylamide above and below the 20ng/mL cut-off was provided to each site. The following results were tabulated:

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

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 Lysergic acid diethylamide positive whole blood/serum/plasma. The following compounds show no cross-reactivity when tested with the LSD Rapid Test Device (Whole Blood/Serum/Plasma) at a concentration of 100 μg/mL.

Non Cross-Reacting Compounds

(+/-)-Norephedrine	Dopamine	Oxalic Acid
Albumin	(+/-)-Epinephrine	Penicillin-G
Ampicillin	Erythromycin	Pheniramine
Ascorbic	Acid Ethanol	Phenothiazine
Aspartame	Furosemide	L-Phenylephrine
Aspirin	Glucose	β-Phenylethylamine
Atropine	Guaiacol Glyceryl Ether	Procaine
Benzocaine	Hemoglobin	Quinidine
Bilirubin	Ibuprofen	Ranitidine
Caffeine	(+/-)-Isoproterenol	Riboflavin
Chloroquine	Ketamine	Sodium Chloride
(+)-Chlorpheniramine	Levorphanol	Sulindac
(+/-)-Chlorpheniramine	Lidocaine	Tyramine
Creatine	(+)-Naproxen	4-Dimethylaminoantipyrine
Dexbrompheniramine	Niacinamide	(1R,2S)-(-)-N-Methyl-Ephedrine
Dextromethorphan	Nicotine	Fentanyl
Diphenhydramine		

Interfering Substances

The LSD Rapid Test Device (Whole Blood/Serum/Plasma) has been tested for possible interference from visibly hemolyzed and lipemic specimens. In addition, no interference was observed in specimens containing up to 100 mg/dL hemoglobin; up to 100 mg/dL bilirubin and up to 200 mg/dL human serum albumin.

BIBLIOGRAPHY

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

Index of Symbols

	Consult instructions for use		Contains sufficient for <*n*> test		Authorized representative in the European Community/European Union
	*In vitro* diagnostic medical device		Use-by date		Do not reuse
	Store between 2-30°C		Batch code		Catalogue number
	Do not use if package is damaged and consult instructions for use		Manufacturer		Date of manufacture

Advena Ltd. Tower Business Centre, 2nd Flr.,
Tower Street, Swatar, BKR 4013 Malta

Rapid Labs Ltd
Unit 2 & 2A Hall Farm Business
Centre Church Road Little Bentley Colchester
Essex CO7 8SD
United Kingdom

Revision 1 24/06/2024

RAPID BIOTEC™

CE IVD

TML Rapid Test Device (Whole Blood/Serum/Plasma)

CATALOGUE NUMBER
D-DOA30WBD20

A rapid test for the qualitative detection of TML in human whole blood or serum or plasma.
For medical and other professional in vitro diagnostic use only.

INTENDED USE

The TML Rapid Test Device (Whole Blood/Serum/Plasma) is a lateral flow chromatographic immunoassay for the detection of Tramadol in whole blood or serum or plasma at a cut-off concentration of 50ng/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.

SUMMARY

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, glucoronidation or sulfation in the liver.

The TML Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid whole 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 Tramadol in whole blood/serum/plasma. The TML Rapid Test Device yields a positive result when Tramadol in whole blood exceed 50 ng/mL.[1]

PRINCIPLE

The TML Rapid Test Device (Whole Blood/Serum/Plasma) is an immunoassay based on the principle of competitive binding. Drugs that may be present in the whole blood/serum/plasma specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a whole blood/serum/plasma specimen migrates upward by capillary action. Tramadol, if present in the whole blood/serum/plasma 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 Tramadol-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 Tramadollevel exceeds the cut-off level because it will saturate all the binding sites of anti-Tramadolantibodies.

A drug-positive whole blood/serum/plasma specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative whole blood/serum/plasma 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 controlline region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains mouse monoclonal anti-Tramadolantibody coupled particles and Tramadol-protein conjugate. A goat antibody is employed in the controlline system.

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 ofspecimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection whenspecimens are being tested.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adverselyaffect results.

STORAGE AND STABILITY

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

SPECIMEN COLLECTION AND PREPARATION

- The TML Rapid Test Device can be performed using whole blood (from venipuncture or fingerstick) /serum/plasma.
- 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 40 μL. 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 well of the test device.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days, 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 devices • Droppers • Buffer • Package insert

Materials Required But Not Provided

• Specimen collection containers • Centrifuge
• Lancets (for fingerstick whole blood only) • Timer
• Heparinized 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.

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

For serum or plasma specimen:

•Hold the dropper vertically and transfer **1 full drop of serum or plasma** (approximately 40μL), then add **2 drops of buffer** (approximately 80μL) to the specimen well(S) of the device, and then start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.

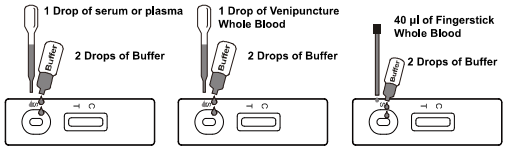
For Venipuncture Whole blood specimen:

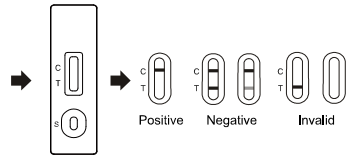
•Hold the dropper vertically and transfer **1 drop of whole blood** (approximately 40μL) to the specimen well(S), then **add 2 drops of buffer** (approximately 80μL), and start the timer. See illustration below.

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 well(S) of test device, then add **2 drops of buffer** (approximately 80μL) and start the timer. See illustration below.

Wait for the colored line(s) to appear. **Read the result 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 controlline region (C) and another colored line should be in the test line region (T). This negative result indicates that the Tramadolconcentration 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 controlline region (C). No line appears in the test line region (T). This positive result indicates that the Tramadol 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 controlline 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 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 TML Rapid Test Device (Whole blood /Serum/Plasma) 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.[2]
2. It is possible that technical or procedural errors, as well as other interfering substances in thewhole 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 TML Rapid Test Device and GC/MS at the cut-off of 50ng/mL. Testing was performed on 97 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Clinic Result of Whole Blood

Method		GC/MS		Total Results
	Results	Positive	Negative	
TML Rapid Test Device	Positive	19	1	20
	Negative	2	75	77
Total Results		21	76	97
% Agreement		90.5%	98.7%	96.9%

Clinic Result of Serum or Plasma

Method		GC/MS		Total Results
	Results	Positive	Negative	
TML Rapid Test Device	Positive	19	1	20
	Negative	2	75	77
Total Results		21	76	97
% Agreement		90.5%	98.7%	96.9%

Analytical Sensitivity

A drug-free whole blood/serum/plasma pool was spiked with TML at the following concentrations of ±50% cutoff and 3x cutoff, the data are summarized below:

For whole blood:

TML Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
25	-50%	30	30	0
50	Cut-off	30	15	15
75	+50%	30	0	30
150	3X	30	0	30

For serum or plasma:

TML Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
25	-50%	30	30	0
50	Cut-off	30	15	15
75	+50%	30	0	30
150	3X	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in whole blood by the TML Rapid Test Device (Whole Blood/Serum/Plasma) at 5 minutes.

Compound	Concentration (ng/mL)
n-Desmethyl-cis-tramadol	100

Cis-tramadol	50
Procyclidine	50
o-Desmethyl-cis-tramadol	5,000
Phencyclidine	50,000
d,l-O-Desmethyl venlafaxine	25,000

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 no TML and 50% TML above and below the 50ng/mL cut-off was provided to each site. The following results were tabulated:

TML 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
75	10	0	10	0	10	0	10

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 determine positive whole blood. The following compounds show no cross-reactivity when tested with the TML Rapid Test Device (Whole Blood/Serum/Plasma) at a concentration of 100 μg/mL.

Non Cross-Reacting Compounds

4-Acetaminophenol	Acetone	Acetophenetidin	N-Acetylprocainamide
Acetylsalicylic acid	Albumin	Amitriptyline	Amobarbital
Amoxapine	Amoxicillin	Ampicillin	Ascorbic acid
Aminopyrine	Apomorphine	Aspartame	Atropine
Benzilic acid	Benzoic acid	Benzphetamine	Bilirubin
Brompheniramine	Buspirone	Caffeine	Cannabidiol
Cannabinol	Cimetidine	Chloralhydrate	Chloramphenicol
Chlordiazepoxide	Chloroquine	Chlorothiazide	(+) -Chlorpheniramine
(+/-)-Chlorpheniramine	Chlorpromazine	Chlorprothixene	Cholesterol
Clomipramine	Clonidine	Codeine	Cortisone
(-) Cotinine	Creatinine	Cyclobarbital	Cyclobenzaprine
Deoxycorticosterone	(-) Deoxyephedrine	R (-)Deprenyl	Dextromethorphan
Diazepam	Diclofenac	Diflunisal	Digoxin
4-Dimethylaminoantipyrine	Diphenhydramine	Dicyclomine	5,5-Diphenylhydantoin
Disopyramide	Doxylamine	Ecgonine	EcgonineMethylester
EDDP	EMDP	Ephedrine	l-Ephedrine
(-) -Ψ-Ephedrine	[1R,2S] (-) Ephedrine	l-Epinephrine	(+/-)-Epinephrine
Erythromycin	β-Estradiol	Estrone-3-sulfate	Ethanol (Ethyl alcohol)
Ethyl-p-aminobenzoate	Etodolac	Famprofazone	Fenfluramine
Fenoprofen	Fentanyl	Fluoxetine	Furosemide
Gentisic acid	d-Glucose	GuaiacolGlyceryl Ether	Hydrochlorothiazide
Hemoglobin	Hydralazine	Hydromorphone	Hydrocodone
Hydrocortisone	3-Hydroxytyramine (Dopamine)	o-Hydroxyhippuric acid	p-Hydroxymethamphetamine
Imipramine	Hydroxyzine	Ibuprofen	Isoxsuprine
Iproniazide	(-) Isoproterenol	Ketoprofen	Kanamycin
Ketamine	Lidocaine	Labetalol	Levorphanol
Loperamide	Lithium Carbonate	Meperidine	Methamphetamine
Meprobamate	Lindane (Hexachlorocyclohexane)	Methylphenidate	Mephentermine
l-Methamphetamine	Maprotiline	Morphine sulfate	Naloxone
Methoxyphenamine	Methadone	Naproxen	Naltrexone
Methyprylon	Metoprolol	Niacinamide	Nifedipine
Nalidixic acid	(+)-3,4-Methylendioxy-methamphetamine	Nimesulide	d/l-Octopamine
α-Naphthaleneacetic acid	Morphine-3-β-D Glucuronide	Oxazepam	Orphenadrine
Norethindrone	Nalorphine	Oxolinic acid	Oxycodone
d-Norpropoxyphene	Norcodeine	Pemoline	Pentobarbital
Oxalic acid	Normorphine	Phenelzine	Perphenazine
Oxymorphone	Noscapine	Pheniramine	Phenobarbital

Interfering Substances

The TML Rapid Test Device (Whole Blood/Serum/Plasma) has been tested for possible interferencefrom visibly hemolyzed and lipemic specimens. In addition, no interference was observed in specimens containing up to 100 mg/dL hemoglobin; up to 100 mg/dL bilirubin and up to 200 mg/dL human serum albumin.

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

Index of Symbols

	Consult instructions for use		Contains sufficient for <*n*> test	EC REP	Authorized representative in the European Community/European Union
IVD	*In vitro* diagnostic medical device		Use-by date		Do not reuse
	Store between 2-30°C	LOT	Batch code	REF	Catalogue number
	Do not use if package is damaged and consult instructions for use		Manufacturer		Date of manufacture

EC REP Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta

Rapid Labs Ltd
Unit 2 & 2A Hall Farm Business
Centre Church Road Little Bentley Colchester
Essex CO7 8SD
United Kingdom

Revision 1 12/07/2024

RAPID BIOTEC™

CE IVD

MOP Rapid Test Device
(Whole Blood/Serum/Plasma)

CATALOGUE NUMBER
D-DOA38WBD40

A rapid test for the qualitative detection of Morphine in human whole blood or serum or plasma.
For medical and other professional in vitro diagnostic use only.

INTENDED USE
The MOP Rapid Test Device (Whole Blood/Serum/Plasma) is a lateral flow chromatographic immunoassay for the detection of Morphine in whole blood or serum or plasma at a cut-off concentration of 40ng/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.

SUMMARY
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 or serum or plasma for several days after an opiate dose.[1]
The MOP Rapid Test Device 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 Morphine in whole blood/serum/plasma. The MOP Rapid Test Device yields a positive result when Morphine in whole blood/serum/plasma reaches 40ng/mL.

PRINCIPLE
The MOP Rapid Test Device (Whole Blood/Serum/Plasma) is an immunoassay based on the principle of competitive binding. Drugs that may be present in the whole blood/serum/plasma specimen compete against the drug conjugate for binding sites on the antibody.
During testing, a whole blood/serum/plasma specimen migrates upward by capillary action .Morphine, if present in the whole blood/serum/plasma 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 Morphine-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 Morphine level exceeds the cut-off level because it will saturate all the binding sites of anti-Morphine antibodies.
A drug-positive whole blood/serum/plasma specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative whole blood/serum/plasma 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
1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Do not use test if pouch is damaged
4. 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.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
6. The used test should be discarded according to local regulations.
7. 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 MOP Rapid Test Device can be performed using whole blood (from venipuncture or fingerstick)/serum/plasma.
- 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 to the test by using **a capillary tube**:
    - Touch the end of the capillary tube to the blood until filled to approximately 40 μL. 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 well of the test device.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days, 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 devices • Droppers • Buffer • Package insert
Materials Required But Not Provided
• Specimen collection containers • Centrifuge
• Lancets (for fingerstick whole blood only) • Timer
• Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

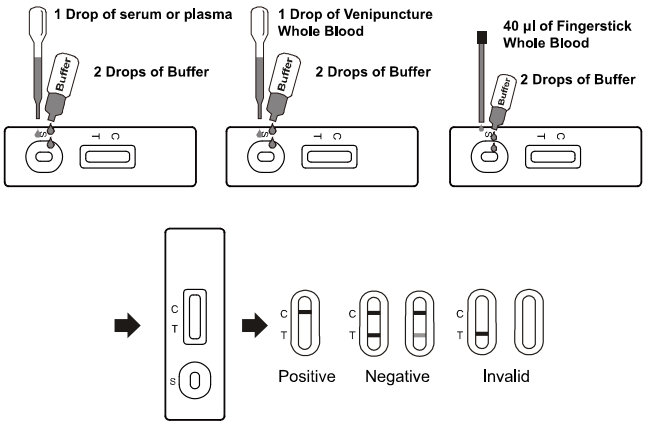
DIRECTIONS FOR USE
Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.
1. Bring the pouch to room temperature before opening it. Remove the device from the sealed pouch and use it within one hour.
2. Place the device on a clean and level surface.

For serum or plasma specimen:
•Hold the dropper vertically and transfer **1 full drop of serum or plasma** (approximately 40μL), then add **2 drops of buffer** (approximately 80μL) to the specimen well(S) of the device, and then start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.

For Venipuncture Whole blood specimen:
•Hold the dropper vertically and transfer **1 drop of whole blood** (approximately 40μL) to the specimen well(S), then **add 2 drops of buffer** (approximately 80μL), 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 well(S) of test device, then add **2 drops of buffer** (approximately 80μL) and start the timer. See illustration below.

3. Wait for the colored line(s) to appear. **Read the result 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 Morphine 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 Morphine 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 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.

LIMLTATIONS
1. The MOP Rapid Test Device (Whole Blood/Serum/Plasma) 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.[2]
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 MOP Rapid Test Device and GC/MS at the cut-off of 40ng/mL. Testing was performed on 90 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Clinic Result of Whole Blood

Method		GC/MS		Total Results
MOP Rapid Test Device	Results	Positive	Negative	
	Positive	23	2	25
	Negative	2	63	65
Total Results		25	65	90
% Agreement		92%	96.9%	95.6%

Clinic Result of Serum or Plasma

Method		GC/MS		Total Results
MOP Rapid Test Device	Results	Positive	Negative	
	Positive	23	2	25
	Negative	2	63	65
Total Results		25	65	90
% Agreement		92%	96.9%	95.6%

Analytical Sensitivity
A drug-free whole blood/serum/plasma pool was spiked with MOP at the following concentrations of ±50% cutoff and 3x cutoff, the data are summarized below:
For whole blood:

MOP Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
20	-50%	30	30	0
40	Cut-off	30	15	15
60	+50%	30	0	30
120	3X	30	0	30

For serum or plasma:

MOP Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
20	-50%	30	30	0
40	Cut-off	30	15	15
60	+50%	30	0	30
120	3X	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in whole blood/serum/plasma by the MOP Rapid Test Device (Whole Blood/Serum/Plasma) at 5 minutes.

Compound	Concentration (ng/mL)
Codeine	50
levorphanol	200
Morphine-3-β-D-Glucuronide	120
Ethylmorphine	500
Hydrocodone	5,000
Hydromorphone	300
6-Monoacethylmorphine	100
Norcodeine	500
Normorphone	5,000
Oxycodone	4,000
Oxymorphone	500
Procaine	1,500
Thebaine	500
Morphine	40

Precision

A study was conducted at three volunteer using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens, containing no MOP and 50% MOP above and below the 40ng/mL cut-off was provided to each site. The following results were tabulated:

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

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 determine positive whole blood/serum/plasma. The following compounds show no cross-reactivity when tested with the MOP Rapid Test Device (Whole Blood/Serum/Plasma) at a concentration of 100 μg/mL.

Non Cross-Reacting Compounds

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

Interfering Substances

The MOP Rapid Test Device (Whole Blood/Serum/Plasma) has been tested for possible interference from visibly hemolyzed and lipemic specimens. In addition, no interference was observed in specimens containing up to 100 mg/dL hemoglobin; up to 100 mg/dL bilirubin and up to 200 mg/dL human serum albumin.

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

Index of Symbols

	Consult instructions for use	Σ	Contains sufficient for <*n*> test	EC REP	Authorized representative in the European Community/European Union
IVD	*In vitro* diagnostic medical device		Use-by date		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Batch code	REF	Catalogue number
	Do not use if package is damaged and consult instructions for use		Manufacturer		Date of manufacture

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Revision 1 24/06/2024

RAPID BIOTEC™ CE IVD

α-Pyrrolidinovalerophenone (α-PVP) Rapid Test Device (Urine)

CATALOGUE NUMBER
D-DOA54D40

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

This assay provides only a qualitative, preliminary test result. A more specific alternate chemical method must be used in order to obtain a confirmed 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.

SUMMARY

alpha-Pyrrolidinovalerophenone (also known as α-PVP, A-PVP, alpha-PVP, and Flakka) is a synthetic stimulant substance of the cathinone and pyrrolidine chemical classes.[1] 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.[2] 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.[3, 4] It has also been linked to at least one death where it was combined with pentedrone and caused heart failure.

The α-Pyrrolidinovalerophenone (α-PVP) Rapid Test Device (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-Pyrrolidinovalerophenone (α-PVP) Rapid Test Device (Urine) yields a positive result when alpha-Pyrrolidinovalerophenone in urine exceeds 1,000ng/mL.

PRINCIPLE

The α-Pyrrolidinovalerophenone (α-PVP) Rapid Test Device (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 1,000ng/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 1,000ng/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 Devices
- Package Insert
- Droppers

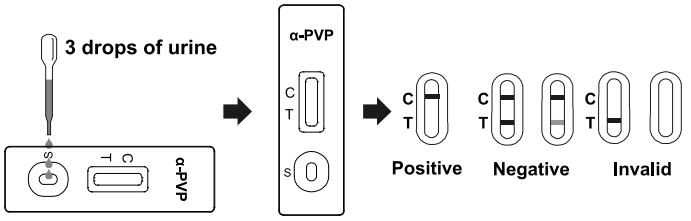
Materials Required But Not Provided

- 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.

1. Bring the pouch to room temperature before opening it. Remove the test Device 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 Device, 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

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 (1,000ng/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 (1,000ng/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

1. The α-Pyrrolidinovalerophenone (α-PVP) Rapid Test Device (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.
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 indicates 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 α-Pyrrolidinovalerophenone (α-PVP) Rapid Test Device and GC/MS at the cut-off of 1,000 ng/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
α-Pyrrolidinovalerophenone (α-PVP) Rapid Test Device	Results	Positive	Negative	
	Positive	35	2	37
	Negative	3	60	63
Total Results		38	62	100
% Agreement		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, 750 ng/mL, 1,000 ng/mL, 1,250 ng/mL, 1,500 ng/mL and 3,000 ng/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
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 α-Pyrrolidinovalerophenone (α-PVP) Rapid Test Device (Urine) at 5 minutes.

Compound	Concentration (ng/mL)
alpha-Pyrrolidinovalerophenone	1,000

Precision

A study was conducted at 3 hospitals 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 1000 ng/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
1,250	10	2	8	3	7	1	9
1,500	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 500 ng/mL and 1,500 ng/mL. The α-Pyrrolidinovalerophenone (α-PVP) Rapid Test Device (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 500 ng/mL and 1,500 ng/mL. The spiked, pH-adjusted urine was tested with the α-Pyrrolidinovalerophenone (α-PVP) Rapid Test Device (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-Pyrrolidinovalerophenone (α-PVP) Rapid Test Device (Urine) at a concentration of 100 μg/mL.

Non Cross-Reacting Compounds

Acetophenetidin	(±) 3,4-Methylendioxy amphetamine	Nimesulide	Metronidazole
N-Acetylprocainamide	Nalidixic acid	Buspirone	Vancomycin
Acetylsalicylic acid	Naloxone	5,5-Diphenylhydantoin	Spironolactone
Aminopyrine	Niacinamide	l-Thyroxine	Emetine
Amitriptyline	Nifedipine	EDDP	Paroxetine
Amobarbital	Norethindrone -	Oxymorphone	Diacetylmorphine
Amoxcillin	Norethisterone	Cyclobenzaprine	S(-)-Cathinone
Atropine	d-Norpropoxyphene	Lidocaine	R(+)-Methcathinone
Aspartame -	Noscapine	Guaifenesin	S(-)-Methcathinone
Asp-Phemethylester	d,l- Octopamine	Amoxapine	Barbital
Benzilic acid	Oxazepam	(+)- Chlorpheniramine	Carbamazepine
Benzoic acid	Oxymetazoline	Guaiacol Glyceryl -	Lansoprazole
Bilirubin	Papaverine	Ether carbamate	Diphenoxylate
Chloramphenicol	Penicillin	Chlorprothixene	7-Amino-clonazepam
Chlorothiazide	Promethazine	R (-)Deprenyl	p-Acetamidophenyl-β-
Chlorpromazine	Hydrochioride	Pheniramine	D-glucuronide
Chloroquine	Perphenazine	4-Dimethylaminoantipyrine	Clonazepam
Cholesterol	Phenelzine	Riboflavin	Terbutaline hemisulfate salt
Clomipramine	Phenobarbital	α -Naphthaleneacetic Acid	Zolpiden hemitartrate
Clonidine Hydrochloride	β-Phenylethylamine	(+/-) Epinephrine	Valproic acid
Cocaine	Prednisolone	Phenothiazine	Isoniazid
Codeine	Prednisone	Albumin	7-Aminoflunitrazepam
Cortisone	l-Phenylephrine -	d (+) Glucose	DL-Homatropine –
(-)Cotinine	(R)-(-)-Phenylephrine	Sodium chloride	Hydrobromide
Creatinine	Procaine	Pemoline	Alprazolam
Deoxycorticosterone	Quinidine	Cimetidine	3,4-Methylenedioxy-
Diazepam	Quinine	Disopyramide	ethylamphetamine
Diflunisal	5-Hydroxytryptamine	Hexachlorocyclohexane	Estazolam
Digoxin	Sulfamethazine	Etodolac	Bromazepam
		Metoprolol	

Doxylamine	Temazepam	Amantadine	Ethylmorphine
Erythromycin	Tetracycline	Chlorpropamide	Clorazepam dipotassium
β-Estradiol Estradiol	Tetrahydrozoline	Clozapine	Norchlordiazepoxide
Diphenhydramine	Thebaine	Baclofen	Methotrexate
-Hydrochloride	Thiamine	Amikacin	Nortriptyline
Estrone	Thioridazine	Droperidol	Doxepin
Ethyl-p-aminobenzoate	Tolbutamide	Gentamicin	Desipramine
Fenoprofen	Triamterene	Indomethacin	Nordoxepin
Furosemide	Trimethoprim	Sulfamethoxazole	Desalkylflurazepam
Gentisic acid	Trimipramine	Sulfisoxazole	Ciprofloxacin Hydrochloride
Hydralazine	Tryptamine	Nimesulide	pantoprazole
Hydrochlorothiazide	d,l-Tyrosine -	Buspirone	Pseudoephedrine -
O-Hydroxyhippuric acid	L-Tyrosine	5,6-Diphenylhydantoin	Hydrochloride
3-Hydroxytyramine	d,l-Tryptophan	l-Thyroxine	PEG-400
Ibuprofen	Uric acid	Oxymorphone	Amlodipine Besylate
		Cyclobenzaprine	
p-Hydroxy -	Verapamil	Lidocaine	(S)-(+)-Methoxy-α-Methyl
methamphetamine	Zomepirac		-2-napthaleneacetic acid
Imipramine	Ampicillin	Guaifenesin	Valsartan capsules
(-) Isoproterenol	Caffeine	Amoxapine	Sildenafil Citate
Ketoprofen	(+/-)-Chlorpheniramine	Guaiacol Glyceryl - Ether carbamate	Tizanidine HCL
Maprotiline	Ranitidine	(+)- Chlorpheniramine	Pantoprazole Sodium
Meprobamate	Quinacrine		Enteric-Coated
Meperidine	Dicyclomine	Gabapentin	Pyridoxine HCL
Methoxyphenamine	Trazodone	(+)-Nopseudoephedrine	Dihydrocodeine
Atomoxetine	Trans-2-Phenylcy-	Pregablin	
levetiracetam	clopropylamine	(1R, 2S) - (-)-Ephedrine	

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2. 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.
3. 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.
4. Waugh; et al. (2013). "Deaths Involving the Recreational Use of α-PVP (α-pyrrolidinopentiophenone)" (PDF). AAFS Proceedings. Abstract K16.

Index of Symbols

	Consult instructions for use	Σ	Contains sufficient for <*n*> test	EC REP	Authorized representative in the European Community/European Union
IVD	*In vitro* diagnostic medical device		Use-by date		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Batch code	REF	Catalogue number
	Do not use if package is damaged and consult instructions for use		Manufacturer		Date of manufacture

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Revision 1 25/06/2024

RAPID BIOTEC™

CE IVD

Methylenedioxypyrovalerone (MDPV) Rapid Test Device (Urine)

CATALOGUE NUMBER
D-DOA62D40

For medical and other professional in vitro diagnostic use only.
A rapid test for the qualitative detection of 3, 4-methylenedioxypyrovalerone in human urine.

INTENDED USE

The Methylenedioxypyrovalerone (MDPV) Rapid Test Device (Urine) is a rapid chromatographic immunoassay for the detection of 3, 4-methylenedioxypyrovalerone in human urine at a cut-off concentration of 1,000 ng/mL.

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) 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.

SUMMARY

3, 4-methylenedioxypyrovalerone (Methylenedioxypyrovalerone (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. Methylenedioxypyrovalerone (MDPV) remained an obscure stimulant until around 2004 when it was reportedly sold as a designer drug. Products labeled as bath salts containing Methylenedioxypyrovalerone (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.

Methylenedioxypyrovalerone (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 Methylenedioxypyrovalerone (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.

Methylenedioxypyrovalerone (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 urine.

The Methylenedioxypyrovalerone (MDPV) Rapid Test Device (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 3,4-methylenedioxypyrovalerone in urine. The Methylenedioxypyrovalerone (MDPV) Rapid Test Device (Urine) yields a positive result when 3,4-methylenedioxypyrovalerone in urine exceeds 1,000 ng/mL.

PRINCIPLE

The Methylenedioxypyrovalerone (MDPV) Rapid Test Device (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. 3, 4-methylenedioxypyrovalerone, if present in the urine specimen below 1,000 ng/mL, will not saturate the binding sites of antibody-coated particles in the test. The antibody-coated particles will then be captured by immobilized 3, 4-methylenedioxypyrovalerone 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 3, 4-methylenedioxypyrovalerone level exceeds 1,000 ng/mL because it will saturate all the binding sites of anti-3, 4-methylenedioxypyrovalerone 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, indiaceVing that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains mouse monoclonal anti-3, 4-methylenedioxypyrovalerone antibody-coupled particles and 3, 4-methylenedioxypyrovalerone-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 Devices
- Droppers
- Package insert

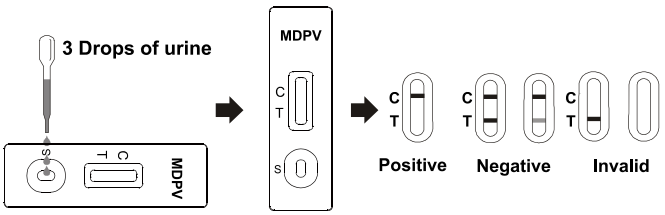
Materials Required But Not Provided

- Specimen collection containers
- Timer

DIRECTIONS FOR USE

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

1. Bring the pouch to room temperature before opening it. Remove the test Device 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 Device, 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 3, 4-methylenedioxypyrovalerone concentrations are below the detectable level (1,000 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 3, 4-methylenedioxypyrovalerone concentration exceeds the detectable level (1,000 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

1. The Methylenedioxypyrovalerone (MDPV) Rapid Test Device (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.[2,3]
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 indicates 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 Methylenedioxypyrovalerone (MDPV) Rapid Test Device and GC/MS at the cut-off of 1,000 ng/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
Methylenedioxypyrovalerone (MDPV) Rapid Test Device	Results	Positive	Negative	
	Positive	28	1	29
	Negative	2	69	71
Total Results		30	70	100
% Agreement		93.3%	98.6%	97.0%

Analytical Sensitivity

A drug-free urine pool was spiked with 3, 4-methylenedioxypyrovalerone at the following concentrations: 0 ng/mL, 500 ng/mL, 750 ng/mL, 1,000 ng/mL, 1250 ng/mL, 1,500 ng/mL and 3,000 ng/mL. The result demonstrates > 99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

3, 4-methylenedioxypyrovalerone 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	14	16
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 Methylenedioxypyrovalerone (MDPV) Rapid Test Device (Urine) at 5 minutes.

Compound	Concentration (ng/mL)
3, 4-methylenedioxypyrovalerone	1,000

Precision

A study was conducted at 3 hospitals 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 3, 4-methylenedioxypyrovalerone, 25% 3, 4-methylenedioxypyrovalerone above and below the cutoff and 50% 3, 4-methylenedioxypyrovalerone above and below the 1,000 ng/mL cutoff were provided to each site. The following results were tabulated:

3, 4-methylenedioxypyrovalerone 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	9	1	9	1	8	2
1,250	10	1	9	1	9	1	9
1,500	10	0	10	0	10	0	10

Effect of Urinary Specific Gravity

Fifteen urine samples with specific gravities ranging from 1.004 to 1.034 were spiked with 3, 4-methylenedioxypyrovalerone to the concentrations of 500 ng/mL and 1,500 ng/mL. The Methylenedioxypyrovalerone (MDPV) Rapid Test Device (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 3, 4-methylenedioxypyrovalerone to 500 ng/mL and 1,500 ng/mL. The spiked, pH-adjusted urine was tested with the Methylenedioxypyrovalerone (MDPV) Rapid Test Device (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 3, 4-methylenedioxypyrovalerone positive urine. The following compounds show no cross-reactivity when tested with the Methylenedioxypyrovalerone (MDPV) Rapid Test Device (Urine) at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

Acetone	Dopamine	Oxalic Acid
Albumin	(+/-)-Epinephrine	Penicillin-G
Ampicillin	Erythromycin	Pheniramine
Ascorbic	Acid Ethanol	Phenothiazine
Aspartame	Furosemide	L-Phenylephrine
Aspirin	Glucose	β-Phenylethylamine
Atropine	Guaiacol Glyceryl Ether	Procaine
Benzocaine	Hemoglobin	Quinidine
Bilirubin	Ibuprofen	Ranitidine
Caffeine	(+/-)-Isoproterenol	Riboflavin
Chloroquine	Ketamine	Sodium Chloride
(+)-Chlorpheniramine	Levorphanol	Sulindac
(+/-)-Chlorpheniramine	Lidocaine	Tyramine
Creatine	(+)-Naproxen	4-Dimethylaminoantipyrine
Dexbrompheniramine	Niacinamide	(1R,2S)-(-)-N-Methyl-Ephedrine
Dextromethorphan	Nicotine	Diphenhydramine
(+/-)-Norephedrine		

BIBLIOGRAPHY

1. Glass, IB. The International Handbook of Addiction Behavior. Routledge Publishing, New York, NY. 1991, 216
2. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 6th Ed. Biomedical Publ., Davis, CA.,129, 2002
3. Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.

Index of Symbols

	Consult instructions for use		Contains sufficient for <*n*> test	EC REP	Authorized representative in the European Community/European Union
IVD	*In vitro* diagnostic medical device		Use-by date		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Batch code	REF	Catalogue number
	Do not use if package is damaged and consult instructions for use		Manufacturer		Date of manufacture

EC REP Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta

Rapid Labs Ltd
Unit 2 & 2A Hall Farm Business
Centre Church Road Little Bentley Colchester
Essex CO7 8SD
United Kingdom

Revision 1 26/06/2024

RAPID BIOTEC™

CE IVD

MDPV Rapid Test Device (Whole Blood/Serum/Plasma)

CATALOGUE NUMBER
D-DOA62WBD40

A rapid test for the qualitative detection 3, 4-methylenedioxypyrovalerone in human whole blood or serum or plasma.
For medical and other professional in vitro diagnostic use only.

INTENDED USE

The MDPV Rapid Test Device (Whole Blood/Serum/Plasma) is a lateral flow chromatographic immunoassay for the detection 3, 4-methylenedioxypyrovalerone in whole blood or serum or plasma 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 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 used.

SUMMARY

3, 4-methylenedioxypyrovalerone (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 BoehringerIngelheim. 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 methylenedioxyphenylalkylamine 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 or serum or plasma.
The MDPV Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid whole blood or 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-methylenedioxypyrovalerone in whole blood or serum or plasma. The MDPV Rapid Test Device (Whole Blood/Serum/Plasma) yields a positive result when 3, 4-methylenedioxypyrovalerone in whole blood or serum or plasma exceeds 500ng/mL.

PRINCIPLE

The MDPV Rapid Test Device (Whole Blood/Serum/Plasma) is an immunoassay based on the principle of competitive binding. Drugs that may be present in the specimen compete against the drug conjugate for binding sites on the antibody. During testing, a specimen migrates upward by capillary action. 3, 4-methylenedioxypyrovalerone, if present in the 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 3, 4-methylenedioxypyrovalerone-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 3, 4-methylenedioxypyrovalerone level exceeds the cut-off level because it will saturate all the binding sites of anti-3, 4-methylenedioxypyrovalerone antibodies.
A drug-positive specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative 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-3, 4-methylenedioxypyrovalerone antibody coupled particles and 3, 4-methylenedioxypyrovalerone-protein conjugate. A goat antibody is employed in the control line system.

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 MDPV Rapid Test Device can be performed using whole blood (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 40 μL. 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 well of the test device.
- 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/serum/plasma 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 or serum or plasma specimens. Whole blood/serum/plasma 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 devices • Droppers • Buffer • Package insert

Materials Required But Not Provided

• Specimen collection containers • Centrifuge
• Lancets (for fingerstick whole blood only) • Timer
• Heparinized 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.

1. Bring the pouch to room temperature (15-30°C) before opening it. Remove the device from the sealed pouch and use it within one hour.
2. Place the device on a clean and level surface.

For serum or plasma specimen:

•Hold the dropper vertically and transfer **1 full drop of serum or plasma** (approximately 40 μL), then add **2 drops of buffer** (approximately 80 μL) to the specimen well(S) of the device, and then start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.

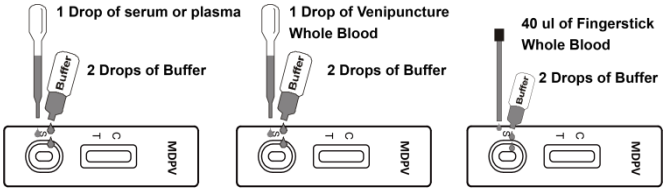
For Venipuncture Whole blood specimen:

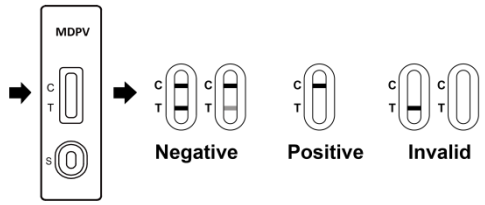
•Hold the dropper vertically and transfer **1 drop of whole blood** (approximately 40 μL) to the specimen well(S), then **add 2 drops of buffer** (approximately 80 μL), and start the timer. See illustration below.

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 well(S) of test device, then add **2 drops of buffer**(approximately 80 μL) and start the timer. See illustration below.

3. Wait for the colored line(s) to appear. **Read the result 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 3, 4-methylenedioxypyrovalerone 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 3, 4-methylenedioxypyrovalerone 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 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 MDPV Rapid Test Device (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.
2. It is possible that technical or procedural errors, as well as other interfering substances in the 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 MDPV Rapid Test Device and GC/MS at the cut-off of 500ng/mL. Testing was performed on 100 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Clinic Result of Whole Blood

Method		GC/MS		Total Results
MDPV Rapid Test Device	Results	Positive	Negative	
	Positive	28	2	30
	Negative	2	68	70
Total Results		30	70	100
% Agreement		93.3%	97.1%	96.0%

Clinic Result of Serum or Plasma

Method		GC/MS		Total Results
MDPV Rapid Test Device	Results	Positive	Negative	
	Positive	28	2	30
	Negative	2	68	70
Total Results		30	70	100
% Agreement		93.3%	97.1%	96.0%

Analytical Sensitivity

A drug-free whole blood/serum/plasma pool was spiked with 3, 4-methylenedioxypyrovalerone at the following concentrations of negative ±50%cut off and 3x cut off, the data are summarized below:

MDPV Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
250	-50%	30	30	0
500	Cut-off	30	15	15
750	+50%	30	0	30
1,500	3X	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in whole blood/serum/plasma by the MDPV Rapid Test Device (Whole Blood/Serum/Plasma) at 5 minutes.

Compound	Concentration (ng/mL)
3, 4-methylenedioxypyrovalerone	500

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 no MDPV and 50% MDPV above and below the 500ng/ml cut-off was provided to each site. The following results were tabulated:

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

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free whole blood or determine positive whole blood/serum/plasma. The following compounds show no cross-reactivity when tested with the MDPV Rapid Test Device (Whole Blood/Serum/Plasma) at a concentration of 100 μg/mL.

Non Cross-Reacting Compounds

Acetone	Dopamine	Oxalic Acid
Albumin	(+/-)-Epinephrine	Penicillin-G
Ampicillin	Erythromycin	Pheniramine
Ascorbic	Acid Ethanol	Phenothiazine
Aspartame	Furosemide	L-Phenylephrine
Aspirin	Glucose	β-Phenylethylamine
Atropine	GuaiacolGlyceryl Ether	Procaine
Benzocaine	Hemoglobin	Quinidine
Bilirubin	Ibuprofen	Ranitidine
Caffeine	(+/-)-Isoproterenol	Riboflavin
Chloroquine	Ketamine	Sodium Chloride
(+)-Chlorpheniramine	Levorphanol	Sulindac
(+/-)-Chlorpheniramine	Lidocaine	Tyramine
Creatine	(+)-Naproxen	4-Dimethylaminoantipyrine
Dexbrompheniramine	Niacinamide	(1R,2S)-(-)-N-Methyl-Ephedrine
Dextromethorphan	Nicotine	
Diphenhydramine	(+/-)-Norephedrine	

Interfering Substances

The MDPV Rapid Test Device (Whole Blood/Serum/Plasma) has been tested for possible interference from visibly hemolyzed and lipemic specimens. In addition, no interference was observed in specimens containing up to 100 mg/dL hemoglobin;up to 100 mg/dL bilirubin; and up to 200 mg/dL human serum albumin.

BIBLIOGRAPHY

1. Glass, IB. The International Handbook of Addiction Behavior. Routledge Publishing, New York, NY. 1991, 216
2. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 6th Ed. Biomedical Publ., Davis, CA.,129, 2002
3. Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.

Index of Symbols

	Consult instructions for use		Contains sufficient for <*n*> test		Authorized representative in the European Community/European Union
	*In vitro* diagnostic medical device		Use-by date		Do not reuse
	Store between 2-30°C		Batch code		Catalogue number
	Do not use if package is damaged and consult instructions for use		Manufacturer		Date of manufacture

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Tower Street, Swatar, BKR 4013 Malta

Rapid Labs Ltd
Unit 2 & 2A Hall Farm Business
Centre Church Road Little Bentley Colchester
Essex CO7 8SD
United Kingdom

Revision 1 24/06/2024

RAPID BIOTEC™

CE IVD

THC Rapid Test Device
(Whole Blood/Serum/Plasma)

CATALOGUE NUMBER

D-DOA67WBD40

A rapid test for the qualitative detection of Marijuana in human whole blood or serum or plasma.
For medical and other professional in vitro diagnostic use only.

INTENDED USE

The THC Rapid Test Device (Whole Blood/Serum/Plasma) is a lateral flow chromatographic immunoassay for the detection of Marijuana in whole blood or serum or plasma at a cut-off concentration of 35ng/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.

SUMMARY

THC (9-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-(9-tetrahydrocannabinol-9-carboxylic acid (THC-COOH).[1]

PRINCIPLE

The THC Rapid Test Device (Whole Blood/Serum/Plasma) is an immunoassay based on the principle of competitive binding. Drugs that may be present in the whole blood/serum/plasma specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a whole blood/serum/plasma specimen migrates upward by capillary action. Marijuana, if present in the whole blood/serum/plasma 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 Marijuana-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 Marijuana level exceeds the cut-off level because it will saturate all the binding sites of anti-Marijuana antibodies.

A drug-positive whole blood/serum/plasma specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative whole blood/serum/plasma 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-Marijuana antibody coupled particles and Marijuana-protein conjugate. A goat antibody is employed in the control line system.

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 THC Rapid Test Device can be performed using whole blood (from venipuncture or fingerstick) /serum/plasma.
- 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 40 μL. 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 well of the test device.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days, 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 devices • Droppers • Buffer • Package insert

Materials Required But Not Provided

• Specimen collection containers • Centrifuge
• Lancets (for fingerstick whole blood only) • Timer
• Heparinized 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.

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

For serum or plasma specimen:

•Hold the dropper vertically and transfer **1 full drop of serum or plasma** (approximately 40μL), then add **2 drops of buffer** (approximately 80μL) to the specimen well(S) of the device, and then start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.

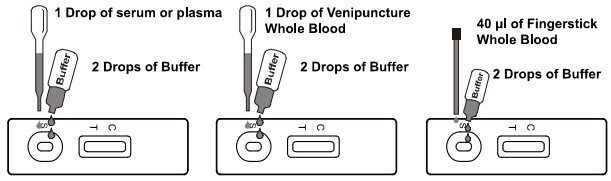
For Venipuncture Whole blood specimen:

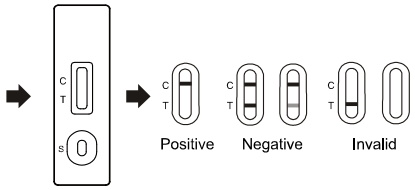
•Hold the dropper vertically and transfer **1 drop of whole blood** (approximately 40μL) to the specimen well(S), then **add 2 drops of buffer** (approximately 80μL), and start the timer. See illustration below.

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 well(S) of test device, then add **2 drops of buffer**(approximately 80μL) and start the timer. See illustration below.

3. Wait for the colored line(s) to appear. **Read the result 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 Marijuana 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 Marijuana 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 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 THC Rapid Test Device (Whole Blood/Serum/Plasma) 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.[2]
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 THC Rapid Test Device and GC/MS at the cut-off of 35ng/mL. Testing was performed on 90 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Clinic Result of Whole Blood

Method		GC/MS		Total Results
	Results	Positive	Negative	
THC Rapid Test Device	Positive	24	1	25
	Negative	2	63	65
Total Results		26	64	90
% Agreement		92.3%	98.4%	96.7%

Clinic Result of Serum or Plasma

Method		GC/MS		Total Results
	Results	Positive	Negative	
THC Rapid Test Device	Positive	24	1	25
	Negative	2	63	65
Total Results		26	64	90
% Agreement		92.3%	98.4%	96.7%

Analytical Sensitivity

A drug-free whole blood/serum/plasma pool was spiked with Marijuana at the following concentrations of ±50% cutoff and 3x cutoff, the data are summarized below:

For whole blood:

THC Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
17.5	-50%	30	30	0
35	Cut-off	30	15	15
52.5	+50%	30	0	30
105	3X	30	0	30

For serum or plasma:

THC Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
17.5	-50%	30	30	0
35	Cut-off	30	15	15
52.5	+50%	30	0	30
105	3X	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in Whole blood/Serum/Plasma by the THC Rapid Test Device (Whole Blood/Serum/Plasma) at 5 minutes.

Compound	Concentration (ng/mL)
Cannabinol	25,000
11-nor-Δ^8-THC-9 COOH	25
11-nor-Δ^9-THC-9 COOH	35
Δ^8-THC	12,000
Δ^9-THC	12,000

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 no marijuana, and 50% marijuana above and below the 35ng/mL cut-off was provided to each site. The following results were tabulated:

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

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 marijuana positive whole blood/serum/plasma. The following compounds show no cross-reactivity when tested with the THC Rapid Test Device (Whole Blood/Serum/Plasma) at a concentration of 100 μg/mL.

Non Cross-Reacting Compounds

4-Acetamidophenol	Deoxycorticosterone	(+) 3,4-Methylenedioxy-	Prednisolone
Acetophenetidin	Dextromethorphan	amphetamine	Prednisone
N-Acetylprocainamide	Diazepam	(+) 3,4-Methylenedioxy-	Procaine
Acetylsalicylic acid	Diclofenac	methamphetamine	Promazine
Aminopyrine	Diflunisal	Methylphenidate	Promethazine
Amitryptyline	Digoxin	Methyprylon	D,l-Propanolol
Amobarbital	Diphenhydramine	Morphine-3-	D-Propoxyphene
Amoxicillin	Doxylamine	β-D-glucuronide	D-Pseudoephedrine
Ampicillin	Ecgonine hydrochloride	Nalidixic acid	Quinidine
l-Ascorbic acid	Ecgoninemethylester	Nalorphine	Quinine
D,l-Amphetamine	(-)-ψ-Ephedrine	Naloxone	Ranitidine
l-Amphetamine	Erythromycin	Naltrexone	Salicylic acid
Apomorphine	β-Estradiol	Naproxen	Secobarbital
Aspartame	Estrone-3-sulfate	Niacinamide	Serotonin (5-Hydroxytyramine)
Atropine	Ethyl-p-aminobenzoate	Nifedipine	Sulfamethazine
Benzilic acid	Fenoprofen	Norcodein	Sulindac
Benzoic acid	Furosemide	Norethindrone	Temazepam
Benzoylecgonine	Gentisic acid	D-Norpropoxyphene	Tetracycline
Benzphetamine	Hemoglobin	Noscapine	Tetrahydrocortisone,
Bilirubin	Hydralazine	D,l-Octopamine	3-Acetate
(±)-Brompheniramine	Hydrochlorothiazide	Oxalic acid	Tetrahydrocortisone
Caffeine	Hydrocodone	Oxazepam	3 (β-D-glucuronide)
Cannabidiol	Hydrocortisone	Oxolinic acid	Tetrahydrozoline
Chloralhydrate	O-Hydroxyhippuric acid	Oxycodone	Thebaine
Chloramphenicol	3-Hydroxytyramine	Oxymetazoline	Thiamine
Chlordiazepoxide	Ibuprofen	p-Hydroxy-	Thioridazine
Chlorothiazide	Imipramine	methamphetamine	D, l-Thyroxine
(±) Chlorpheniramine	Iproniazid	Papaverine	Tolbutamine
Chlorpromazine	(±) - Isoproterenol	Penicillin-G	Triamterene
Chlorquine	Isoxsuprine	Pentazocine	Trifluoperazine
Cholesterol	Ketamine	Pentobarbital	Trimethoprim
Clomipramine	Ketoprofen	Perphenazine	Trimipramine
Clonidine	labetalol	Phencyclidine	Tryptamine
Cocaine hydrochloride	levorphanol	Phenelzine	D, l-Tryptophan
Codeine	loperamide	Phenobarbital	Tyramine
Cortisone	Maprotiline	Phentermine	D, l-Tyrosine
(-) Cotinine	Meprobamate	l-Phenylephrine	Uric acid

Interfering Substances

The THC Rapid Test Device (Whole Blood/Serum/Plasma) has been tested for possible interference from visibly hemolyzed and lipemic specimens. In addition, no interference was observed in specimens containing up to 100 mg/dL hemoglobin; up to 100 mg/dL bilirubin and up to 200 mg/dL human serum albumin.

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

Index of Symbols

	Consult instructions for use		Contains sufficient for <*n*> test	EC REP	Authorized representative in the European Community/European Union
IVD	*In vitro* diagnostic medical device		Use-by date		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Batch code	REF	Catalogue number
	Do not use if package is damaged and consult instructions for use		Manufacturer		Date of manufacture

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