

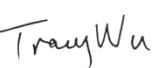


STATEMENT

We, **Rapid Labs Limited** having a registered office at Unit 2 & 2A, Hall Farm Business Centre, Church Road, Little Bentley, Colchester, Essex CO7 8SD, United Kingdom assign SRL Sanmedico, having a registered office at A. Corobceanu street 7A, apt. 9, Chișinău MD-2012, Moldova, as authorized representative in Republic of Moldova.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Date: March 5th, 2025

Signature:  **Rapid Labs**
Rapid Labs Limited

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



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/0/0002/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'.

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Issued by

Mukesh Singhal - On behalf of the Schemes Manager





Date: 15/05/2022

EU Declaration of Conformity

Declaration of Conformity

for Rapid strips & devices

DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 27 October 1998 on in vitro diagnostic medical devices

The undersigned, under their sole responsibility, declares that the products described in this document meet the Council 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 membrane of 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.



Date: 15/05/2022

EU Declaration of Conformity

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS): EN ISO 13485:2016, EN ISO 14971:2019, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, ISO 20916:2019, EN ISO 23640:2015, EN 13641:2002, EN ISO 15223-1:2021, EN 62366-1:2015

Part/Catalogue Number	Description/Name
D-ADOD25	Adenovirus Rapid Test Device – Feces
D-ASTD10	Astrovirus Rapid Test Device – Feces
D-AFPD20	AFP Rapid Test Device – WB/S/P
D-CTTD10	Cardiac Troponin T Rapid Test Device – WB/S/P
D-CAMD10	Campylobacter Rapid Test Device – Feces
D-CA125D10	CA125 Rapid Test Device – WB/S/P
D-CA153D10	CA15-3 Rapid Test Device – WB/S/P
D-CA199D10	CA19-9 Rapid Test Device – WB/S/P
D-CRYD10	Cryptosporidium Rapid Test Device – Feces
D-CAND10	Candida Albicans Rapid Test Device – Swab
D-CHIKWBD40	Chikungunya IgG/IgM Rapid Test Device – WB/S/P
D-CALAD10	Calprotectin & Lactoferrin Combo Rapid test Device- Feces
D-CRYGLD10	Cryptosporidium & Gardia Lamblia Combo Rapid Test Device –
D-ENTD10	Entamoeba Histolytica Rapid Test Device – Feces
D-EGCD10	Entamoeba/Giardia/Crypto Rapid test Device- Faces
D-FABD10	H-FABP Rapid Test Device – WB/S/P
D-HCGD20	hCG Pregnancy Rapid Test Device – Urine/S/P
D-HCGD40	hCG Pregnancy Rapid Test Device – Urine/S/P
D-HCGS50	hCG Pregnancy Rapid Test Strip – Urine/S/P
D-HCGS100	hCG Pregnancy Rapid Test Strip – Urine/S/P
D-HCGUS25	hCG Pregnancy Rapid Test Cannister Strip – Urine
D-HCGUS50	hCG Pregnancy Rapid Test Strip – Urine
D-HCGUS100	hCG Pregnancy Rapid Test Strip – Urine
D-HCGUD40	hCG Pregnancy Rapid Test Device - Urine
D-IGED10	IgE Rapid Test Device – WB/S/P
D-LACFD10	Lactoferrin Rapid test Device- Feces
D-LYMD10	Lyme IgG/IgM Rapid Test Device -WB/S/P
D-LPSPD10	Streptococcus pneumoniae and Legionella pneumophila Combo Rapid Test Device -Urine
D-LHD20	LH Ovulation Rapid Test Device – Urine
D-LHS50	LH Ovulation Rapid Test Strip – Urine
D-HPS50	H.pylori Antibody Rapid Test Strip – WB/S/P
D-HPAGD20	H.pylori antigen Rapid Test Device – Feces
D-TBD20	Tuberculosis Rapid Test Device – WB/S/P
D-DGMD20	Dengue Rapid Test Device – WB/S/P
D-DAGMD20	Dengue Combo Rapid Test Device – WB/S/P
D-DAGD20	Dengue NS1 Rapid Test Device – WB/S/P
D-CHIKMD20	Chikungunya IgG/IgM Rapid Test Device– WB/S/P
D-NTPD10	NT-proBNP Rapid Test Device - WB/S/P
D-FILGMD20	Filariasis IgG/IgM Rapid Test Device – WB/S/P
D-HEVD20	HEV IgG/IgM Rapid Test Device – S/P
D-INFS20	Influenza A Rapid Test Strip - Swab/Nasal Aspirate Influenza A Rapid Test Device - Swab/Nasal Aspirate
D-LEIGMD20	Leishmania IgG/IgM Rapid Test Device – WB/S/P
D-LEPGMD20	Leptospira IgG/IgM Rapid Test Device – WB/S/P
D-MPFD20	Malaria Pf Rapid Test Device – WB

D-PNEUD20	Mycoplasma pneumoniae Antigen Rapid Test Device – Swab
D-NOROD25	Norovirus Rapid Test Device – Feces
D-COVD25	2019-nCOV IgG/IgM Rapid Test Device – WB/S/P
D-COVAGD25	COVID-19 Antigen Rapid Test Strip - Nasopharyngeal Swab
D-COVAGIFD25	COVID-19 and Influenza A+B Antigen Combo Rapid Test Device (Nasopharyngeal Swab)
D-COVAGD25B	SARS-CoV-2 Antigen Rapid Test Device – Swab
D-MPFPVPAND20	Malaria P.f./P.v./Pan Rapid Test Device – WB
D-MPFPAND20	Malaria P.f./Pan Rapid Test Device – WB
D-MPFPVD20	Malaria P.f./P.v. Rapid Test Device - WB
D-MYPMD20	Mycoplasma Pneumoniae IgM Rapid Test Device – WB/S/P
D-MYPGMD20	Mycoplasma Pneumoniae IgG/Ig M Rapid Test Device – WB/S/P
D-MONOD25	MONO Rapid Test Device – WB/S/P
D-TYPGMD20	Typhoid Rapid Test Strip - WB/S/P Typhoid Rapid Test Device - WB/S/P
D-FOBD10	FOB Rapid Test Device – Feces
D-FOBD20	FOB Rapid Test Device – Feces
D-FOBS10	FOB Rapid Test Strip – Feces
D-TROPD20	Cardiac Troponin I Rapid Test Device – WB/S/P
D-MCKTMD20	Myoglobin/CK-MB/Troponin I Combo Rapid Test Device – WB/S/P
D-CALD10	Calprotectin Rapid Test Device – Feces
D-DIMERD10	D-Dimer Rapid Test Device – WB/P
D-GLD10	Giardia Lamblia Rapid Test Device - Feces
D-PCTD40	PCT Rapid Test Device – S/P
D-MYOD10	Myoglobin Rapid Test Device – WB/S/P
D-CHABD20	Chagas Rapid Test Device – WB/S/P
D-SAAD10	SAA Rapid Test Device – WB/S/P
D-STRAS20	Strep A Rapid Test Strips – Throat Swab
D-TPSPD40	Syphilis Rapid Test Device – S/P
D-TPSPS50	Syphilis Rapid Test Strip – S/P
D-TRFOBD20	Transferrin and FOB Combo Rapid Test Device - Feces
D-RSVD20	RSV Rapid Test Device – Nasopharyngeal swab/Nasal Aspirate
D-SAACRPD10	SAA & CRP Combo Rapid Test Device – WB/S/P
D-TPD20	Syphilis Rapid Test Device – WB/S/P
D-TPS50	Syphilis Rapid Test Strip – WB/S/P
D-TPD40	Syphilis Rapid Test Device – WB/S/P
D-TETD40	Tetanus Rapid Test Device – WB/S/P
D-TSHD20	TSH Rapid Test Device – WB/S/P
D-STRBS20	Strep B Rapid Test Strip – Swab
D-GOND20	Gonorrhea Rapid Test Device - Swab
D-INFAS20	Influenza A Rapid Test Strip – Swab/Nasal Aspirate
D-RFD20	RF Rapid Test Device– WB/S/P
D-HSV12D10	HSV 1/2 IgM Rapid Test Device - WB/S/P
D-TYGMD20	Typhoid Rapid Test Device – S/P
D-TYGMCD20	Typhoid IgG/IgM Rapid Tes Device– WB/S/P
D-ROTAGD20	Rotavirus Rapid Test Device – Feces
D-ROAAGD20	Rotavirus & Adenovirus Combo Rapid Test Device – Feces

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

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

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

D-ZNSD10	Zika NS1 Rapid Test Device -WB/S/P
D-ZGMD10	Zika IgG/IgM Rapid Test Device – WB/S/P
D-ZGMNSD10	Zika IgG/IgM & NS1 Combo Rapid Test Device – WB/S/P
D-FILGMD40	Filariasis IgG/IgM rapid Test Device – WB/S/P
D-TYGMS50	Typhoid Rapid Test Strip – S/P
D-PAAGD25	Salmonella paratyphi Antigen Rapid Test Device -Feces
D-TYPAGD20	Salmonella typhi and paratyphi Antigen Combo Rapid Test Device – WB/S/P
D-MPFS50	Malaria Pf Rapid Test Strip – WB
D-HAVGMD25	HAV IgG/IgM Combo Rapid Test Device – WB/S/P
D-HAVMWBD20	HAVIgM Rapid Test Device – WB/S/P
D-STRABD20	Strep A Rapid Test Device – Throat Swab
D-STRARD20	Strep A Rapid Test Device – Throat Swab
D-LPD25	Legionella pneumophila Rapid Test Device – Urine
D-SPAGD10	Streptococcus pneumoniae antigen Rapid Test Device – Urine
D-CRAGD10	Cryptococcus Antigen Rapid Test Device – WB/S/P/CSF
D-EVGD10	EBV VCA IgG Rapid Test Device – WB/S/P
D-ENGD10	EBNA IgG Rapid Test Device – WB/S/P
D-EVNGD10	EBV VCA and EBNA IgG Combo Rapid Test Device – WB/S/P
D-ADAGD20	Adenovirus Antigen Rapid Test Device – Swab
D-INFABS20	Influenza A+B Rapid Test Strip-Swab / Nasal Aspirate
D-HNAGD20	H1N1 Antigen Rapid Test Device – Swab
D-IHD10	Influenza A/B + H1N1 Combo Rapid Test Device – Swab
D-RID10	RSV & Influenza A+B Combo Rapid Test Device – Swab/Nasal
D-ARD10	Adenovirus & RSV Combo Rapid Test Device – Nasopharyngeal Swab
D-ARID10	Adenovirus, RSV and Influenza A+B Combo Rapid Test Device - Nasopharyngeal Swab
D-BRUD20	Brucella Abortus Antigen Rapid Test Device – WB/S/P
D-SCTD10	Scrub Typhus IgG/IgM Rapid Test Device – WB/S/P
D-TBS50	Tuberculosis Rapid Test Strip – WB/S/P
D-DOA52D40	AB-PINACA (ABP) Rapid Test Device – Urine
D-DOA52P40	AB-PINACA (ABP) Rapid Test Panel – Urine
D-DOA52S50	AB-PINACA (ABP) Rapid Test Strip – Urine
D-DOA32P40	Acetaminophen (ACE) Rapid Test Panel – Urine
D-DOA53D40	7-Aminoclonazepam (7-ACL) Rapid Test Device – Urine
D-DOA53P40	7-Aminoclonazepam (7-ACL) Rapid Test Panel – Urine
D-DOA53S50	7-Aminoclonazepam (7-ACL) Rapid Test Strip – Urine
D-DOA44D20	Alprazolam (ALP) Rapid Test Device – Urine
D-DOA44P40	Alprazolam (ALP) Rapid Test Panel – Urine
D-DOA44S50	Alprazolam (ALP) Rapid Test Strip – Urine
D-DOA1P40	Amphetamine (AMP) Rapid Test Panel – Urine
D-DOA54D40	α -Pyrrolidinovalerophenone (α -PVP) Rapid Test Device – Urine
D-DOA54P40	α -PVP Rapid Test Panel – Urine
D-DOA54S50	α -PVP Rapid Test Strip – Urine
D-DOA4P40	Barbiturate (BAR) Rapid Test Panel – Urine
D-DOA11P40	Buprenorphine (BUP) Rapid Test Panel – Urine
D-DOA5P40	Benzodiazepines (BZO) Rapid Test Panel – Urine
D-DOA45D20	Cathine (CAT) Rapid Test Device – Urine

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

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

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

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

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

D-DOA13WBD40	PCP Rapid Test Device-WB/S/P
D-DOA65WBD40	PPX Rapid Test Device – WB/S/P
D-DOA51WBD40	K2 Rapid Test Device-WB/S/P
D-DOA10WBD40	TCA Rapid Test Device – WB/S/P
D-DOA67WBD40	THC Rapid Test Device – WB/S/P
D-DOA30WBD20	TML Rapid Test Device – WB/S/P
D-DOAWBM2	Multi-drug 2 drugs Rapid Test Device – WB/S/P
D-DOAWBM3	Multi-drug 3 drugs Rapid Test Device – WB/S/P
D-DOAWBM4	Multi-drug 4 drugs Rapid Test Device – WB/S/P
D-DOAWBM5	Multi-drug 5 drugs Rapid Test Device – WB/S/P
D-DOAWBM6	Multi-drug 6 drugs Rapid Test Device – WB/S/P
D-DOAWBM7	Multi-drug 7 drugs Rapid Test Device – WB/S/P
D-DOAWBM8	Multi-drug 8 drugs Rapid Test Device – WB/S/P
D-DOAWBM9	Multi-drug 9 drugs Rapid Test Device – WB/S/P
D-DOAWBM10	Multi-drug 10 drugs Rapid Test Device – WB/S/P
D-DOAWBM11	Multi-drug 11 drugs Rapid Test Device – WB/S/P
D-DOAWBM12	Multi-drug 12 drugs Rapid Test Device – WB/S/P
D-DOAWBM13	Multi-drug 13 drugs Rapid Test Device – WB/S/P
D-DOAWBM14	Multi-drug 14 drugs Rapid Test Device – WB/S/P
D-DOAWBM15	Multi-drug 15 drugs Rapid Test Device – WB/S/P
D-DOAWBM16	Multi-drug 16 drugs Rapid Test Device – WB/S/P
D-DOAWBM17	Multi-drug 17 drugs Rapid Test Device – WB/S/P
D-DOA1D20H	Amphetamine (AMP) Rapid Test Device – Hair
D-DOA4D20H	Barbiturates (BAR) Rapid Test Device – Hair
D-DOA11D20H	Buprenorphine (BUP) Rapid Test Device – Hair
D-DOA5D20H	Benzodiazepine (BZO) Rapid Test Device – Hair
D-DOA6D20H	Cocaine (COC) Rapid Test Device – Hair
D-DOA31D20H	Cotinine (COT) Rapid Test Device – Hair
D-DOA9D20H	Ketamine (KET) Rapid Test Device – Hair
D-DOA43D20H	6-Monoacetylmorphine (6-MAM)Rapid Test Device – Hair
D-DOA12D20H	Ecstasy (MDMA) Rapid Test Device – Hair
D-DOA2D20H	Methamphetamine (MET) Rapid Test Device – Hair
D-DOA38D20H	Morphine (MOP) Rapid Test Device -Hair
D-DOA39D20H	Oxycodone (OXY) Rapid Test Device -Hair
D-DOA13D20H	Phencyclidine (PCP) Rapid Test Device – Hair
D-DOAM2H	Multi-drug 2 drugs Rapid Test Device – Hair
D-DOAM3H	Multi-drug 3 drugs Rapid Test Device – Hair
D-DOAM4H	Multi-drug 4 drugs Rapid Test Device -Hair
D-DOAM5H	Multi-drug 5 drugs Rapid Test Device – Hair
D-DOAM6H	Multi-drug 6 drugs Rapid Test Device – Hair
D-DOAM7H	Multi-drug 7 drugs Rapid Test Device – Hair
D-DOAM8H	Multi-drug 8 drugs Rapid Test Device – Hair
D-DOAM9H	Multi-drug 9 drugs Rapid Test Device – Hair
D-CEAD20	CEA Rapid Test Device – WB/S/P
D-CFOBD10	Calprotectin and FOB Combo Rapid Test Device – Feces
D-HBHBD20	Hb+Hb-Hp Combo Rapid Test Device – Feces
D-TRFOBHB20	Transferrin/FOB and Hb-Hp Combo Rapid Test Device - Feces
D-CKMBD10	CK-MB Rapid Test Device – WB/S/P

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

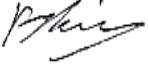
D-RDOA51D40	Synthetic Marijuana (K2) Rapid Test Device-urine
D-RDOA10D40	Tricyclic Antidepressants (TCA) Rapid Test Device -urine
D-RDOA8D40	Marijuana (THC) Rapid Test Device-urine
D-RDTMLD40	Tramadol (TML) Rapid Test Device -urine
D-RDOA29D40	Lysergic Acid Diethylamide (LSD) Rapid Test Device -urine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

D-RNGALD10	NGAL (neutrophil gelatinase-associated lipocalin) Rapid Test Device -WB/S/P
D-RCKMBD10	CK-MB Rapid Test Device -WB/S/P
D-RMYOD10	Myoglobin Rapid Test Device -WB/S/P
D-INFABD20	Influenza A+B Rapid Test Device – Swab/Nasal Aspirate
D-RHPAGD25	H. pylori Antigen Rapid Test Device -Feces
D-RMONOD25	MONO Rapid Test Device -WB/S/P
D-RINFAD20	Influenza A Rapid Test Device -Swab/Nasal Aspirate
D-RSTRAS20	Strep A Rapid Test Device -Throat Swab
D-RTPD40	Syphilis Rapid Test Device -S/P
D-RDGMD20	Dengue IgG/IgM Rapid Test Device -WB/S/P
D-RDAGD20	Dengue NS1 Rapid Test Device-WB/S/P
D-RFFD25	Fetal Fibronectin (fFN) Rapid Test Device -Vaginal Discharge
D-RFSD20	Follicle Stimulating Hormone (FSH) Rapid Test Device -Urine
D-RTSHD20	TSH Rapid Test Device -WB/S/P
D-RFED10	Ferritin Rapid test Device -WB/S/P
D-RTSHSQD20	Thyroid Stimulating Hormone (TSH) Rapid Test Device -WB/S/P
D-RVDD10	Vitamin D Rapid Test Device -WB/S/P
D-RPCTCD10	Procalcitonin (PCT) Rapid Test Device -WB/S/P
D-RCALD10	Calprotectin Rapid Test Device -Feces
D-RCRD10	CRP Rapid Test Device -WB/S/P
D-FICEAD20	CEA Test Device -S/P
D-FIAFPD20	AFP Test Device -S/P
D-FIDIMERD10	D-Dimer Test Device -WB/P
D-FICKMBD10	CK-MB Test Device -WB/S/P
D-FITROPID20	cTnI Test Device -WB/S/P
D-FIMYOD25	Myoglobin Rapid Test Device —WB/S/P
D-FIFABD10	H-FABP Test Device -WB/S/P
D-FINTPD10	NT-proBNP Test Device -WB/S/P
D-FITIMCKD20	Troponin I/Myoglobin/CK-MB (3 in 1) Test Device -WB/S/P
D-FITMCKD20	Troponin T/Myoglobin/CK-MB (3 in 1) Test Device -WB/S/P
D-FILHD20	LH Test Device -WB/S/P
D-FISTRAS20	Strep A Test Device -Swab
D-FIIABD20	Influenza A+B Test Device -Swab
D-FIDGMD20	Dengue IgG/IgM Test Device -WB/S/P
D-FIDAGD25	Dengue NS1 Test Device -WB/S/P
D-FIRSVD20	RSV Test Device -Swab
D-FICDTABD10	Clostridium difficile Toxin A/Toxin B Combo Test Device -Feces
D-FICDGD10	Clostridium difficile GDH Test Device -Feces
D-FIADED25	Adenovirus antigen Test Device -Feces
D-FISPD10	Streptococcus pneumoniae Test Device -urine
D-FILPD25	Legionella pneumophila Test Device -urine
D-FITPSPD40	Syphilis Test Device -WB/S/P
D-FIZAGD10	Zika antigen Test Device -WB/S/P
D-FIZMD10	Zika IgM Test Device -WB/S/P
D-FIAMHD10	AMH Test Device -WB/S/P
D-FIFFD25	Fetal Fibronectin (fFN) Test Device-Swab
D-FIFSHD20	FSH Test Device -WB/S/P

D-FIRFSPD20	Rheumatoid Factor IgM Test Device -WB/S/P
D-FICRPD25	CRP Test Device-WB/S/P
D-FIPCTD25	PCT Test Device-WB/S/P
D-FIFOBD25	FOB Test Device-Feces
D-FIT4D25	T4 Test Device-S/P
D-FIHCG D25	β -HCG Test Device-S/P
D-FITSHD25	TSH Test Device-S/P
D-FIT3D25	T3 Test Device-S/P
D-FITESD25	Testosterone Test Device-S/P
D-FIP4D25	Progesterone(P4) Test Device-S/P
D-FICYSCD25	CysC Test Device-WB/S/P
D-FI2MGD25	β 2MG Test Device-WB/S/P
D-FINGALD25	N-GAL Test Device-Urine
D-FIHBA1CD25	HbA1c Test Device-WB
D-FIIGED25	IgE Test Device-WB/S/P
D-FIFED25	Ferritin Test Device-S/P
D-CAND20	Candida Albicans Rapid Test Device – Swab
D-CHAGBD20	Cholera Ag O139 Rapid Test Device – Feces
D-COVAGD20B	SARS-CoV-2 Antigen Rapid Test Device – swab
D-COVAGD20H	COVID-19 Antigen Rapid Test Device – Oral Fluid
D-COVGD25	COVID-19 IgG Rapid Test Device – WB/S/P
D-COVID1	SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test Device – Nasopharyngeal Swab
D-COVID20	SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test Device – Nasopharyngeal Swab
D-DOA12D20S	Ecstasy (MDMA) Rapid Test Device – Saliva
D-DOA2D20S	Methamphetamine (MET) Rapid Test Device - Saliva
D-DOA31D20S	Cotinine (COT) Rapid Test Device – Salvia
D-DOA3D20S	Opiates (OPI) Rapid Test Device – Saliva
D-DOA43D20D	6-Monoacetylmorphine (6-MAM) Rapid Test Device – Salvia
D-DOA50D40	Pregabaline (PGB) Rapid Test Device – Urine
D-DOA50S50	Pregabaline (PGB) Rapid Test Strip – Urine
D-DOA51D20	Synthetic Marijuana (K2) Rapid Test Device – Urine
D-DOA51S50	Synthetic Marijuana (K2) Rapid Test Strip – Urine
D-DOA58S40	Ethyl Glucuronide (ETG) Rapid Test Strip – Urine
D-DOA62S25S	Methylenedioxypyrovalerone (MDPV) Rapid Test Device – Saliva
D-DOA6D20S	Cocaine (COC) Rapid Test Device – Saliva
D-DOA7D20S	Methadone (MTD) Rapid Test Device – Saliva
D-DOAS50	Methadone (MTD) Rapid Test Strip – Urine
D-DOA8D20S	Marijuana (THC) Rapid Test Device – Saliva
D-DOAM10UT	Multi- Drug 10 drugs inc. T ramadol Rapid Test Device – Urine
D-GL10D	Giardia Lamblia Rapid Test Device – Feces
D-GONOD20	Gonorrhea Rapid Test Device – Swab
D-HBAC1CD10	HbA1c Rapid Test Device – WB
D-HCGS0	(hCG) Rapid Test Device plain/no box – Urine/S/P
D-HPD20	H.pylori Rapid Test Device – WB/S/P
D-HPD40	H.pylori Antibody Rapid Test Device – WB/S/P
D-HPVD20	HPV Antigen Rapid Test Device – Cervical Swab

D-INFABS50	Influenza A+B Rapid Test Strip – Swab/Nasal Aspirate
D-LACFD20	Lactoferrin Rapid Test Device – Feces
D-MASQS50	Micro-Albumin Semi-Quantitative Rapid Test Strip – Urine
D-MCKTMD40	Myoglobin/CK-MB/Troponin I Combo Rapid Test Device – WB/S/P
D-TETD20	Tetanus Rapid Test Device – WB/S/P
D-TPS100	Syphilis Rapid Test Strip – WB/S/P
D-TRFOBHB	Transferrin, FOB, Hb+Hb+Hp Rapid Test Device – Feces
D-TROPQD20	Troponin I (cTNI) Semi Quantitative Test Rapid Test Device –
D-TRVAD10	Trichomonas Vaginalis Rapid Test Device – Swab
D-TYGMCD40	Typhoid Rapid Test Device – WB/S/P
D-TYGMDD40	Typhoid Rapid Test Device – S/P
D-COVAGD25H	SARS-CoV-2 Antigen Rapid Test Device – Oral Fluid
D-DOA30DM25S	Tramadol (TML) Rapid Test Device – Midstream Saliva
D-SHID20	Shigella Rapid Test Device – Faeces
D-FICOVID10	COVID-19 Antigen Rapid Test Device – Nasopharyngeal Swab
D-HAVMD20	HAV IgM Rapid Test S/P
D-NGALD10	NGAL Rapid test WB/S/P
D-COVD25B	SARS-CoV-2 IgG/ IgM Rapid Test Device (WB/S/P)
D-CHAGS50	Cholera Ag Rapid test - Feces
D-RDOA40D40	Alcohol(ALC) Rapid Test Device-Urine
D-RDOA6725S	Marijuana (THC) Rapid Test device (for Reader)-Saliva
D-RDOA1M25S	Amphetamine (AMP) Rapid Test Midstream (for Reader)-Saliva
D-RDOA4M25S	Barbiturate (BAR) Rapid Test Midstream (for Reader)-Saliva
D-RDOA11M25S	Buprenorphine (BUP) Rapid Test Midstream (for Reader)-Saliva
D-RDOA5M20S	Benzodiazepines (BZO) Rapid Test Midstream (for Reader)-Saliva
D-RDOA6M25S	COCAINE (COC) Rapid Test Midstream (for Reader)-Saliva
D-RDOA2M25S	Methamphetamine (MET) Rapid Test Midstream (for Reader)-Saliva
D-RDOA7M25S	Methadone (MTD) Rapid Test Midstream (for Reader)-Saliva
D-RDOA3M25S	Opiates (OPI) Rapid Test Midstream (for Reader)-Saliva
D-RDOA13M25S	Phencyclidine (PCP) Rapid Test Midstream (for Reader)-Saliva
D-RDOA51M25S	Synthetic Marijuana (K2) Rapid Test Midstream (for Reader)-Saliva
D-FIMAD25	Micro-albumin Test device(for Analyzer)-urine
D-LEIGID20	Legionella Antigen Rapid Test Device – T hroat Swab
D-RUBMD10	Rubella Ig M Rapid Test Device – Serum/Plasma
D-TOXOWBS50	Toxoplasmosis IgG/ Ig M Rapid Test Strip – WB/S/ P
D-TBSPD20	Tuberculosis (TB) Rapid Test Device – WB/S/P
D-MPFPVBD20	Malaria P.f./P.v. Rapid Test Device -WB/S/P
D-DGMCMD20	Dengue + Chik (IgG/IgM-Chik IgM) Test– WB/S/P

Annex

Date of Update	Update made	Signature
15/12/2023	Added new GMDN codes	
Part/Catalogue Number	Description/Name	
D-HPVCS25	HPV Antigen Rapid Test -Cervical Swab	
D-HEMS50	HB Hemoglobin Strip	
D-COVIRCS20	COVID-19, Flu A+B & RSV Combo Rapid Test - Swab	
D-SCIABRSVAPNS20	SARS-CoV-2 & Influenza A+B & RSV & Adenovirus & M.pneumoniae Antigen Combo Rapid Test -Nasopharyngeal swab	
D-DOA70D40	apentadol (TAP) Rapid Test -Urine	
D-DOA70P40	Tapentadol (TAP) Rapid Test -Urine	
D-DOA70S50	Tapentadol (TAP) Rapid Test -Urine	
D-DOA40SS50	Alcohol Rapid Test Dipstick(Saliva)	
D-DOA40D25	Alcohol (ALC) Oral Fluid Device	
D-DOA40BBD15	Breath Alcohol Test (With Blow bag) Device	
D-DOA40BBD20	Breath Alcohol Test (Without Blow bag) Device	
D-LPD25	Legionella pneumophila Rapid Test -Urine	
D-LPSPD10	Legionella pneumophila & Streptococcus pneumoniae Rapid Test -Urine	
D-U12100	Urinalysis Strips 12 Parameter	
D-U13100	Urinalysis Strips 13 Parameter	
D-U14100	Urinalysis Strips 14 Parameter	
D-HSV1D20	HSV-1 IgG/IgM Rapid Test -WB/S/P	
D-HSV2D20	HSV-2 IgG/IgM Rapid Test -WB/S/P	
D-CLOSGTD10	C. difficile GDH+ Toxin A +Toxin B Combo Rapid Test -Faeces	

A rapid test for the qualitative detection of Influenza A and Influenza B virus in nasopharyngeal swab, throat swab or nasal aspirate specimens.

For professional *in vitro* diagnostic use only.

INTENDED USE

The Influenza A+B Rapid Test Device is a rapid chromatographic immunoassay for the qualitative detection of influenza A and B antigens in nasopharyngeal swab, throat swab or nasal aspirate specimens. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections.

SUMMARY

Influenza (commonly known as 'flu') is a highly contagious, acute viral infection of the respiratory tract. It is a communicable disease easily transmitted through the coughing and sneezing of aerosolized droplets containing live virus.¹ Influenza outbreaks occur each year during the fall and winter months. Type A viruses are typically more prevalent than type B viruses and are associated with most serious influenza epidemics, while type B infections are usually milder.

The gold standard of laboratory diagnosis is 14-day cell culture with one of a variety of cell lines that can support the growth of influenza virus.² Cell culture has limited clinical utility, as results are obtained too late in the clinical course for effective patient intervention. Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) is a newer method that is generally more sensitive than culture with improved detection rates over culture of 2-23%.³ However, RT-PCR is expensive, complex and must be performed in specialized laboratories.

The Influenza A+B Rapid Test Device (Swab/Nasal Aspirate) qualitatively detects the presence of Influenza A and/or Influenza B antigen in nasopharyngeal swab or throat swab or nasal aspirate specimens, providing results within 15 minutes. The test uses antibodies specific for Influenza A and Influenza B to selectively detect Influenza A and Influenza B antigen in nasopharyngeal swab, throat swab or nasal aspirate specimens.

PRINCIPLE

The Influenza A+B Rapid Test Device (Swab/Nasal Aspirate) is a qualitative, lateral flow immunoassay for the detection of Influenza A and Influenza B nucleoproteins in nasopharyngeal swab, throat swab or nasal aspirate specimens. In this test, antibodies specific to the Influenza A and Influenza B nucleoproteins are separately coated on the test line regions of the test Device. During testing, the extracted specimen reacts with the antibodies to Influenza A and/or Influenza B that are coated onto particles. The mixture migrates up the membrane to react with the antibodies to Influenza A and/or Influenza B on the membrane and generate one or two colored lines in the test regions. The presence of this colored line in either or both of the test regions indicates a positive result. To serve as a procedural control, a colored line will always appear in the control region if the test has performed properly.

REAGENTS

The test Device contains anti-Influenza A and B particles and anti-Influenza A and B coated on the membrane.

PRECAUTIONS

Please read all the information in this package insert before performing the test.

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

STORAGE AND STABILITY

Store as packaged 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

• Nasopharyngeal swab sample

1. Insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx.

2. Swab over the surface of the posterior nasopharynx 5-10 times.

• Throat swab sample

Insert a sterilized swab into pharynx and collect mucocidermis mainly wiping flare region of post-pharyngeal wall and palatine tonsil several times, and be careful not to make saliva attach to the swab.

• Nasal aspirate

Connect an aspiration catheter to an aspiration trap that is attached to an aspiration device, insert the catheter to nasal cavity from a nostril, start the aspiration device and then collect nasal aspirate sample. Dip a sterilized swab into the collected nasal aspirate sample and make the specimen cling to the swab.

MATERIALS

Materials provided

- Test Devices
- Sterile Swabs
- Extraction Tube Tips
- Extraction Reagent
- Package Insert
- Workstation

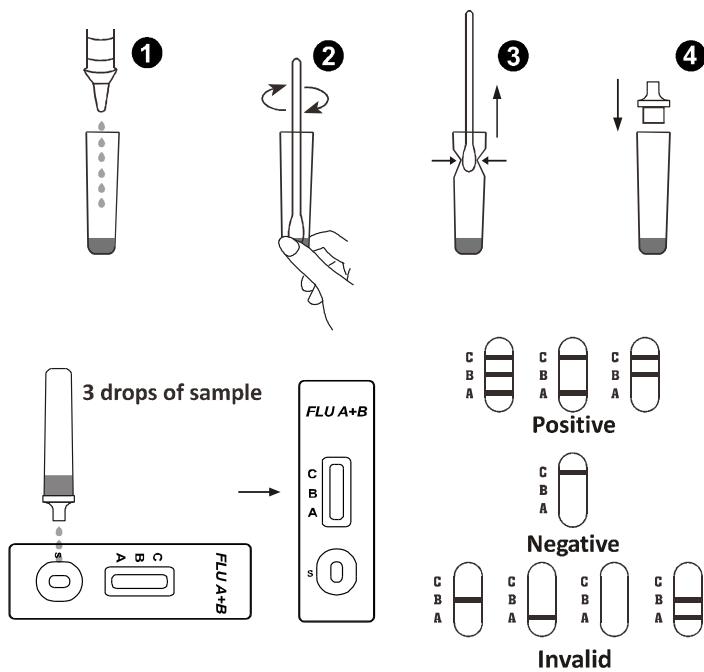
Materials required but not provided

- Aspiration Device

DIRECTIONS FOR USE

Allow the test, specimen, extraction buffer to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test Device from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
2. Place the Extraction Tube in the workstation. Hold the extraction reagent bottle upside down vertically. Squeeze the bottle and let the solution drop into the extraction tube freely without touching the edge of the tube. Add **10 drops of solution (Approx. 400 µl)** to the Extraction Tube. See illustration 1.
3. Place the swab specimen in the Extraction Tube. Rotate the swab for approximately **10 seconds** while pressing the head against the inside of the tube to release the antigen in the swab. See illustration 2.
4. Remove the swab while squeezing the swab head against the inside of the Extraction Tube as you remove it to expel as much liquid as possible from the swab. Discard the swab in accordance with your biohazard waste disposal protocol. See illustration 3.
5. Fit the dropper tip on top of the extraction tube. Place the test Device on a clean and level surface. See illustration 4.
6. Add **three drops of the solution (approx.120 µl)** to the sample well and then start the timer. Read the result at 15 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE Influenza A: **Two colored lines appear.** One colored line should be in the control region (C) and another colored line should be in the Influenza A region (A). A positive result in the Influenza A region indicates that Influenza A antigen was detected in the sample.

POSITIVE Influenza B: **Two colored lines appear.** One colored line should be in the control region (C) and another colored line should be in the Influenza B region (B). A positive result in the Influenza B region indicates that Influenza B antigen was detected in the sample.

POSITIVE Influenza A and Influenza B: **Three colored lines appear.** One colored line should be in the control region (C) and two colored line should be in the Influenza A region (A) and Influenza B region (B). A positive result in the Influenza A region and Influenza B region indicates that Influenza A antigen and Influenza B antigen were detected in the sample.

***NOTE:** The intensity of the color in the test line regions (A or B) will vary based on the amount of Flu A or B antigen present in the sample. So any shade of color in the test regions (A or B) should be considered positive.

NEGATIVE: **One colored line appears in the control region (C).** No apparent colored line appears in the test line regions (A or B).

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 Device. 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 a positive control and a negative control be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The Influenza A+B Rapid Test Device (Swab/Nasal Aspirate) is for professional *in vitro* diagnostic use only. The test should be used for the detection of Influenza A and/or B virus in nasopharyngeal swab, throat swab or nasal aspirate specimens. Neither the quantitative value nor the rate of increase in Influenza A and/or B virus concentration can be determined by this qualitative test.
2. The Influenza A+B Rapid Test Device (Swab/Nasal Aspirate) will only indicate the presence of Influenza A and/or B virus in the specimen from both viable and non-viable Influenza A and B strains.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. A negative result obtained from this kit should be confirmed by culture. A negative result may be obtained if the concentration of the Influenza A and/or B virus present in the nasopharyngeal swab is not adequate or is below the detectable level of the test.
5. Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false positive result.
6. The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage.
7. The use of over-the-counter and prescription nasal sprays at high concentrations can interfere with results, leading to either invalid or incorrect test results.
8. A positive result for influenza A and/or B does not preclude an underlying co-infection with another pathogen, therefore the possibility of an underlying bacterial infection should be considered.

EXPECTED VALUES

The Influenza A+B Rapid Test Device (Swab/Nasal Aspirate) has been compared with a leading commercial RT-PCR test. The correlation between these two systems is over 97%.

PERFORMANCE CHARACTERISTICS

Sensitivity, Specificity and Accuracy

The Influenza A+B Rapid Test Device (Swab/Nasal Aspirate) has been evaluated with specimens obtained from the patients. RT-PCR is used as the reference method for the Influenza A+B Rapid Test Device (Swab/Nasal Aspirate). Specimens were considered positive if RT-PCR indicated a positive result. Specimens were considered negative if RT-PCR indicated a negative result.

Nasopharyngeal Swab Specimen

		Type A		Type B			
		RT-PCR		Total	RT-PCR		
		Positive	Negative		Positive	Negative	
Flu A+B Rapid Test	Positive	100	2	102	85	2	87
	Negative	1	180	181	2	200	202
	Total	101	182	283	87	202	289
Relative Sensitivity		99.0%		97.7%			
Relative Specificity		98.9%		99.0%			
Accuracy		98.9%		98.6%			

Throat Swab Specimen

		Type A		Type B			
		RT-PCR		Total	RT-PCR		
		Positive	Negative		Positive	Negative	
Flu A+B Rapid Test	Positive	58	1	59	65	1	66
	Negative	3	150	153	4	162	166
	Total	61	151	212	69	163	232
Relative Sensitivity		95.1%		94.2%			
Relative Specificity		99.3%		99.4%			
Accuracy		98.1%		97.8%			

Nasal Aspirate Specimen

		Type A		Type B			
		RT-PCR		Total	RT-PCR		
		Positive	Negative		Positive	Negative	
Flu A+B Rapid Test	Positive	46	2	48	94	1	95
	Negative	0	241	241	2	158	160
	Total	46	243	289	96	159	255
Relative Sensitivity		100%		97.9%			
Relative Specificity		99.2%		99.4%			
Accuracy		99.3%		98.8%			

Reactivity with Human Influenza Strain

The Influenza A+B Rapid Test Device (Swab/Nasal Aspirate) was tested with the following human influenza strains and a discernible line at appropriate test-line regions was observed:

Influenza A Virus	Influenza B Virus
A/NWS/33/10(H1N1)	B/R5
A/Hong Kong/8/68(H3N2)	B/Russia/69
A/Port Chalmers/1/73(H3N2)	B/Lee/40
A/WS/33(H1N1)	B/Hong Kong/5/72
A/New Jersey/8/76(HswN1)	
A/Mal/302/54(H1N1)	
A/chicken/Yuyao/2/2006 (H5N1)	
A/swine/Hubei/251/2001 (H9N2)	
A/Duck/Hubei/216/1983(H7N8)	
A/Duck/Hubei/137/1982(H10N4)	
A/Anhui/1/2013 (H7N9)	

Specificity Testing with Various Viral Strains

Description	Test Level
Human adenovirus C	5.62 x 10 ⁵ TCID50/ml
Human adenovirus B	1.58 x 10 ⁴ TCID50/ml
Adenovirus type 10	3.16 x 10 ³ TCID50/ml
Adenovirus type 18	1.58 x 10 ⁴ TCID50/ml
Human coronavirus OC43	2.45 x 10 ⁶ LD50/ml
Coxsackievirus A9	2.65 x 10 ⁴ LD50/ml 1.58 x 10 ⁵ TCID50/ml
Coxsackievirus B5	1.58 x 10 ⁷ TCID50/ml
Human herpesvirus 5	1.58 x 10 ⁴ TCID50/ml
Echovirus 2	3.16 x 10 ⁵ TCID50/ml
Echovirus 3	1 x 10 ⁴ TCID50/ml
Echovirus 6	3.16 x 10 ⁶ TCID50/ml
Herpes simplex virus 1	1.58 x 10 ⁶ TCID50/ml
Human herpesvirus 2	2.81 x 10 ⁵ TCID50/ml
Human Rhinovirus 2	2.81 x 10 ⁴ TCID50/ml
Human Rhinovirus 14	1.58 x 10 ⁶ TCID50/ml
Human Rhinovirus 16	8.89 x 10 ⁶ TCID50/ml
Measles	1.58 x 10 ⁴ TCID50/ml
Mumps	1.58 x 10 ⁴ TCID50/ml
Sendai virus	8.89 x 10 ⁷ TCID50/ml
Parainfluenza virus 2	1.58 x 10 ⁷ TCID50/ml
Parainfluenza virus 3	1.58 x 10 ⁸ TCID50/ml
Respiratory syncytial virus	8.89 x 10 ⁴ TCID50/ml
Human respiratory syncytial virus	1.58 x 10 ⁶ TCID50/ml
Rubella	2.81 x 10 ⁶ TCID50/ml
Varicella-Zoster	1.58 x 10 ³ TCID50/ml

TCID50 = Tissue Culture Infectious Dose is the dilution of virus that under the conditions of the assay can be expected to infect 50% of the culture vessels inoculated.

LD50 = Lethal Dose is the dilution of virus that under the conditions of the assay can be expected to kill 50% of the suckling mice inoculated.

Precision
Intra-Assay & Inter-Assay

Within-run and Between-run precision has been determined by using five specimens of Influenza standard control. Three different lots of the Influenza Rapid Test Device (Swab/Nasal Aspirate) have been tested using negative, Influenza A weak, Influenza B Weak,

Influenza A Strong and Influenza B Strong. Ten replicates of each level were tested each day for 3 consecutive days. The specimens were correctly identified >99% of the time.

Cross-reactivity

The following organisms were tested at 1.0x10⁸org/ml and all found to be negative when tested with the Influenza A+B Rapid Test Device (Swab/Nasal Aspirate):

Arcanobacterium	Pseudomonas aeruginosa
Candida albicans	Staphylococcus aureus subspaeus
Corynebacterium	Staphylococcus epidermidis
Enterococcus faecalis	Staphylococcus saprophyticus
Enterococcus faecium	Streptococcus agalactiae
Escherichia coli	Streptococcus bovis
Haemophilus	Streptococcus dysgalactiae / subsp.dysgalactiae
Moraxella catarrhalis	Streptococcus oralis formerly Streptococcus
Neisseria gonorrhoeae	Streptococcus pneumoniae
Neisseria lactamica	Streptococcus pyogenes
Neisseria subflava	Streptococcus salivarius
Proteus vulgaris	Streptococcus sp group F.type 2

BIBLIOGRAPHY

- Williams, KM, Jackson MA, Hamilton M. (2002) Rapid Diagnostic Testing for URIs in Children; Impact on Physician Decision Making and Cost. *Infec. Med.* 19(3): 109-111.
- Betts, R.F. 1995. Influenza virus, p. 1546-1567. In G.L. Mandell, R.G. Douglas, Jr. and J.E. Bennett (ed.), *Principle and practice of infectious diseases*, 4th ed. Churchill Livingstone, Inc., New York, N.Y.
- WHO recommendations on the use of rapid testing for influenza diagnosis, World Health Organisation, July 2005.

Index of Symbols

	Consult instructions for use		For in vitro diagnostic use only		Use by
	REF Catalog Number		Lot Number		Tests per kit
	Store between 2-30°C		Do not re-use		EC REP Authorized Representative
	Manufacturer		Date of manufacture		

EC REP

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