



浙江东方基因生物制品股份有限公司
Zhejiang Orient Gene Biotech Co.,LTD

STATEMENT

We, Zhejiang Orient Gene Biotech Co., Ltd , having a registered office at 3787#, East Yangguang Avenue, Dipu Street Anji 313300, Huzhou, Zhejiang, China assign SRL SANMEDICO having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova, as exclusive authorized representative for Orient Gene Brand product in correspondence with the conditions of directive 98/79/EEC in Moldova only. The detailed product list is in the Annex 1 in the following pages.

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.

This Statement letter will be valid from Mar.10th,2025to Mar.09th, 2027.

Zhejiang Orient Gene Biotech Co., Ltd

General Manager:

Date:2025/3/10



地址：浙江省湖州市安吉县递铺镇阳光大道东段 3787 号
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电话 Tel:+86-572-5226111 传真 Fax: +86-572-5226222 邮编 P.C.:313300



浙江东方基因生物制品股份有限公司
Zhejiang Orient Gene Biotech Co.,LTD

Annex 1

Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul
GCCOV-702a-H1	TEST RAPID	Orient Gene	Rapid COVID-19 Antigen Oral Fluid Self-Test
GCCOV-702a-H5	TEST RAPID	Orient Gene	Rapid COVID-19 Antigen Oral Fluid Self-Test
GCCOV-702a-H20	TEST RAPID	Orient Gene	Rapid COVID-19 Antigen Oral Fluid Self-Test
GCCOV-502a-H1OGE	TEST RAPID	Orient Gene	Rapid COVID-19 (Antigen) Self-test
GCCOV-502a-H5OGE	TEST RAPID	Orient Gene	Rapid COVID-19 (Antigen) Self-test
GCCOV-502a-H20OGE	TEST RAPID	Orient Gene	Rapid COVID-19 (Antigen) Self-test

GIHSA-102a	TEST RAPID	Orient Gene	One Step Microalbumin Test Cassette
GIHSA-101a	TEST RAPID	Orient Gene	One Step Microalbumin Test Strip (Urine)
GCROA-602a	TEST RAPID	Orient Gene	Rotavirus rapid test cassette (feces)
GCMAL(pf/pv)-402a	TEST RAPID	Orient Gene	Malaria P.f./P.v. Ag Rapid Test Cassette (Whole Blood)
GCROA/ADE-602a	TEST RAPID	Orient Gene	Rotavirus and Adenovirus Combo Rapid Test Cassette (Feces)
GASPE-902a	TEST RAPID	Orient Gene	Male Fertility Rapid Test Cassette (Semen)
GAFSH-101a	TEST RAPID	Orient Gene	One Step Menopause Test Strip (Urine)
GAFSH-102a	TEST RAPID	Orient Gene	One Step Menopause Test Cassette (Urine)
GAIGF1-502a	TEST RAPID	Orient Gene	iGFBP-1 Rapid test Cassette (Swab)

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GAIGF1-501a	TEST RAPID	Orient Gene	iGFBP-1 Rapid Test Strip (Cervical Secretion)
GALH-101a	TEST RAPID	Orient Gene	One Step Ovulation Test Strip (Urine) (25mlU)
GALH-101b	TEST RAPID	Orient Gene	One Step Ovulation Test Strip (Urine) (40mlU)
GALH-102a	TEST RAPID	Orient Gene	One Step Ovulation Test Cassette (Urine) (25mlU)
GALH-102b	TEST RAPID	Orient Gene	One Step Ovulation Test Cassette (Urine) (40mlU)
GCTYP-302a	TEST RAPID	Orient Gene	Typhoid IgG/IgM Rapid Test Cassette (serum/plasma)
GCMAL(pf/pan)-402a	TEST RAPID	Orient Gene	Malaria P.f./Pan Ag Rapid Test Cassette (Whole Blood)
GCDEN-425a	TEST RAPID	Orient Gene	Dengue NS1+IgM/IgG Combo Rapid Test Cassette (Whole blood/serum/plasma)
GCDEN(NS)-402c	TEST RAPID	Orient Gene	Dengue NS1 Antigen Rapid Test Cassette (Whole blood/serum/plasma)
GCDEN(ab)-402c	TEST RAPID	Orient Gene	Dengue IgM/IgG Rapid Test Cassette (Whole blood/serum/plasma)
GCVCH(O1/O9)-602a	TEST RAPID	Orient Gene	V.cholerae O1/O139 Ag Combo Rapid Test Cassette (Feces)
GCMAL(pf)-402a	TEST RAPID	Orient Gene	Malaria Pf Ag Rapid Test Cassette (Whole blood)
GCSAL(ST)-602a	TEST RAPID	Orient Gene	S. typhi Ag Rapid Test Cassette (Serum/plasma/Feces)
GCCHK(IgM)-402a	TEST RAPID	Orient Gene	Chikungunya IgM Rapid Test Cassette (Whole blood/Serum/Plasma)
GCCOV-502a-NN	TEST RAPID	Orient Gene	Coronavirus Ag Rapid Test Cassette (Swab)
GCCOV (Nab)-402b	TEST RAPID	Orient Gene	SARS-CoV-2 Neutralizing Antibody Rapid Test Cassette (Whole blood/Serum/Plasma)
GCCOV-502a-NA	TEST RAPID	Orient Gene	Coronavirus Ag Rapid Tests Cassette (Swab)

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GCCOV (Ag)-PN10	TEST RAPID	Orient Gene	COVID-19 Antigen Control Kit
GCCOV (Ag)-PN20	TEST RAPID	Orient Gene	COVID-19 Antigen Control Kit
GCFERA-545a	TEST RAPID	Orient Gene	Flu, COVID-19,RSV&Adeno Ag Combo Tests Cassette (Swab)
GCTV-502a	TEST RAPID	Orient Gene	Trichomonas Ag Rapid Test Cassette (Swab)
GCVCH(O1)-602a	TEST RAPID	Orient Gene	V.cholerae O1 Ag Rapid Test Cassette (Feces)
GCCHA-402a	TEST RAPID	Orient Gene	Chagas Ab Rapid Test Cassette (Whole blood/serum/plasma)
GCMAL(pf/pv Ab)-302a	TEST RAPID	Orient Gene	Malaria Pf/Pv Ab Rapid Test Cassette (Serum/plasma)
GCMAL(pf/pv Ab)-402a	TEST RAPID	Orient Gene	Malaria Pf/Pv Ab Rapid Test Cassette (Whole blood/Serum/plasma)
GCMKP-502b	TEST RAPID	Orient Gene	Monkeypox Ag Rapid Test Cassette (Swab)
GCCOV(Del)-T502a	TEST RAPID	Orient Gene	SARS-CoV-2 Delta-series Mutant Strain Ag Rapid Test cassette (Swab)
GCCOV-PN10	TEST RAPID	Orient Gene	COVID-19 IgG/IgM Control kit
GCCOV-PN20	TEST RAPID	Orient Gene	COVID-19 IgG/IgM Control kit
GCFER-T525a	TEST RAPID	Orient Gene	COVID-19/Flu A&B/ RSV Ag Combo Rapid Test Cassette (Swab)
GCCOV(B117)-525a	TEST RAPID	Orient Gene	COVID-19 Ag&B.1.1.7 Mutant Strain Combo Test Cassette (Swab)
GCFERA-T525a	TEST RAPID	Orient Gene	COVID-19/Flu A&B/ RSV/Adeno Ag Combo Rapid Test Cassette (Swab)
GCCOV-702a	TEST RAPID	Orient Gene	COVID-19 Ag Rapid Test Cassette (Oral fluid)
GCFE-T502a	TEST RAPID	Orient Gene	COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab)

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GCMKP-402a	TEST RAPID	Orient Gene	Monkeypox IgG/IgM Rapid Test Cassette (Whole blood/serum/plasma)
GCKa1-401a	TEST RAPID	Orient Gene	Leishmania Ab Rapid Test strip (Whole blood/serum/plasma)
GCKa1-T402a	TEST RAPID	Orient Gene	Leishmania IgG/IgM Rapid test cassette (whole blood/serum/plasma)
GCCOV-503a	TEST RAPID	Orient Gene	Smart Rapid COVID-19 Ag Test Device
GCBRU-402a	TEST RAPID	Orient Gene	Brucella Antibody Rapid Test Cassette (Whole blood/serum/plasma)
GCCHA-302a	TEST RAPID	Orient Gene	Chagas Ab Rapid Test Cassette (Serum/plasma)
GCCHK(IgM)-302a	TEST RAPID	Orient Gene	Chikungunya IgM Rapid Test Cassette (Serum/Plasma)
GCCOV-501a	TEST RAPID	Orient Gene	Rapid COVID-19 Antigen Test Strip
GCMON-352a	TEST RAPID	Orient Gene	Mononucleosis IgG/IgM Rapid Test Cassette (Serum/plasma)
GCMON-402a	TEST RAPID	Orient Gene	Mononucleosis Rapid Test Cassette (Whole blood/Serum/plasma)
GCMON-425a	TEST RAPID	Orient Gene	Mononucleosis IgG/IgM Rapid Test Cassette (Whole blood/Serum/plasma)
GCEV71 (IgM)-302a	TEST RAPID	Orient Gene	EV71 IgM Rapid Test Cassette (Serum/plasma)
GCEV71 (IgM)-402a	TEST RAPID	Orient Gene	EV71 IgM Rapid Test Cassette (Whole blood/Serum/plasma)
GENMP22-102a	TEST RAPID	Orient Gene	One Step Nuclear Matrix Protein 22 Test Cassette (Urine)
GEFOB/TF-602a	TEST RAPID	Orient Gene	Fecal Occult Blood and Transferrin Combo Rapid Test Cassette (Feces)
GCHEV-302a	TEST RAPID	Orient Gene	HEV IgM Rapid Test Cassette (Serum/Plasma)
GCMP (IgM)-302a	TEST RAPID	Orient Gene	M.pneumonia IgM Rapid Test Cassette (Serum/plasma)

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FCCOV-502a	TEST RAPID	Orient Gene	SARS-CoV-2 Ag Fluorescence Rapid Test Cassette (Swab)
GCCOV-402Ba	TEST RAPID	Orient Gene	COVID-19 IgG/IgM Rapid test cassette (whole blood/serum/plasma)
GCCOV-402a	TEST RAPID	Orient Gene	COVID-19 IgG/IgM Rapid test cassette (whole blood/serum/plasma)
GCCOV-502a	TEST RAPID	Orient Gene	Coronavirus Ag Rapid Test Cassette (Swab)
GCFC-T503a	TEST RAPID	Orient Gene	Smart Rapid COVID-19 &Flu A/B Ag Test Device
GAHCG-101a	TEST RAPID	Orient Gene	One step pregnancy test strip (urine)
GAHCG-101d	TEST RAPID	Orient Gene	One step pregnancy test strip (urine)
GAHCG-101b	TEST RAPID	Orient Gene	One step pregnancy test strip (urine)
GAHCG-102a	TEST RAPID	Orient Gene	One step pregnancy test cassette (urine)
GAHCG-102d	TEST RAPID	Orient Gene	One step pregnancy test cassette (urine)
GAHCG-102b	TEST RAPID	Orient Gene	One step pregnancy test cassette (urine)

GEFOB-602c	TEST RAPID	Orient Gene	Fecal Occult Blood Rapid Test Cassette (Feces)
GEFOB-602b	TEST RAPID	Orient Gene	Fecal Occult Blood Rapid Test Cassette (Feces)
GEFOB-601c	TEST RAPID	Orient Gene	Fecal Occult Blood Rapid Test Strip (Feces)
GEFOB-601b	TEST RAPID	Orient Gene	Fecal Occult Blood Rapid Test Strip (Feces)
GECEA-402a	TEST RAPID	Orient Gene	Carcinoembryonic Antigen Rapid Test Cassette (Whole blood/serum/plasma)

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GECEA-401a	TEST RAPID	Orient Gene	Carcinoembryonic Antigen Rapid Test Strip (Whole blood/serum/plasma)
GETF-602a	TEST RAPID	Orient Gene	Transferrin Rapid Test Cassette (Feces)
GETF-601a	TEST RAPID	Orient Gene	Transferrin Rapid Test Strip (Feces)
GEAFP-401a	TEST RAPID	Orient Gene	Alpha-Fetoprotein Rapid Test Strip (Whole blood/serum/plasma)
GEAFP-402a	TEST RAPID	Orient Gene	Alpha-Fetoprotein Rapid Test Cassette (Whole blood/serum/plasma)
GIHSA-101a	TEST RAPID	Orient Gene	One step microalbumin test strip (urine)
GIHSA-102a	TEST RAPID	Orient Gene	One step microalbumin test cassette (urine)
GDCAR-335a	TEST RAPID	Orient Gene	Myoglobin/CK-MB/Troponin I Combo Test Cassette (Serum/plasma)
GDCKM-302a	TEST RAPID	Orient Gene	One step CK-MB Test Cassette (Serum/Plasma)
GDCKM-402a	TEST RAPID	Orient Gene	CK-MB Rapid Test Cassette (Whole blood/serum/plasma)
GDCRP-402a	TEST RAPID	Orient Gene	C-Reactive Protein Semi-Quantitative Rapid Test Cassette (Whole Blood/serum/plasma)
GDTRO-302a	TEST RAPID	Orient Gene	Troponin I Rapid Test Cassette (Serum/Plasma)
GDTRO-402a	TEST RAPID	Orient Gene	Troponin I Rapid Test Cassette (Whole blood/Serum/Plasma) (Except the tender No. ocds-b3wdp1-MD-1722410248839 din 05.09.2024, limited to the quantity 28060 pcs only, as per the tender)
GDTRO-402b	TEST RAPID	Orient Gene	Troponin I Rapid Test Cassette (Whole blood/Serum/Plasma)

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GDMYO-402a	TEST RAPID	Orient Gene	Myoglobin Rapid Test Cassette (Whole blood/serum/plasma)
GDCAR-W435a	TEST RAPID	Orient Gene	Myoglobin/CK-MB/Troponin I Combo Rapid Test Cassette (whole blood/Serum/plasma)
GDPCT-402a	TEST RAPID	Orient Gene	Procalcitonin Rapid Test Cassette (Whole blood/serum/plasma)
GDPCT-T402a	TEST RAPID	Orient Gene	Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole blood/serum/plasma)
GDPCT-T401a	TEST RAPID	Orient Gene	Procalcitonin Semi-Quantitative Rapid Test Strip (Whole blood/serum/plasma)
FDPCT -302a	TEST RAPID	Orient Gene	Procalcitonin Rapid Test Kit (serum/plasma)
GDDDI-402b	TEST RAPID	Orient Gene	D-Dimer Rapid Test Cassette (Whole blood/plasma)
FDCAR-T302a	TEST RAPID	Orient Gene	Troponin I/CK-MB/Myoglobin Fluorescence Combo Test Kit (Serum/plasma)
FDTRO-302a	TEST RAPID	Orient Gene	Troponin I Fluorescence Rapid Test Kit (Serum/plasma)
FDBNP-302a	TEST RAPID	Orient Gene	NT-ProBNP Fluorescence Rapid Test Kit (Serum/plasma)
FDCRP-402a	TEST RAPID	Orient Gene	C-Reactive Protein Rapid Test Kit (Whole blood/serum/plasma)
GDCKM-402a	TEST RAPID	Orient Gene	CK-MB Rapid Test Cassette (whole blood/serum/plasma)
GAHCG-201a	TEST RAPID	Orient Gene	One step pregnancy test strip (Urine/serum)
GAHCG-202a	TEST RAPID	Orient Gene	One step pregnancy test cassette (Urine/serum)
GAHCG-201b	TEST RAPID	Orient Gene	One step pregnancy test strip (Urine/serum)
GAHCG-202b	TEST RAPID	Orient Gene	One step pregnancy test cassette (Urine/serum)
GCHAV(IgM)-302Ba	TEST RAPID	Orient Gene	HAV IgM Rapid Test Cassette (Serum/plasma)
GCHAV-602a	TEST RAPID	Orient Gene	HAV Ag Rapid Test Cassette (Feces)

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GCHAV(IgG/IgM) -302a	TEST RAPID	Orient Gene	HAV IgG/IgM Rapid Test Cassette (Serum/plasma)
GCHSV(IgG)-402a	TEST RAPID	Orient Gene	HSV IgG Rapid Test Cassette (Whole blood/serum/plasma)
GCHSV(IgM)-302a	TEST RAPID	Orient Gene	HSV IgM Rapid test Cassette (serum/plasma)
GCHP-601a	TEST RAPID	Orient Gene	H.pylori Ag Rapid Test Strip (feces)
GCHP-602a	TEST RAPID	Orient Gene	H.pylori Ag Rapid Test Cassette(feces)
GCTB-302a	TEST RAPID	Orient Gene	Tuberculosis IgG/IgM Rapid Test Cassette (serum/plasma)
GCTB-402a	TEST RAPID	Orient Gene	Tuberculosis IgG/IgM Rapid Test Cassette (whole blood/serum/plasma)
GCFLU(A/B)-501a	TEST RAPID	Orient Gene	Influenza A&B Ag Rapid Test Strip (Swab)
GCFLU(A/B)-502a	TEST RAPID	Orient Gene	Influenza A&B Ag Rapid Test Cassette (Swab)
GCFLU(A/B)-502Ca	TEST RAPID	Orient Gene	Influenza A&B Ag Rapid Test Cassette (Swab)
GCFLU(A)-501a	TEST RAPID	Orient Gene	Influenza A Ag Rapid Test Strip (Swab)
GCFLU(A)-502a	TEST RAPID	Orient Gene	Influenza A Ag Rapid Test Cassette (Swab)
GCHP-301a	TEST RAPID	Orient Gene	H.Pylori Ab Rapid Test Strip (serum/plasma)
GCHP-302a	TEST RAPID	Orient Gene	H.pylori Ab Rapid Test Cassette (serum/plasma)
GCHP-401a	TEST RAPID	Orient Gene	H.pylori Ab Rapid Test Strip (Whole blood/serum/plasma)
GCHP-402a	TEST RAPID	Orient Gene	H.pylori Ab Rapid Test Cassette (Whole blood/serum/plasma)
GCCA-502a	TEST RAPID	Orient Gene	Candida albicans Antigen rapid test cassette (swab)
GCGON-502b	TEST RAPID	Orient Gene	Gonorrhea Rapid Test Cassette (Swab)
GCGIA-602a	TEST RAPID	Orient Gene	Giardia lamblia Antigen Rapid tests cassette (feces)

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GCSTR-501a	TEST RAPID	Orient Gene	Strep A Rapid Test Strip (Throat swab)
GCSTR-502a	TEST RAPID	Orient Gene	Strep A Rapid Test Cassette (Throat swab)
GCFC-525a	TEST RAPID	Orient Gene	Rapid COVID-19 + Influenza Antigen Test
GCRSV-502a	TEST RAPID	Orient Gene	RSV Antigen Rapid Test Cassette (swab)
GCADE-502a	TEST RAPID	Orient Gene	Adenovirus antigen rapid test cassette (swab)
GCADE-602a	TEST RAPID	Orient Gene	Adenovirus Rapid test cassette (feces)
GCCD(GDH)-602a	TEST RAPID	Orient Gene	Clostridium difficile Antigen GDH Rapid Test cassette (feces)
GCCD (Toxin A/B)-602a	TEST RAPID	Orient Gene	Clostridium difficile Toxin A&B rapid test cassette (feces)
GCCD-602a	TEST RAPID	Orient Gene	Clostridium difficile GDH & Toxin A/B Rapid Test Cassette (Feces)
GCHSV (IgM)-402a	TEST RAPID	Orient Gene	HSV IgM Rapid test Cassette (whole blood/serum/plasma)
GCHSV(IgG)-302a	TEST RAPID	Orient Gene	HSV IgG Rapid Test Cassette (serum/plasma)
GCSYP-301a	TEST RAPID	Orient Gene	Syphilis Ab Rapid Test Strip (serum/plasma)
GCSYP-302a	TEST RAPID	Orient Gene	Syphilis Ab Rapid Test Cassette (serum/plasma)
GCSYP-401a	TEST RAPID	Orient Gene	Syphilis Ab Rapid test strip (whole blood/serum/plasma)
GCSYP-402a	TEST RAPID	Orient Gene	Syphilis Ab Rapid test cassette (whole blood/serum/plasma)
GBBAR-101a	TEST RAPID	Orient Gene	One Step Barbiturates Test Strip (Urine)
GBBAR-102a	TEST RAPID	Orient Gene	One Step Barbiturates Test Cassette (Urine)
GBAMP-101a	TEST RAPID	Orient Gene	One Step Amphetamine Test Strip (Urine)
GBAMP-102a	TEST RAPID	Orient Gene	One Step Amphetamine Test Cassette (Urine)
GBAMP-105a	TEST RAPID	Orient Gene	One Step Amphetamine Dip Card (Urine)

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GBPPX-101a	TEST RAPID	Orient Gene	One Step Propoxyphene Test Strip (Urine)
GBPPX-102a	TEST RAPID	Orient Gene	One Step Propoxyphene Test Cassette (Urine)
GBDSA-XXXXFX	TEST RAPID	Orient Gene	Oral Fluid Drug test Cube
GBDSA-XXXXEX	TEST RAPID	Orient Gene	Oral Fluid Drug test
GBDSA-XXXXFSI	TEST RAPID	Orient Gene	Oral Fluid Drug test Cube
GBDSA-XXXXCX	TEST RAPID	Orient Gene	Oral Fluid Drug test cylinder
GBOPI-102a	TEST RAPID	Orient Gene	One Step Opiate Test Cassette (Urine)
GBOPI-101a	TEST RAPID	Orient Gene	One Step Opiate Test Strip (Urine)
GBETG-101b	TEST RAPID	Orient Gene	One Step Ethyl Glucoronide Test Strip (urine)
GBETG-102b	TEST RAPID	Orient Gene	One Step Ethyl Glucoronide Test Cassette (urine)
GBMOP-101a	TEST RAPID	Orient Gene	One step Morphine Test strip (urine)
GBMOP-102a	TEST RAPID	Orient Gene	One step Morphine Test Cassette (urine)
GBMOP-105a	TEST RAPID	Orient Gene	One step Morphine Test dip card (urine)
GBTHC-101a	TEST RAPID	Orient Gene	One Step Marijuana Test Strip (Urine)
GBTHC-102a	TEST RAPID	Orient Gene	One Step Marijuana Test Cassette (Urine)
GBTHC-105a	TEST RAPID	Orient Gene	One Step Marijuana Test Dip Card (Urine)
GBMTD-101a	TEST RAPID	Orient Gene	One step Methadone Test strip (urine)
GBMTD-102a	TEST RAPID	Orient Gene	One step Methadone Test cassette (urine)
GBXXX-101	TEST RAPID	Orient Gene	One Step Drugs of Abuse Test Strip (Urine)
GBXXX-102	TEST RAPID	Orient Gene	One Step Drugs of Abuse Test Cassette (Urine)
GBXXX-105	TEST RAPID	Orient Gene	One Step Drugs of Abuse Test Dip Card (Urine)

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GBDSA-XXXXJSI	TEST RAPID	Orient Gene	Oral fluid drug test cylinder
GBDSA-XXXXJX	TEST RAPID	Orient Gene	Oral fluid drug test cylinder
GBDSA-XXXXKX	TEST RAPID	Orient Gene	Oral fluid drug test cylinder
GBDSA-XXXXMX	TEST RAPID	Orient Gene	Oral fluid drug test device
GBDSA-XXXXA/B/G/H/I	TEST RAPID	Orient Gene	Multi-drug rapid screen test cassette (oral fluid)
GBMTC-101a	TEST RAPID	Orient Gene	One Step Methcathinone Test Strip (Urine)
GBMTC-102a	TEST RAPID	Orient Gene	One Step Methcathinone Test Cassette (Urine)
GBKRA-101a	TEST RAPID	Orient Gene	One step kratom test strip (urine)
GBKRA-102a	TEST RAPID	Orient Gene	One step kratom test cassette (urine)
GBLSD-101a	TEST RAPID	Orient Gene	One Step Lysergic Acid Diethylamide Test Strip (Urine)
GBLSD-102a	TEST RAPID	Orient Gene	One Step Lysergic Acid Diethylamide Test Cassette (Urine)
FBXXX-1102	TEST RAPID	Orient Gene	Hair Multi-drug rapid test kit
GBETG-105a	TEST RAPID	Orient Gene	One step ethyl glucuronide test dip card (urine)
GBPGB-102b	TEST RAPID	Orient Gene	One step pregabalin test cassette (urine)
GBTRA-101a	TEST RAPID	Orient Gene	One step tramadol test strip (urine)
GBTRA-102a	TEST RAPID	Orient Gene	One step tramadol test cassette (urine)
GBOXY-101a	TEST RAPID	Orient Gene	One step oxycodone Test strip (urine)
GBOXY-102a	TEST RAPID	Orient Gene	One step oxycodone Test cassette (urine)
GBMDP-101a	TEST RAPID	Orient Gene	One step 3,4-Methylenedioxypyrovalerone Test strip (urine)

地址：浙江省湖州市安吉县递铺镇阳光大道东段 3787 号

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浙江东方基因生物制品股份有限公司
Zhejiang Orient Gene Biotech Co.,LTD

GBMDP-101a	TEST RAPID	Orient Gene	One step 3,4-Methylenedioxypropylvalerone Test cassette (urine)
GBMQL-102a	TEST RAPID	Orient Gene	One step Methaqualone Test cassette (urine)
GBMQL-101a	TEST RAPID	Orient Gene	One step Methaqualone Test strip (urine)
GBMPD-101a	TEST RAPID	Orient Gene	One step Methylphenidate Test strip (urine)
GBMPD-102a	TEST RAPID	Orient Gene	One step Methylphenidate Test cassette (urine)
GBUR-101a	TEST RAPID	Orient Gene	One step UR-144 test strip (urine)
GBUR-102a	TEST RAPID	Orient Gene	One step UR-144 test cassette (urine)
GBBUP-101a	TEST RAPID	Orient Gene	One step buprenorphine test strip (urine)
GBBUP-102a	TEST RAPID	Orient Gene	One step buprenorphine test cassette (urine)
GBPCP-101a	TEST RAPID	Orient Gene	One step Phencyclidine Test strip (urine)
GBPCP-102a	TEST RAPID	Orient Gene	One step Phencyclidine Test cassette (urine)
GBTCA-101a	TEST RAPID	Orient Gene	One step Tricyclic Antidepressants test strip (urine)
GBTCA-102a	TEST RAPID	Orient Gene	One step Tricyclic Antidepressants test cassette (urine)
GBEDD-101a	TEST RAPID	Orient Gene	One step EDDP test strip (urine)
GBEDD-102a	TEST RAPID	Orient Gene	One step EDDP test cassette (urine)
GBFEN-101b	TEST RAPID	Orient Gene	One step Fentanyl Test strip (urine)
GBFEN-102b	TEST RAPID	Orient Gene	One step Fentanyl Test cassette (urine)
GBALC-101a	TEST RAPID	Orient Gene	Urine Alcohol Test Strip
GBMAM-S102	TEST RAPID	Orient Gene	One step 6-MAM Test cassette (urine)

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GBMAM-S101	TEST RAPID	Orient Gene	One step 6-MAM Test cassette (urine)
GBHCD-101a	TEST RAPID	Orient Gene	One step Hydrocodone test strip (urine)
GBHCD-102a	TEST RAPID	Orient Gene	One step Hydrocodone test cassette (urine)
GBNFT-101c	TEST RAPID	Orient Gene	One step Norfentanyl test strip (urine)
GBNFT-102c	TEST RAPID	Orient Gene	One step Norfentanyl test cassette (urine)
GBXXX-1102	TEST RAPID	Orient Gene	Hair Multi-Drug Rapid Test Kit (ICA)
GBDSA-XXXXLX	TEST RAPID	Orient Gene	Oral Fluid Drug Test Mini Cube
GBDUA-1X4	TEST RAPID	Orient Gene	One Step Multi-Drug Screen Test Dip Card (urine)
GBDOA-1X5	TEST RAPID	Orient Gene	One Step Multi-Drug Screen Test Cassette (urine)
GBDUA-1X6	TEST RAPID	Orient Gene	One Step Multi-Drug Screen Test Cup (urine)
GBCOT-102a	TEST RAPID	Orient Gene	One step cotinine test cassette (urine)
GBK2-101a	TEST RAPID	Orient Gene	One step K2 Test strip (urine)
GBK2-102a	TEST RAPID	Orient Gene	One step K2 Test cassette (urine)
GBKET-101a	TEST RAPID	Orient Gene	One step Ketamine Test strip (urine)
GBKET-102a	TEST RAPID	Orient Gene	One step Ketamine Test cassette (urine)
GBBZO-101a	TEST RAPID	Orient Gene	One step Benzodiazepines Test Strip (urine)
GBBZO-102a	TEST RAPID	Orient Gene	One step Benzodiazepines Test Cassette (urine)
GBCOC-101a	TEST RAPID	Orient Gene	One step Cocaine Test strip (urine)
GBCOC-102a	TEST RAPID	Orient Gene	One step Cocaine Test cassette (urine)
GBCOC-105a	TEST RAPID	Orient Gene	One step Cocaine Test dip card (urine)
GBMDM-101a	TEST RAPID	Orient Gene	One step ecstasy Test strip (urine)

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GBMDM-102a	TEST RAPID	Orient Gene	One step ecstasy Test cassette (urine)
GBMET-101a	TEST RAPID	Orient Gene	One step Methamphetamine test strip (urine)
GBMET-102a	TEST RAPID	Orient Gene	One step Methamphetamine test cassette (urine)
GBMET-105a	TEST RAPID	Orient Gene	One step Methamphetamine test dip card (urine)
GCTOXI(IgG/IgM)-302a	TEST RAPID	Orient Gene	Toxoplasma gondii test cassette (serum/plasma)
GCTOXI(IgG)-302a	TEST RAPID	Orient Gene	Toxoplasma gondii IgG test cassette (serum/plasma)
GCTOXI(IgM)-302a	TEST RAPID	Orient Gene	Toxoplasma gondii IgM test cassette (serum/plasma)
GCCHL-502a	TEST RAPID	Orient Gene	Chlamydia Trachomatis Antigen test cassette (swab/urine)
GEPSA-402a	TEST RAPID	Orient Gene	Prostate specific antigen test cassette (whole blood/serum/plasma)
GEPSA-401a	TEST RAPID	Orient Gene	Prostate specific antigen test strip (whole blood/serum/plasma)
GEPSA-302a	TEST RAPID	Orient Gene	Prostate specific antigen test cassette (serum/plasma)
GEPSA-301a	TEST RAPID	Orient Gene	Prostate specific antigen test strip (serum/plasma)
GALH-101a-1T	TEST RAPID	Orient Gene	LH Ovulation Test Strip
GALH-101a-5T	TEST RAPID	Orient Gene	LH Ovulation Test Strip
GALH-101a-7T	TEST RAPID	Orient Gene	LH Ovulation Test Strip
GALH-101b-1T	TEST RAPID	Orient Gene	LH Ovulation Test Strip
GALH-101b-5T	TEST RAPID	Orient Gene	LH Ovulation Test Strip
GALH-101b-7T	TEST RAPID	Orient Gene	LH Ovulation Test Strip
GALH-102a-1T	TEST RAPID	Orient Gene	LH Ovulation Test Cassette
GALH-102a-5T	TEST RAPID	Orient Gene	LH Ovulation Test Cassette
GALH-102a-7T	TEST RAPID	Orient Gene	LH Ovulation Test Cassette
GALH-102b-5T	TEST RAPID	Orient Gene	LH Ovulation Test Cassette
GALH-102b-1T	TEST RAPID	Orient Gene	LH Ovulation Test Cassette

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GALH-102b-7T	TEST RAPID	Orient Gene	LH Ovulation Test Cassette
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VPH-502a	TEST RAPID	Orient Gene	Vaginal pH test cassette (Vaginal secretions)
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URS-1T to 14T with various combination	STRIPURI DE URINA	Orient Gene	LEU/NIT/URO/MA/PRO/PH/BLO/S G/ASC/CRE/KET/BIL/GLU/CA
GCHCV-302a	TEST RAPID	Orient Gene	HCV Hepatitis C Virus Rapid Test (serum/plasma) cassette
GCHCV-402a	TEST RAPID	Orient Gene	HCV Hepatitis C Virus Rapid Test (whole blood/serum/plasma) cassette
GCHIV-302a	TEST RAPID	Orient gene	HIV 1/2 Human Immunodeficiency Virus (Serum/Plasma) cassette
GCHIV-402a	TEST RAPID	Orient gene	HIV 1/2 Human Immunodeficiency Virus (Whole blood/serum/plasma)cassette
GCHBsg-302a	TEST RAPID	Orient gene	HBsAg Hepatitis B Surface Antigen Rapid Test (Serum/Plasma)
GCHBsg-402a	TEST RAPID	Orient gene	HBsAg Hepatitis B Surface Antigen Rapid Test(Whole Blood/Serum/Plasma)

The end.



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Certificate

No. Q5 092305 0001 Rev. 02

Holder of Certificate: **Zhejiang Orient Gene Biotech Co., Ltd.**
3787#, East Yangguang Avenue, Dipu Street Anji
313300 Huzhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Reagent and Instrument for the Detection of Drugs of Abuse, Fertility, Infectious Diseases, Oncology, Biochemistry, Cardiac Diseases, Allergic Disease based on Rapid Test, PCR and Liquid Biochip Method.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 092305 0001 Rev. 02

Report No.: SH2398804

Valid from: 2024-03-17

Valid until: 2027-03-16

Date, 2024-03-01

Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 092305 0001 Rev. 02

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **Zhejiang Orient Gene Biotech Co., Ltd.**
3787#, East Yangguang Avenue, Dipu Street Anji, 313300
Huzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate



浙江东方基因生物制品股份有限公司
Zhejiang Orient Gene Biotech Co., LTD



CE-DOC-OG053
Version 1.0

EC Declaration of Conformity

In accordance with Directive 98/79/EC

Legal Manufacturer: *Zhejiang Orient Gene Biotech Co., Ltd*

Legal Manufacturer Address: *3787#, East Yangguang Avenue, Dipu Street,
Anji 313300, Huzhou, Zhejiang, China*

Declares, that the products
Product Name and Model(s)

Urinalysis Strips	URS-XXT
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Classification: *Other*
Conformity assessment route: *Annex III (EC DECLARATION OF CONFORMITY)*

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint

EC Representative's Name: *Shanghai International Holding Corp. GmbH (Europe)*

EC Representative's Address: *Eiffestrasse 80, 20537 Hamburg, Germany*

to act as our European Authorized Representative as defined in the aforementioned Directive.

I, the undersigned, hereby declare that the medical devices specified above conform with the directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements

Date Signed: November 28, 2017

Name of authorized signatory: *Joyce Pang*
Position held in the company: *Vice-President*

URINALYSIS STRIPS



FEATURES

- Analytical sensitivity comparable to market leaders
- Compatible for visual and analyzer reading
- Automated production, more stable product performance
- OEM available, multiple combinations and packaging options

SPECIFICATIONS

- Shelf life: 24 months
- Storage: 2 - 30 °C
- Time to results: Within 2 minutes

The Urine Reagent Strips (URS) for Urinalysis is a fundamental diagnostic tool used to identify pathological alterations in a patient's urine. A typical urine test strip may contain up to 14 distinct chemical pads or reagents, each of which reacts (changes color) when placed in and then withdrawn from a urine sample.

PRODUCT LIST

NAME	SPECIMEN	FORMAT	CUT-OFF	UOM	REGISTRATION
Ascorbate	Urine	Strip	0.5-0.6 mmol/L	100 Tests/Canister	CE 510(k)
Bilirubin	Urine	Strip	8.6-17 µmol/L	100 Tests/Canister	CE 510(k)
Blood	Urine	Strip	5-15 Ery/µL	100 Tests/Canister	CE 510(k)
Ca	Urine	Strip	2.5 mmol/L	100 Tests/Canister	CE
Creatinine	Urine	Strip	50 mg/dL	100 Tests/Canister	CE
Glucose	Urine	Strip	2.8~5.5 mmol/L	100 Tests/Canister	CE 510(k)
Ketone	Urine	Strip	0.5~1.0 mmol/L	100 Tests/Canister	CE 510(k)
Leukocytes	Urine	Strip	5-15 Leuko/µL	100 Tests/Canister	CE 510(k)
Micro Albumin	Urine	Strip	0.08~0.15 mg/dL	100 Tests/Canister	CE
Nitrite	Urine	Strip	13~22 µmol/L	100 Tests/Canister	CE 510(k)
pH	Urine	Strip	0.5	100 Tests/Canister	CE 510(k)
Protein	Urine	Strip	0.15~0.3 g/L	100 Tests/Canister	CE 510(k)
Specific Gravity	Urine	Strip	0.005	100 Tests/Canister	CE 510(k)
Urobilinogen	Urine	Strip	3.3-16 µmol/L	100 Tests/Canister	CE 510(k)
Urinary Tract Infection Test Strip	Urine	Strip	LEU: 10-15 Leuko/µL NIT: 13~22 µmol/L	3 Tests/Kit	CE 510(k)



URINE ANALYZER

The Urine Analyzer is intended to be used with the urinalysis strips for clinical urine testing. The urinalysis strip could detect Urobilinogen, Bilirubin, Ketone (acetoacetic acid), Occult blood, Protein, Nitrite, Leukocytes, Glucose, Specific Gravity, pH, Vitamin C, Microalbumin or Creatinine in human urine.



MODEL	Healgen 501
TEST MODE	Single-step test
DISPLAY	LCD, resolution: 320*240
PRINCIPLE	RGB tricolor test theory
COMMUNICATION INTERFACE	Micro USB interface, Bluetooth wireless communication (optional Bluetooth)
REPEATABILITY	CV≤1%
STABILITY	CV≤1%
RECORD MODE	LCD display, Flash ROM data storage
RELATIVE HUMIDITY	≤80%
POWER SUPPLY	Built-in rechargeable lithium battery 3.7V, 1900mAh Host computer: DC 5V, 1A Adapter: AC 100V~240V, 50/60Hz
OPERATING ENVIRONMENT	Temperature: 10°C ~30°C Relative humidity: ≤80% Atmospheric pressure: 76kPa~106kPa Away from the strong electric field (magnetic field), avoid direct sunlight
DIMENSION	126mm(L)*73.5mm(W)*30mm(H)



MODEL	Healgen 500
TEST MODE	One step (60 pieces/hour), Slow (60 pieces/hour), Fast (120 pieces/hour)
DISPLAY	LCD, resolution: 320*240
PRINCIPLE	RGB tricolor test theory
COMMUNICATION INTERFACE	Standard RS232 interface, USB interface
REPEATABILITY	CV≤1%
STABILITY	CV≤1%
RECORD MODE	Micro-thermal printer, LCD, Flash ROM data storage.
PRINTER	Built-in micro-thermal printer, row width for the paper: 57mm
OPERATION TEMPERATURE	10°C ~30°C
RELATIVE HUMIDITY	≤80%
POWER SUPPLY	100-240VAC 50/60Hz
FUSE	T1.6AL250V
DIMENSION	240mm(L)*220mm(W)*130mm(H)

URINE ANALYZER



MODEL	Healgen 800
TEST MODE	Normal mode (120 pieces/hour), Continuous mode (500 pieces/hour)
DISPLAY	LCD color touch screen
PRINCIPLE	RGB tricolor test theory
COMMUNICATION INTERFACE	Standard RS232 interface
REPEATABILITY	CV≤1%
STABILITY	CV≤1%
REPORT MEMORY	2000 results
OPERATION TEMPERATURE	10°C ~30°C
RELATIVE HUMIDITY	≤80%
PRINTER	Built-in thermal printer, row width for the paper: 57mm
POWER SUPPLY	100-240VAC 50/60Hz
DIMENSION	380mm(L)*380mm(W)*280mm(H)



浙江东方基因生物制品股份有限公司
Zhejiang Orient Gene Biotech Co., LTD



CE-DOC-OG060
Version 1.0

EC Declaration of Conformity

In accordance with Directive 98/79/EC

Legal Manufacturer: *Zhejiang Orient Gene Biotech Co., Ltd*

Legal Manufacturer Address: *3787#, East Yangguang Avenue, Dipu Street,
Anji 313300, Huzhou, Zhejiang, China*

Declares, that the products
Product Name and Model(s)

Fecal Occult Blood Rapid Test Strip (Feces)	GEFOB-601b
Fecal Occult Blood Rapid Test Cassette (Feces)	GEFOB-602b

Classification: *Other*
Conformity assessment route: *Annex III (EC DECLARATION OF CONFORMITY)*

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint

EC Representative's Name: *Shanghai International Holding Corp. GmbH (Europe)*

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to act as our European Authorized Representative as defined in the aforementioned Directive.

I, the undersigned, hereby declare that the medical devices specified above conform with the directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements

Date Signed: November 28, 2017

Name of authorized signatory: *Joyce Pang*
Position held in the company: *Vice-President*

Fecal Occult Blood Rapid Test Cassette (Feces)



INTENDED USE

Fecal Occult Blood Rapid Test Cassette (Feces) is a rapid chromatographic immunoassay for the qualitative detection of human occult blood in feces by professional laboratories or physician's offices. It is useful to detect bleeding caused by a number of gastrointestinal disorders, e.g., diverticulitis, colitis, polyps, and colorectal cancer.

Fecal Occult Blood Rapid Test Cassette (Feces) is recommended for use in 1) routine physical examinations, 2) hospital monitoring for bleeding in patients, and 3) screening for colorectal cancer or gastrointestinal bleeding from any source.

INTRODUCTION

Most of diseases can cause hidden blood in the stool. In the early stages, gastrointestinal problems such as colon cancer, ulcers, polyps, colitis, diverticulitis, and fissures may not show any visible symptoms, only occult blood. Traditional guaiac-based method lacks sensitivity and specificity, and has diet-restriction prior to the testing.

Fecal Occult Blood Rapid Test Cassette (Feces) is a rapid test to qualitatively detect low levels of fecal occult blood in feces. The test uses double antibody-sandwich assay to selectively detect as low as 50 ng/mL of hemoglobin or 6 µg hemoglobin/g feces. In addition, unlike the guaiac assays, the accuracy of the test is not affected by the diet of the patients.

PRINCIPLE

Fecal Occult Blood Rapid Test Cassette (Feces) is a lateral flow chromatographic immunoassay based on the principle of the double antibody-sandwich technique. The membrane is pre-coated with anti-hemoglobin antibodies on the test line region of the device. During testing, the specimen reacts with the colloidal gold coated with anti-hemoglobin antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-hemoglobin antibodies on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. 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.

MATERIALS PROVIDED

20 Test cassettes
20 Specimen collection tubes with buffer
1 Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection containers 2. Clock or timer

STORAGE AND STABILITY

All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test is not stable out of the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
3. Do not use it if the tube/pouch is damaged or broken.
4. Test is for single use only. Do not re-use under any circumstances.
5. **Do not use specimen with visible blood for the testing.**
6. Handle all specimens as if they contain infectious agents. Observe established standard procedure for proper disposal of specimens.
7. Specimen extraction buffer contains Sodium Azide (0.1%). Avoid contact with skin or eyes. Do not ingest.
8. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
9. Humidity and temperature can adversely affect results.
10. Do not perform the test in a room with strong air flow, i.e. electric fan or strong air conditioning.

PATIENT PREPARATION

1. A specimen should not be collected from a patient with following conditions that may interfere with the test results:

- Menstrual bleeding
 - Bleeding hemorrhoids
 - Constipating bleeding
 - Urinary bleeding.
2. Dietary restrictions are not necessary.
 3. Alcohol and certain medications such as aspirin, indomethacin, phenylbutazone, reserpine, corticosteroids, and nonsteroidal anti-inflammatory drugs may cause gastrointestinal irritation and subsequent bleeding, thus gives positive reactions. On the advice of the physician, such substances should be discontinued at least 48 hours prior to testing.

SPECIMEN COLLECTION AND PREPARATION

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

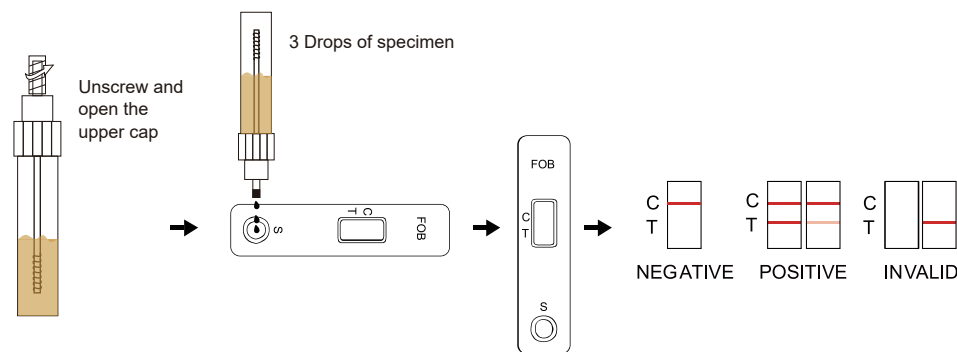
1. Collect a random sample of feces in a clean, dry receptacle.
2. Unscrew the top of the collection tube and remove the applicator stick.
3. Randomly pierce the fecal specimen in at least five (5) different sites.
4. Remove excess sample off the shaft and outer grooves. Be sure sample remains on inside grooves.
5. Replace the stick in the tube and tighten securely.
6. Shake the specimen collection bottle so that there is proper homogenisation of feces in buffer solution.

Note: Specimens prepared in the specimen collection tube may be stored at room temperature (15-30°C) for 3 days maximum, at 2-8°C for 7 days maximum or at -20°C for 3 months maximum if not tested within 1 hour after preparation.

TEST PROCEDURE

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

1. Remove the test cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test cassette on a clean, flat surface.
3. Shake the specimen collection tube several times.
4. Hold the specimen collection tube upright and then unscrew and open the upper cap.
5. Squeeze 3 drops (~90 µL) of the sample solution in the sample well of the cassette and start the timer.
6. Wait for the colored line(s) to appear. Read results in 5 minutes. Do not interpret the result after 5 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

Positive: Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).

Negative: One colored line appears in the control line region (C). No line appears in the test line region (T).

Invalid: Control line fails to appear. The test should be repeated using a new cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

NOTE:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and

Fecal Occult Blood Rapid Test Cassette (Feces)

cannot determine the concentration of analytes in the specimen.

2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is 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 a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. This test kit is to be used for the qualitative detection of human hemoglobin in fecal samples. A positive result suggests the presence of human hemoglobin in fecal samples. In addition to intestinal bleeding the presence of blood in stools may have other causes such as hemorrhoids, blood in urine etc.
2. Not all colorectal bleedings are due to precancerous or cancerous polyps. The information obtained by this test should be used in conjunction with other clinical findings and testing methods, such as colonoscopy gathered by the physician.
3. Negative results do not exclude bleeding since some polyps and colorectal region cancers can bleed intermittently or not at all. Additionally, blood may not be uniformly distributed in fecal samples. Colorectal polyps at an early stage may not bleed.
4. Urine and excessive dilution of sample with water from toilet bowl may cause erroneous test results. The use of a receptacle is recommended.
5. Feces specimens should not collect during the menstrual period and not three day before or afterwards, at bleeding due to constipation, bleeding haemorrhoids, or at taking rectally administered medication. It could cause false positive results.
6. This test may be less sensitive for detecting upper g.i. Bleeding because blood degrades as it passes through the g.i. Track.
7. The Fecal Occult Blood Rapid Test Cassette (Feces) is to aid in diagnosis and is not intended to replace other diagnostic procedures such as G.I. fibroscope, endoscopy, colonoscopy, or X-ray analysis. Test results should not be deemed conclusive with respect to the presence or absence of gastrointestinal bleeding or pathology. A positive result should be followed up with additional diagnostic procedures to determine the exact cause and source for the occult blood in the feces.

PERFORMANCE CHARACTERISTICS

1. Sensitivity: 99.6%

Fecal Occult Blood Rapid Test Cassette (Feces) can detect the levels of human occult blood as low as 50 ng/mL hemoglobin or 6 µg hemoglobin/g feces.

2. Prozone Effect:

It is observed that this FOB test can detect 2 mg/mL hemoglobin.

3. Specificity: 99.9%

Fecal Occult Blood Rapid Test Cassette (Feces) is specific to human hemoglobin. Specimen containing the following substances at the standard concentration was tested on both positive and negative controls and showed no effects on test results at standard concentration.

Substances	Concentrations (Diluted with the extraction buffer)
Beef hemoglobin	2 mg/mL
Chicken hemoglobin	0.5 mg/mL
Pig hemoglobin	0.5 mg/mL
Goat hemoglobin	0.5 mg/mL
Horse hemoglobin	20 mg/mL
Rabbit hemoglobin	0.06 mg/mL

REFERENCES

1. Simon J.B. Occult Blood Screening for Colorectal Carcinoma: A Critical Review, Gastroenterology, Vol. 1985;88:820.
2. Blebea J. and Nepherson RA. False-Positive Guaiac Testing With Iodine, Arch Pathol Lab Med, 1985;109:437-40.

INDEX OF SYMBOLS

	Consult instructions for use		Tests per kit		Authorized Representative
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2~30°C		Lot Number		Catalog#

Zhejiang Orient Gene Biotech Co., Ltd
Address: 3787#, East Yangguang Avenue, Dipu Street,
Anji 313300, Huzhou, Zhejiang, China
Tel: +86-572-5226111 Fax: +86-572-5226222
Website: www.orientgene.com

Shanghai International Holding Corp. GmbH (Europe)
Add: Eiffestrasse 80, 20537 Hamburg, Germany

GEFOB-602b



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, Chişinău 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:

Tracy Wu

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/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 Singh - 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/8/0002/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



Declaration of Conformity

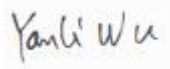
for the

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 concerning 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
Legal Manufacturer: (Name on Label)	<u>Rapid Labs Limited</u> Unit 2 & 2A Hall Farm, Business Centre, Church road, Little Bentley, Colchester, Essex, CO7 8SD United Kingdom
SRN:	GB-MF-000026335
Basic UDI-DI:	N/A
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	Professional use
IVDR Classification:	As per Appendix II (This document) – Product Listing/Schedule
Notified Body:	N/A
CE Certificate:	N/A
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2 nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	MT-AR-000000234
IVDR Assessment Route:	<i>Provide indication of conformity assessment route chosen in accordance with Article 48 of the IVDR. For Class A: Issuing of the Declaration of Conformity in accordance with Article 17 after drawing up the technical documentation in Annexes II and III of the EU IVDR 2017/746. If Class A provided sterile, must also apply the procedures laid out in Annex IX or Annex XI.</i>

Name Yanli Wu **Position** Company Director

Signed  **Date** 22/10/2024 **Place** Colchester, UK

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 this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

Standard/CS/Document Name	Description
2017/746	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 concerning In Vitro Diagnostic Medical Devices
EN ISO 13485:2016+A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019+A11:2021	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2021	Medical devices. Symbols to be used with information to be supplied by the manufacturer - General requirements
EN ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer
EN ISO 18113-1:2011	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements

Version History

Version	Compiled by	Date	Description
1.0	Yanli Wu	22/10/2024	Initial Issue

Appendix II – Product listing / Schedule

Part/Catalogue Number	Description/Name	GMD N Code	IVD R 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 & Giardia 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- Feces	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 Test Device - 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 HCl (MEP) Rapid Test Device – Urine	46994	B	6
D-DOA23S50	Mephedrone HCl (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	Tropicamide (TRO) Rapid Test Device – Urine	46994	B	6

D-DOA25S50	Tropicamide (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 10mIU/mL Rapid Test Strip –	66850	B	6
D-HCGUES100	hCG Pregnancy Enhanced Sensitivity 10mIU/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 10mIU/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-ENG10	EBNA IgG Rapid Test Device – WB/S/P	49689	C	3e
D-EVENG10	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-Aminoclonazepam (7-ACL) Rapid Test Panel – Urine	46994	B	6
D-DOA53S50	7-Aminoclonazepam (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	Fluorketamine (FKET) Rapid Test Device – Urine	46994	B	6
D-DOA48P40	Fluorketamine (FKET) Rapid Test Panel-Urine	46994	B	6
D-DOA48S50	Fluorketamine (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	Tropicamide (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-CFOB10	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-TRFOBHBBD20	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 cTnI 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 with Adulteration-urine	46994	B	6
D-RDOAPM6A	Multi-Drug 6 Drugs Rapid Test Panel 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

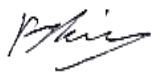
D-RNGALD10	NGAL (neutrophil gelatinase-associated lipocalin) Rapid Test Device -WB/S/P	47430	C	3j
D-RCKMBD10	CK-MB Rapid Test Device -WB/S/P	52995	C	3j
D-RMYOD10	Myoglobin Rapid Test Device -WB/S/P	46987	C	3j
D-INFABD20	Influenza A+B Rapid Test Device – Swab/Nasal Aspirate	49119	B	6
D-RHPAGD25	H. pylori 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	β 2MG 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	Pregabalin (PGB) Rapid Test Device – Urine	46994	B	6
D-DOA50S50	Pregabalin (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-TYGMCD40	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-LEIGID40	Legionella Antigen Rapid Test Device – Throat Swab	51054	C	3c
D-TBSPD10	Tuberculosis (TB) Rapid Test Device – WB/S/P	65814	C	3e
D-TBSPD20	Tuberculosis (TB) Rapid Test Device – WB/S/P	65814	C	3e
D-MPPFVBD20	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	GMD N Code	IVD R 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

ANNEX II

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

Date of Update	Update made	Signature		
10/04/2024	New Brand Addition (Rapid Biotech)	Yanli Wu		
Part/Catalogue Number	Description/Name	GMDN Code	IVDR CLASS	Rule
D-ADAGD20	Adenovirus pneumoniae Antigen Rapid Test -Swab	49856	B	6
D-ARD10	Adenovirus & RSV Combo Rapid Test -Nasal Swab	64770	B	6
D-ARID10	Adenovirus, RSV & Influenza A+B Combo Rapid Test -Nasal Swab	64770	B	6
D-EVGD10	EBV VCA IgG Rapid Test -Whole Blood/Serum/Plasma	64773	C	3e
D-ENGD10	EBNA IgG Rapid Test -Whole Blood/Serum/Plasma	49689	C	3e
D-EVEND10	EBV VCA & EBNA IgG Combo Rapid Test -Whole Blood/Serum/Plasma	64773	C	3e
D-HAVMWBD20	HAV IgM Rapid Test -Whole Blood/Serum/Plasma	48270	B	6
D-HAVGMD25	HAV IgG/IgM Combo Rapid Test -Whole Blood/Serum/Plasma	65737	B	6
D-HEVD20	HEV IgG/IgM Rapid Test -Serum/Plasma	65766	C	3e
D-TPSPD40	TP (Syphilis) Rapid Test -Serum/Plasma	51788	C	3a
D-TPS100	TP (Syphilis) Rapid Test -Whole Blood/Serum/Plasma	51788	C	3a
D-TPSPS50	TP (Syphilis) Rapid Test -Serum/Plasma	51788	C	3a
D-TPD20	TP (Syphilis) Rapid Test -Whole Blood/Serum/Plasma	51788	C	3a
D-TPD40	TP (Syphilis) Rapid Test -Whole Blood/Serum/Plasma	51788	C	3a
D-TPS50	TP (Syphilis) Rapid Test -Whole Blood/Serum/Plasma	51788	C	3a
D-CRAGD10	Cryptococcus Antigen Rapid Test -Whole Blood/Serum/Plasma/CSF	65815	C	3b
D-BRUD20	Brucella Abortus Rapid Test -Whole Blood	50611	C	3b
D-HPABD40	H. pylori Ab Rapid Test -Serum/Plasma	65844	B	6
D-HPD20	H. pylori Ab Rapid Test -Whole Blood/Serum/Plasma	30825	B	6
D-HPD40	H. pylori Ab Rapid Test -Whole Blood/Serum/Plasma	30825	B	6
D-SCTD10	Scrub Typhus IgG/IgM Rapid Test -Whole Blood/Serum/Plasma	51333	C	3e
D-TYGMD20	Typhoid IgG/IgM Rapid Test -Serum/Plasma	63976	C	3e
D-TYGMCD20	Typhoid IgG/IgM Rapid Test -Whole Blood/Serum/Plasma	51560	C	3e
D-TYGMD40	Typhoid IgG/IgM Rapid Test -Serum/Plasma	63976	C	3e
D-TYGMCD40	Typhoid IgG/IgM Rapid Test -Whole Blood/Serum/Plasma	63976	C	3e
D-TYGMS50	Typhoid IgG/IgM Rapid Test -Whole Blood/Serum/Plasma	63976	C	3e

D-LYMD10	Lyme IgG/IgM Rapid Test -Whole Blood/Serum/Plasma	66392	B	6
D-TBS50	Tuberculosis (TB) Rapid Test -Whole Blood/Serum/Plasma	51172	C	3e
D-TBD20	Tuberculosis (TB) Rapid Test -Whole Blood/Serum/Plasma	51172	C	3e
D-HCGUD40	Pregnancy (hCG) Rapid Test -Urine	66850	B	6
D-HCGUM0	Pregnancy (hCG) Rapid Test -Urine	66850	B	6
D-HCGUS50	Pregnancy (hCG) Rapid Test -Urine	66850	B	6
D-HCGUS100	Pregnancy (hCG) Rapid Test -Urine	66850	B	6
D-HCGUED40	Pregnancy (hCG) Enhanced Sensitivity Rapid Test -Urine	66850	B	6
D-HCGUEM0	Pregnancy (hCG) Enhanced Sensitivity Rapid Test -Urine	66850	B	6
D-HCGUES100	Pregnancy (hCG) Enhanced Sensitivity Rapid Test -Urine	66850	B	6
D-HCGUES50	Pregnancy (hCG) Enhanced Sensitivity Rapid Test -Urine	66850	B	6
D-HCGD20	Pregnancy (hCG) Rapid Test -Urine/Serum/Plasma	66850	B	6
D-HCGD40	Pregnancy (hCG) Rapid Test -Urine/Serum/Plasma	66850	B	6
D-HCGS100	Pregnancy (hCG) Rapid Test -Urine/Serum/Plasma	66850	B	6
D-HCGS50	Pregnancy (hCG) Rapid Test -Urine/Serum/Plasma	66850	B	6
D-HCGED20	Pregnancy (hCG) Enhanced Sensitivity Rapid Test -Urine/Serum/Plasma	66850	B	6
D-HCGES20	Pregnancy (hCG) Enhanced Sensitivity Rapid Test -Urine/Serum/Plasma	33819	B	6
D-HCGCD40	Pregnancy (hCG) Rapid Test -Whole Blood/Serum/Plasma	33819	B	6
D-HCGECD40	Pregnancy (hCG) Enhanced Sensitivity Rapid Test -Whole Blood/Serum/Plasma	66850	B	6
D-LHD20	Ovulation (LH) Rapid Test -Urine	54255	B	6
D-LHS50	Ovulation (LH) Rapid Test -Urine	54225	B	6
D-FSHD20	FSH Rapid Test -Urine	65840	B	6
D-FSHS50	FSH Rapid Test -Urine	65840	B	6
D-AMHD10	AMH Rapid Test -Whole Blood/Serum/Plasma	65295	B	6
D-FFD25	Fetal Fibronectin (fFN) Rapid Test -Vaginal Secretion	65270	B	6
D-IGFBP1D25	iGFBP-1 Rapid Test -Vaginal Secretion	64054	B	6
D-GOND20	Gonorrhea Rapid Test -Swabs	51228	C	3a
D-TVD10	Trichomonas Vaginalis Rapid Test -Vaginal Swab	52471	C	3a
D-CAND20	Candida Albicans Rapid Test -Swab	63216	B	6
D-CAND10	Candida Albicans Rapid Test -Swab	63216	B	6
D-CHAD40	Chagas Rapid Test-Serum/Plasma	52480	B	6
D-CHABD20	Chagas Ab Rapid Test -Whole Blood/Serum/Plasma	52480	B	6
D-CHIKMD20	Chikungunya IgM Rapid Test -Whole Blood/Serum/Plasma	60870	B	6
D-CHIKGMD40	Chikungunya IgG/IgM Rapid Test -Serum/Plasma	63970	B	6
D-CHIKWBD40	Chikungunya IgG/IgM Rapid Test -Whole Blood/Serum/Plasma	63970	B	6
D-FILGMD40	Filariasis IgG/IgM Rapid Test -Serum/Plasma	52508	B	6
D-FILGMD20	Filariasis IgG/IgM Rapid Test -Whole Blood/Serum/Plasma	52508	B	6

D-DAGD20	Dengue Ag Rapid Test -Whole Blood/Serum/Plasma	62946	C	3b
D-DGMD20	Dengue IgG/IgM Rapid Test -Whole Blood/Serum/Plasma	63238	B	6
D-DAGMD20	Dengue IgG/IgM And NS1 Combo Rapid Test -Whole Blood/Serum/Plasma	62928	C	3b
D-DAGMD20	Dengue Ag & IgG/IgM Rapid Test -Whole Blood/Serum/Plasma	62928	C	3b
D-ZNSD10	Zika NS1 Rapid Test -Whole Blood/Serum/Plasma	66467	C	3b
D-ZGMD10	Zika IgG/IgM Rapid Test -Whole Blood/Serum/Plasma	63719	B	6
D-ZGMNSD10	Zika IgG/IgM and NS1 Combo Rapid Test -Whole Blood/Serum/Plasma	63767	C	3b
D-LEIGMD20	Leishmania IgG/IgM Rapid Test -Whole Blood/Serum/Plasma	52283	B	6
D-LEPGMD20	Leptospira IgG/IgM Rapid Test -Whole Blood/Serum/Plasma	63726	B	6
D-MPFS50	Malaria P.f. Rapid Test -Whole Blood	52336	C	3c
D-MPFD20	Malaria P.f. Rapid Test -Whole Blood	52336	C	3c
D-MPFPAND20	Malaria P.f./Pan Rapid Test -Whole Blood	52311	C	3c
D-MPFPVBD20	Malaria P.f./P.v. Rapid Test -Whole Blood	63331	C	3c
D-MPFPVPAND20	Malaria P.f./P.v./Pan Rapid Test -Whole Blood	52311	C	3c
D-MONOD25	Mononucleosis Rapid Test -Whole Blood/Serum/Plasma	49689	C	3e
D-PNEUD20	Mycoplasma Pneumoniae Ag Rapid Test -Swab	65851	B	6
D-MYPMD20	Mycoplasma Pneumoniae IgM Rapid Test -Whole Blood/Serum/Plasma	65851	B	6
D-MYPGMD20	Mycoplasma Pneumoniae IgG/IgM Rapid Test -Whole Blood/Serum/Plasma	66460	B	6
D-RSVD20	Respiratory Syncytial Virus (RSV) Rapid Test -Swab	64770	B	6
D-INFAS20	Influenza A Rapid Test -Swab/Nasal Aspirate	49150	B	6
D-INFABS20	Influenza A+B Rapid Test -Swab/Nasal Aspirate	49119	B	6
D-INFABD20	Influenza A+B Rapid Test -Swab/Nasal Aspirate	49119	B	6
D-HNAGD20	H1N1 Antigen Rapid Test -Swab	49150	D	1
D-RID10	RSV & Influenza A+B Combo Rapid Test -Swab/Nasal Aspirate	64770	B	6
D-STRAS20	Strep A Rapid Test -Swab	51707	B	6
D-STRARD20	Strep A Rapid Test (Control Line in Red) -Throat Swab	51707	B	6
D-STRABD20	Strep A Rapid Test (Control Line in Blue) -Throat Swab	51707	B	6
D-STRBS20	Strep B Rapid Test -Swab	51747	C	3b
D-STRBD20	Strep B Rapid Test -Swab	51747	C	3b
D-TETD20	Tetanus Rapid Test -Whole Blood/Serum/Plasma	50867	B	6
D-TETD40	Tetanus Rapid Test -Whole Blood/Serum/Plasma	50867	B	6
D-LPD25	Legionellapneumophila Rapid Test -Urine	51054	C	3c
D-LPSPD10	Legionellapneumophila & Streptococcus pneumoniae Rapid Test -Urine	60765	C	3c
D-SPAGD10	Streptococcus pneumoniae Antigen Rapid Test -Urine	51770	C	3c
D-RFD20	RF Rapid Test -Whole Blood/Serum/Plasma	42230	B	6
D-TSHD20	TSH Rapid Test -Whole Blood/Serum/Plasma	65274	B	6

D-HSV12GD40	HSV 1/2 IgG Rapid Test -Serum/Plasma	49545	C	3a
D-HSV12GCD40	HSV 1/2 IgG Rapid Test -Whole Blood/Serum/Plasma	49545	C	3a
D-HSV12D10	HSV 1/2 IgM Rapid Test -Serum/Plasma	49549	C	3a
D-HSV12CD40	HSV 1/2 IgM Rapid Test -Whole Blood/Serum/Plasma	49549	C	3a
D-HSV12GMD40	HSV 1/2 IgG/IgM Rapid Test -Serum/Plasma	49556	C	3a
D-HSV12GMCD40	HSV 1/2 IgG/IgM Rapid Test -Whole Blood/Serum/Plasma	49556	C	3a
D-HSV12GMD25	HSV 1/2 IgG/IgM Combo Rapid Test -Serum/Plasma	49556	C	3a
D-HSV12GMCD25	HSV 1/2 IgG/IgM Combo Rapid Test -Whole Blood/Serum/Plasma	49556	C	3a
D-ENTD10	Entamoeba histolytica Rapid Test -Faeces	47358	B	6
D-GLD10	Giardia Lamblia Rapid Test -Faeces	52249	B	6
D-CRYD10	Cryptosporidium Rapid Test -Faeces	52163	C	3c
D-CRYGLD10	Cryptosporidium and Giardia Lamblia Combo Rapid Test -Faeces	47358	C	3c
D-EGCD10	Entamoeba & Giardia & Crypto Combo -Faeces	47358	C	3c
D-HPAGD20	H. pylori Ag Rapid Test -Faeces	30825	B	6
D-HPAGS25	H pylori Ag Rapid Test -Faeces	30825	B	6
D-ADOD25	Adenovirus Rapid Test -Faeces	49856	B	6
D-NOROD25	Norovirus Rapid Test -Faeces	48235	B	6
D-ROTAGD20	Rotavirus Rapid Test -Faeces	48235	B	6
D-ASTD10	Astrovirus Rapid Test -Faeces	64772	B	6
D-ROAAGD20	Rotavirus & Adenovirus Rapid Test -Faeces	48235	B	6
D-NRAD10	Norovirus & Rotavirus & Adenovirus Rapid Test -Faeces	48235	B	6
D-NRAAD10	Norovirus & Rotavirus & Adenovirus & Astrovirus Rapid Test -Faeces	48235	B	6
D-TYPAGD20	Salmonella Typhi and Paratyphi Rapid Test -Whole Blood/Serum/Plasma/Faeces	51512	C	3e
D-TYAGD20	Salmonella Typhi Antigen Rapid Test -Faeces	51512	C	3e
D-PAAGD25	Salmonella paratyphi Antigen Rapid Test -Faeces	51543	C	3e
D-CAMD10	Campylobacter Rapid Test -Faeces	50683	B	6
D-CLOSD20	C. difficile GDH Rapid Test -Faeces	50831	B	6
D-CDTABD10	C. difficile Toxin A +Toxin B Combo Rapid Test -Faeces	47382	B	6
D-CDGTABD10	C. difficile GDH+ Toxin A +Toxin B Combo Rapid Test -Faeces	47382	B	6
D-VC01D10	Vibrio Cholera 01 (VC01) Rapid Test -Faeces	51840	c	3c
D-VCPD10	Vibrio Cholera 01/0139 Rapid Test -Faeces	51840	C	3c
D-VC0139D10	Vibrio Cholera 0139 (VC0139) Rapid Test -Faeces	51840	C	3c
D-AFPD20	AFP Rapid Test -Whole Blood/Serum/Plasma	63981	C	3h
D-CEAD20	CEA Rapid Test -Whole Blood/Serum/Plasma	54617	C	3h
D-FOBD10	Faecal Occult Blood (FOB) Rapid Test -Faeces	54532	B	6
D-FOBD20	Faecal Occult Blood (FOB) Rapid Test -Faeces	54532	B	6
D-FOBS10	Faecal Occult Blood (FOB) Rapid Test -Faeces	54532	B	6
D-HBHBD20	Hb+Hb-Hp Rapid Test -Faeces	54557	B	6
D-CFOBD10	Calprotectin and FOB Combo Rapid Test -Faeces	66462	B	6
D-CA125D10	CA125 Rapid Test -Whole Blood/Serum/Plasma	64534	C	3h
D-CA153D10	CA15-3 Rapid Test -Whole Blood/Serum/Plasma	64535	C	3h

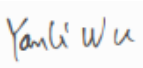
D-CA199D10	CA19-9 Rapid Test -Whole Blood/Serum/Plasma	64536	C	3h
D-TRFOB20	Transferrin/FOB Rapid Test -Faeces	65270	B	6
D-TRFOBHB	Transferrin/FOB & Hb+Hb-Hp Rapid Test -Faeces	65270	B	6
D-TRFOBHBD20	Transferrin/FOB and Hb-Hp Combo Rapid Test -Faeces	65270	B	6
D-TROPD20	Cardiac Troponin I Rapid Test -Whole Blood/Serum/Plasma	46989	C	3j
D-CTTD10	Cardiac Troponin T Rapid Test -Whole Blood/Serum/Plasma	46989	C	3j
D-CRPD10	C-reactive protein (CRP) Rapid Test -Whole Blood/Serum/Plasma	58395	B	6
D-CRPSQD10	C-reactive protein (CRP) (Semi-Quantitative) Rapid Test -Whole Blood/Serum/Plasma	58395	B	6
D-CRPS10	C-reactive protein (CRP) Rapid Test -Whole Blood/Serum/Plasma	58395	B	6
D-CRPSQS10	C-reactive protein (CRP) (Semi-Quantitative) Rapid Test -Whole Blood/Serum/Plasma	58395	B	6
D-DIMERD10	D-Dimer Rapid Test -Whole Blood/Serum/Plasma	47343	C	3k
D-FABD10	H-FABP Rapid Test -Whole Blood/Serum/Plasma	66449	C	3j
D-HFCD25	H-FABP & cTnI Combo Rapid Test -Whole Blood/Serum/Plasma	61295	C	3j
D-HMCKCTD10	H-FABP & Myoglobin & CK-MB & CTNI Combo Rapid Test -Whole Blood/Serum/Plasma	61295	C	3j
D-NTPD10	NT-proBNP rapid test Whole Blood/Serum/Plasma	47041	C	3j
D-MCKTMD20	Myoglobin & CK-MB & Troponin I Combo Rapid Test -Whole Blood/Serum/Plasma	61295	C	3j
D-MYOD10	Myoglobin Test – whole blood/serum/plasma	46987	C	3j
D-PCTD40	Procalcitonin (PCT) Rapid Test -Serum/Plasma	58305	B	6
D-PCTD10	Procalcitonin (PCT) Rapid Test -Serum/Plasma	58305	B	6
D-CKMBD10	CK-MB Rapid Test -Whole Blood/Serum/Plasma	52995	C	3j
D-COVD25	2019-nCoV IgG/IgM Rapid Test (Self Testing) -Whole Blood/Serum/Plasma	64756	D	1
D-COVAGIFD25	COVID-19 and Influenza A+B Antigen Combo Rapid Test (Self Testing) -Swab	64770	D	1
D-COVAGD25B	SARS-CoV-2 Antigen Rapid Test -Nasal Swab	64787	D	1
D-COVAGD20N	SARS-CoV-2 Antigen Rapid Test -Nasal Swab	64787	D	1
D-COVID1	SARS-CoV-2 & Influenza A+B Antigen Rapid Test -Nasal Swab	64770	D	1
D-COVID20	SARS-CoV-2 & Influenza A+B Antigen Rapid Test -Nasal Swab	64770	D	1
D-COVGD25	COVID-19 IgG Rapid Test -Whole Blood/Serum/Plasma	64831	D	1
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-HBA1CD10	HbA1c Rapid Test -Faeces	65322	C	3k
D-IGED10	IgE Rapid Test -Whole Blood/Serum/Plasma	65991	C	3e
D-LACFD10	Lactoferrin Rapid Test -Faeces	53910	B	6
D-CALD10	Calprotectin Rapid Test -Faeces	60775	B	6
D-CALAD10	Calprotectin & Lactoferrin Rapid test - Faeces	60775	B	6
D-FESQD10	Ferritin Rapid Test (Semi-Quantitative) -Whole Blood/Serum/Plasma	66124	B	6
D-FED10	Ferritin Rapid Test -Whole Blood/Serum/Plasma	66124	B	6
D-VDD10	Vitamin D Rapid Test -Whole Blood	60955	B	6
D-DOAM2U	DOA Multi 2 Parameters Rapid Test -Urine	46994	B	6
D-DOAM3U	DOA Multi 3 Parameters Rapid Test -Urine	46994	B	6
D-DOAM4U	DOA Multi 4 Parameters Rapid Test -Urine	46994	B	6
D-DOAM5U	DOA Multi 5 Parameters Rapid Test -Urine	46994	B	6
D-DOAM6U	DOA Multi 6 Parameters Rapid Test -Urine	46994	B	6
D-DOAM7U	DOA Multi 7 Parameters Rapid Test -Urine	46994	B	6
D-DOAM8U	DOA Multi 8 Parameters Rapid Test -Urine	46994	B	6
D-DOAM9U	DOA Multi 9 Parameters Rapid Test -Urine	46994	B	6
D-DOAM10U	DOA Multi 10 Parameters Rapid Test -Urine	46994	B	6
D-DOAM11U	DOA Multi 11 Parameters Rapid Test -Urine	46994	B	6
D-DOAM12U	DOA Multi 12 Parameters Rapid Test -Urine	46994	B	6
D-DOAM13U	DOA Multi 13 Parameters Rapid Test -Urine	46994	B	6
D-DOAM14U	DOA Multi 14 Parameters Rapid Test -Urine	46994	B	6
D-DOAM15U	DOA Multi 15 Parameters Rapid Test -Urine	46994	B	6
D-DOAM16U	DOA Multi 16 Parameters Rapid Test -Urine	46994	B	6
D-DOAM17U	DOA Multi 17 Parameters Rapid Test -Urine	46994	B	6
D-DOACM2	DOA Multi 2 Parameters -1 Step Urine Cup	46994	B	6
D-DOACM3	DOA Multi 3 Parameters -1 Step Urine Cup	46994	B	6
D-DOACM4	DOA Multi 4 Parameters -1 Step Urine Cup	46994	B	6
D-DOACM5	DOA Multi 5 Parameters -1 Step Urine Cup	46994	B	6
D-DOACM6	DOA Multi 6 Parameters -1 Step Urine Cup	46994	B	6
D-DOACM7	DOA Multi 7 Parameters -1 Step Urine Cup	46994	B	6
D-DOACM8	DOA Multi 8 Parameters -1 Step Urine Cup	46994	B	6
D-DOACM9	DOA Multi 9 Parameters -1 Step Urine Cup	46994	B	6
D-DOACM10	DOA Multi 10 Parameters -1 Step Urine Cup	46994	B	6
D-DOACM11	DOA Multi 11 Parameters -1 Step Urine Cup	46994	B	6
D-DOACM12	DOA Multi 12 Parameters -1 Step Urine Cup	46994	B	6
D-DOACM13	DOA Multi 13 Parameters -1 Step Urine Cup	46994	B	6
D-DOACM14	DOA Multi 14 Parameters -1 Step Urine Cup	46994	B	6
D-DOACM15	DOA Multi 15 Parameters -1 Step Urine Cup	46994	B	6
D-DOACM16	DOA Multi 16 Parameters -1 Step Urine Cup	46994	B	6
D-DOACM17	DOA Multi 17 Parameters -1 Step Urine Cup	46994	B	6
D-DOACM18	DOA Multi 18 Parameters -1 Step Urine Cup	46994	B	6
D-DOACM19	DOA Multi 19 Parameters -1 Step Urine Cup	46994	B	6
D-DOACM20	DOA Multi 20 Parameters -1 Step Urine Cup	46994	B	6
D-DOACM21	DOA Multi 21 Parameters -1 Step Urine Cup	46994	B	6
D-DOACM22	DOA Multi 22 Parameters -1 Step Urine Cup	46994	B	6
D-DOACM2S	DOA Multi 2 Parameters -1 Step Saliva Cup	46994	B	6
D-DOACM3S	DOA Multi 3 Parameters -1 Step Saliva Cup	46994	B	6
D-DOACM4S	DOA Multi 4 Parameters -1 Step Saliva Cup	46994	B	6
D-DOACM5S	DOA Multi 5 Parameters -1 Step Saliva Cup	46994	B	6
D-DOACM6S	DOA Multi 6 Parameters -1 Step Saliva Cup	46994	B	6

D-DOACM7S	DOA Multi 7 Parameters -1 Step Saliva Cup	46994	B	6
D-DOACM8S	DOA Multi 8 Parameters -1 Step Saliva Cup	46994	B	6
D-DOACM9S	DOA Multi 9 Parameters -1 Step Saliva Cup	46994	B	6
D-DOACM10S	DOA Multi 10 Parameters -1 Step Saliva Cup	46994	B	6
D-DOACM11S	DOA Multi 11 Parameters -1 Step Saliva Cup	46994	B	6
D-DOACM12S	DOA Multi 12 Parameters -1 Step Saliva Cup	46994	B	6
DDOACM13S	DOA Multi 13 Parameters -1 Step Saliva Cup	46994	B	6
D-DOACM14S	DOA Multi 14 Parameters -1 Step Saliva Cup	46994	B	6
D-DOACM15S	DOA Multi 15 Parameters -1 Step Saliva Cup	46994	B	6
D-DOACM16S	DOA Multi 16 Parameters -1 Step Saliva Cup	46994	B	6
D-DMASQS50	Micro-Albumin Semi-Quantitative Rapid Test-urine	60471	B	6
D-MASQD25	Micro-Albumin Semi-Quantitative RTC-urine	60471	B	6
D-MAQS50	Micro-Albumin Qualitative Rapid Test -urine	60471	B	6
D-MAQD25	Micro-Albumin Qualitative Rapid Test -urine	60471	B	6

ANNEX III

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

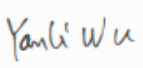
Date of Update	Update made	Signature		
08/07/2024	Added new GMDN codes			
Part/Catalogue Number	Description/Name	GMDN Code	IVDR CLASS	Rule
D-CIIGE40	Total IgE (T-IgE) Test Kit-human serum or plasma	60380	C	3e
D-CIFER40	Ferritin Test Kit-whole blood, serum or plasma	61078	B	6
D-CIAMHK40	Anti-mullerian Hormone (AMH) Test Kit-human serum or plasma	64335	B	6
D-CICEAK40	Carcinoembryonic Antigen (CEA) Test Kit- human serum or plasma	54615	C	3h
D-CIFSHK40	FSH Test Kit-human serum or plasma	54187	B	6
D-CILHK40	LH Test Kit-human serum or plasma	54254	B	6
D-CINBNPK40	N-Terminal pro-B-type Natriuretic Peptide (NT-proBNP) Test Kit - whole blood, serum or plasma	47351	C	3j
D-CITSHK40	Thyroid Stimulating Hormone (TSH) Test Kit-human serum or plasma	54386	B	6
D-CIVDK40	25 OH Vitamin D (25-OH VD) Test Kit -whole blood, serum or plasma	60922	B	6
D-CIβHCGK40	β-human Chorionic Gonadotropin (β-HCG) Test Kit -human serum or plasma	54215	B	6
D-CIT4K40	Thyroxine (T4) Test Kit-human serum or plasma	58322	B	6
D-CIFT4K40	Free Thyroxine (FT4) Test Kit -human serum or plasma	54413	B	6
D-CIPRLK40	Prolactin Test Kit-human serum or plasma	54335	B	6
D-CICA199K40	Carbohydrate Antigen 199 (CA19-9) Test Kit- human serum and plasma	60976	B	6
D-CIAFPK40	Alpha-fetoprotein (AFP) Test Kit- human serum or plasma	58348	C	3h
D-CICKMBK40	Creatine Kinase MB (CKMB) Test Kit - human whole blood, serum or plasma	61000	C	3j
D-CICRPK40	C-reactive Protein (CRP) Test Kit -human whole blood, serum or plasma	65695	B	6
D-CICTIK40	Cardiac Troponin-I (cTnI) Test Kit -human whole blood, serum or plasma	60780	C	3j
D-CIDDMK40	D-Dimer Test Kit-human whole blood and plasma	60530	C	3k
D-CIINSK40	Insulin (INS) Test Kit-human serum or plasma	54237	B	6
D-CIMYOK40	Myoglobin (MYO) Test Kit-human whole blood, serum or plasma	53952	C	3j

D-CIPCTK40	Procalcitonin (PCT) Test Kit-human whole blood,	58731	B	6
D-CICTNTK40	Cardiac Troponin-T (cTnT) Test Kit -human serum or plasma	54007	B	6
D-CIIL6K40	Interleukin-6 (IL-6) Test Kit-human whole blood,	53858	B	6
D-CIT3K40	Triiodothyronine (T3) Test Kit -human serum or plasma	58330	B	6
D-CISAAC40	Serum Amyloid A Protein (SAA) Test Kit-human whole blood, serum or plasma	65690	B	6
D-CIHFAK40	Heart-fatty Acid-binding Protein (H-FABP) Test Kit- human whole blood, serum or plasma	53377	C	3j
D-CIBNPK40	Brain Natriuretic Peptide (BNP)Test Kit-human plasma	47351	C	3k
D-CISST2K40	Growth Stimulation Expressed Gene 2 (ST2) Test Kit- human whole blood, serum or plasma	66516	C	3k
D-CICPEK40	C-Peptide (CP) Test Kit-human serum and plasma	54130	B	6
D-CICA125K40	Cancer Antigen 125 (CA125) Test Kit -human serum or plasma	54588	C	3h
D-CICYFRA211K40	Cytokeratin-19-fragment (CYFRA21-1) Test Kit-human serum or plasma	54612	B	6
D-CISCK40	Squamous Cell Carcinoma Antigen (SCC) Test Kit-human serum or plasma	61418	B	6
D-CIPGIK40	Pepsinogen I (PG I) Test Kit-human serum or plasma	61414	B	6
D-CIPGIK40	Pepsinogen II (PG II) Test Kit -human serum or plasma	61415	B	6
D-CIPGRPK40	Gastrin Releasing Peptide Precursor (ProGRP) Test Kit- human serum or plasma	54660	B	6
D-CIFT3K40	Free Triiodothyronine (FT3) Test Kit-human serum or plasma	54417	B	6
D-CIHBAK40	Glycated Hemoglobin (HbA1c) Test Kit-human whole blood	61010	C	3k
D-CITGK40K40	Thyroglobulin (TG) Test Kit-human serum or plasma	54375	B	6
D-CICA153K40	Cancer Antigen 15-3 (CA15-3) Test Kit-human serum or plasma	60975	C	3h
D-CIFAK40	Folic Acid (FA) Test Kit- human serum	60982	B	6
D-CIhsCTIK40	High Sensitive Cardiac Troponin-I (hs-cTnI) Test Kit- human serum or plasma	60780	C	3j
D-CIPROGK40	Progesterone Test Kit-human serum or plasma	54322	B	6
D-CICA242K40	Cancer Antigen 242 (CA242) Test Kit-human serum or plasma	66062	B	6

D-CICA724K40	Cancer Antigen 72-4 (CA72-4) Test Kit-human serum or plasma	65193	B	6
D-CIG17K40	Gastrin 17 (G-17) Test Kit-human serum	61974	B	6
D-CIHE4K40	Human Epididymis Protein 4 (HE4) Test Kit-human serum or plasma	56656	B	6
D-CINSEK40	Neuron-specific Enolase (NSE) Test Kit-human serum	64542	B	6
D-CIPLGFK40	Placental Growth Factor (PLGF) Test Kit- human serum	56616	C	3j
D- CIsFLT1K40	Soluble fms-like Tyrosine Kinase-1 (sFlt-1) Test Kit-human serum	61081	C	3j
D-MPOXD25	Monkeypox Virus Antibody Rapid Test -Whole Blood/Serum/Plasma	66498	B	6
D-MPOXAGD25	Monkeypox Virus Antigen Rapid Test -Whole Blood/Serum/Plasma	66416	B	6
D-U1MC100AU	Urinalysis Reagent Strips for Urine Analyzer - 1 parameter	63695	B	6
D-U2MC100AU	Urinalysis Reagent Strips for Urine Analyzer - 2 parameters	63695	B	6
D-U3MC100AU	Urinalysis Reagent Strips for Urine Analyzer - 3 parameters	63695	B	6
D-U4MC100AU	Urinalysis Reagent Strips for Urine Analyzer - 4 parameters	63695	B	6
D-U5MC100AU	Urinalysis Reagent Strips for Urine Analyzer - 5 parameters	63695	B	6
D-U6MC100AU	Urinalysis Reagent Strips for Urine Analyzer - 6 parameters	63695	B	6
D-U7MC100AU	Urinalysis Reagent Strips for Urine Analyzer - 7 parameters	63695	B	6
D-U8MC100AU	Urinalysis Reagent Strips for Urine Analyzer - 8 parameters	63695	B	6
D-U9MC100AU	Urinalysis Reagent Strips for Urine Analyzer - 9 parameters	63695	B	6
D-U10MC100AU	Urinalysis Reagent Strips for Urine Analyzer - 10 parameters	63695	B	6
D-U11MC100AU	Urinalysis Reagent Strips for Urine Analyzer - 11 parameters	63695	B	6
D-U12MC100AU	Urinalysis Reagent Strips for Urine Analyzer - 12 parameters	63695	B	6
D-U13MC100AU	Urinalysis Reagent Strips for Urine Analyzer - 13 parameters	63695	B	6
D-U14MC100AU	Urinalysis Reagent Strips for Urine Analyzer - 14 parameters	63695	B	6

ANNEX IV

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

Date of Update	Update made	Signature		
15/07/2024	New Brand Addition (Rapid Biotech)			
Part/Catalogue Number	Description/Name	GMDN Code	IVDR CLASS	Rule
D-CHIKWBD40	Chikungunya IgG/IgM Rapid Test Device – WB/S/P	63970	B	6
D-HCGUS25	hCG Pregnancy Rapid Test Cannister Strip – Urine	66850	B	6
D-HPS50	H.pylori Antibody Rapid Test Strip – WB/S/P	30825	B	6
D-DGMD20	Dengue Rapid Test Device – WB/S/P	63238	B	6
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-FILGMD20	Filariasis IgG/IgM Rapid Test Device – WB/S/P	52508	B	6
D-INFS20	Influenza A Rapid Test Strip - Swab/Nasal Aspirate Influenza A Rapid Test Device - Swab/Nasal	49150	B	6
D-COVAGD25	COVID-19 Antigen Rapid Test Strip - Nasopharyngeal Swab	64787	D	1
D-MPPFPVD20	Malaria P.f./P.v. Rapid Test Device - WB	52311	C	3c
D-TYPGMD20	Typhoid Rapid Test Strip - WB/S/P Typhoid Rapid Test Device - WB/S/P	51560	C	3e
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-SAACRPD10	SAA & CRP Combo Rapid Test Device – WB/S/P	65297	B	6
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 –	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 HCl (MEP) Rapid Test Device – Urine	46994	B	6
D-DOA23S50	Mephedrone HCl (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 –	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	Tropicamide (TRO) Rapid Test Device – Urine	46994	B	6
D-DOA25S50	Tropicamide (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-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-HCGUEM0	hCG Pregnancy Enhanced Sensitivity 10mIU/mL Rapid Test Device – Midstream Urine	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-FSHM2	FSH Rapid Test Midstream-Urine	65840	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-IHD10	Influenza A/B + H1N1 Combo Rapid Test Device –	49119	D	1
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 –	46994	B	6

D-DOA53P40	7-Aminoclonazepam (7-ACL) Rapid Test Panel –	46994	B	6
D-DOA53S50	7-Aminoclonazepam (7-ACL) Rapid Test Strip –	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	Fluorketamine (FKET) Rapid Test Device – Urine	46994	B	6
D-DOA48P40	Fluorketamine (FKET) Rapid Test Panel-Urine	46994	B	6
D-DOA48S50	Fluorketamine (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	Tropicamide (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-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 – Salvia	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-	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-DOACM13S	Multi-Drug 13 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-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-RFSPD20	Rheumatoid Factor Rapid Test Device – S/P	66486	B	6
D-RDOA32D40	Acetaminophen (ACE) Rapid Test Device -Urine	64160	B	6
D-RDOA53D40	7-Aminoclonazepam (7-ACL) Rapid Test Device -	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 with Adulteration-urine	46994	B	6
D-RDOAPM6A	Multi-Drug 6 Drugs Rapid Test Panel 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-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-RFSDH20	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-FITSPD40	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-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-DOA12D20S	Ecstasy (MDMA) Rapid Test Device – Saliva	46994	B	6
D-DOA2D20S	Methamphetamine (MET) Rapid Test Device -	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	Pregabalin (PGB) Rapid Test Device – Urine	46994	B	6
D-DOA50S50	Pregabalin (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-HPVD20	HPV Antigen Rapid Test Device – Cervical Swab	63733	B	6
D-INFABS50	Influenza A+B Rapid Test Strip – Swab/Nasal	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-TROPQD20	Troponin I (cTNI) Semi Quantitative Test Rapid Test Device – WB/S/P	46989	C	3j
D-TRVAD10	Trichomonas Vaginalis Rapid Test Device – Swab	52471	C	3a
D-COVAGD25H	SARS-CoV-2 Antigen Rapid Test Device – Oral Fluid	64787	D	1
D-DOA30DM25S	Tramadol (TML) Rapid Test Device – Midstream	46994	B	6
D-SHID20	Shigella Rapid Test Device – Faeces	64874	C	3b
D-FICOVID10	COVID-19 Antigen Rapid Test Device – Nasopharyngeal Sw	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)-	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 – Throat	51054	C	3c
D-LEIGID40	Legionella Antigen Rapid Test Device – Throat	51054	C	3c
D-TBSPD10	Tuberculosis (TB) Rapid Test Device – WB/S/P	65814	C	3e
D-TBSPD20	Tuberculosis (TB) Rapid Test Device – WB/S/P	65814	C	3e
D-DGMCMD20	Dengue + Chik (IgG/IgM-Chik IgM) Test – WB/S/P	63970	B	6
D-HPVCSD25	HPV Antigen Rapid Test -Cervical Swab	49993	C	3a
D-HEMS50	HB Hemoglobin Strip	63089	B	6
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-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
D-CIIGE40	Total IgE (T-IgE) Test Kit-human serum or plasma	60380	C	3e
D-CIFERK40	Ferritin Test Kit-whole blood, serum or plasma	61078	B	6
D-CIAMHK40	Anti-mullerian Hormone (AMH) Test Kit-human serum or plasma	64335	B	6
D-CICEAK40	Carcinoembryonic Antigen (CEA) Test Kit- human serum or plasma	54615	C	3h
D-CIFSHK40	FSH Test Kit-human serum or plasma	54187	B	6
D-CILHK40	LH Test Kit-human serum or plasma	54254	B	6
D-CINBNPK40	N-Terminal pro-B-type Natriuretic Peptide (NT-proBNP) Test Kit - whole blood, serum or plasma	47351	C	3j
D-CITSHK40	Thyroid Stimulating Hormone (TSH) Test Kit-human serum or plasma	54386	B	6
D-CIVDK40	25 OH Vitamin D (25-OH VD) Test Kit -whole blood, serum or plasma	60922	B	6
D-CIβHCGK40	β-human Chorionic Gonadotropin (β-HCG) Test Kit -human serum or plasma	54215	B	6
D-CIT4K40	Thyroxine (T4) Test Kit-human serum or	58322	B	6
D-CIFT4K40	Free Thyroxine (FT4) Test Kit -human serum or plasma	54413	B	6
D-CIPRLK40	Prolactin Test Kit-human serum or plasma	54335	B	6
D-CICA199K40	Carbohydrate Antigen 199 (CA19-9) Test Kit- human serum and plasma	60976	B	6

D-CIAFPK40	Alpha-fetoprotein (AFP) Test Kit- human serum or plasma	58348	C	3h
D-CICKMBK40	Creatine Kinase MB (CKMB) Test Kit - human whole blood, serum or plasma	61000	C	3j
D-CICRPK40	C-reactive Protein (CRP) Test Kit -human whole blood, serum or plasma	65695	B	6
D-CICTIK40	Cardiac Troponin-I (cTnI) Test Kit -human whole blood, serum or plasma	60780	C	3j
D-CIDDMK40	D-Dimer Test Kit-human whole blood and plasma	60530	C	3k
D-CIINSK40	Insulin (INS) Test Kit-human serum or plasma	54237	B	6
D-CIMYOK40	Myoglobin (MYO) Test Kit-human whole blood, serum or plasma	53952	C	3j
D-CIPCTK40	Procalcitonin (PCT) Test Kit-human whole blood,	58731	B	6
D-CICTNTK40	Cardiac Troponin-T (cTnT) Test Kit -human serum or plasma	54007	B	6
D-CIIL6K40	Interleukin-6 (IL-6) Test Kit-human whole blood,	53858	B	6
D-CIT3K40	Triiodothyronine (T3) Test Kit -human serum or plasma	58330	B	6
D-CISAAK40	Serum Amyloid A Protein (SAA) Test Kit-human whole blood, serum or plasma	65690	B	6
D-CIHFABPK40	Heart-fatty Acid-binding Protein (H-FABP) Test Kit- human whole blood, serum or	53377	C	3j
D-CIBNPK40	Brain Natriuretic Peptide (BNP)Test Kit-human plasma	47351	C	3k
D-CISST2K40	Growth Stimulation Expressed Gene 2 (ST2) Test Kit- human whole blood, serum or plasma	66516	C	3k
D-CICPEK40	C-Peptide (CP) Test Kit-human serum and plasma	54130	B	6
D-CICA125K40	Cancer Antigen 125 (CA125) Test Kit -human serum or plasma	54588	C	3h
D-CICYFRA211K40	Cytokeratin-19-fragment (CYFRA21-1) Test Kit-human serum or plasma	54612	B	6
D-CISCKK40	Squamous Cell Carcinoma Antigen (SCC) Test Kit-human serum or plasma	61418	B	6
D-CIPGIK40	Pepsinogen I (PG I) Test Kit-human serum or plasma	61414	B	6
D-CIPGIK40	Pepsinogen II (PG II) Test Kit -human serum or plasma	61415	B	6
D-CIPGRPK40	Gastrin Releasing Peptide Precursor (ProGRP) Test Kit- human serum or plasma	54660	B	6
D-CIFT3K40	Free Triiodothyronine (FT3) Test Kit-human serum or plasma	54417	B	6

D-CIHBK40	Glycated Hemoglobin (HbA1c) Test Kit-human whole blood	61010	C	3k
D-CITGK40K40	Thyroglobulin (TG) Test Kit-human serum or plasma	54375	B	6
D-CICA153K40	Cancer Antigen 15-3 (CA15-3) Test Kit-human serum or plasma	60975	C	3h
D-CIFAK40	Folic Acid (FA) Test Kit- human serum	60982	B	6
D-CIhsCTIK40	High Sensitive Cardiac Troponin-I (hs-cTnI) Test Kit- human serum or plasma	60780	C	3j
D-CIPROGK40	Progesterone Test Kit-human serum or plasma	54322	B	6
D-CICA242K40	Cancer Antigen 242 (CA242) Test Kit-human serum or plasma	66062	B	6
D-CICA724K40	Cancer Antigen 72-4 (CA72-4) Test Kit-human serum or plasma	65193	B	6
D-CIG17K40	Gastrin 17 (G-17) Test Kit-human serum	61974	B	6
D-CIHE4K40	Human Epididymis Protein 4 (HE4) Test Kit-human serum or plasma	56656	B	6
D-CINSEK40	Neuron-specific Enolase (NSE) Test Kit-human serum	64542	B	6
D-CIPLGFK40	Placental Growth Factor (PLGF) Test Kit- human serum	56616	C	3j
D- CIsFLT1K40	Soluble fms-like Tyrosine Kinase-1 (sFlt-1) Test Kit-human serum	61081	C	3j
D-MPOXD25	Monkeypox Virus Antibody Rapid Test -Whole Blood/Serum/Plasma	66498	B	6
D-MPOXAGD25	Monkeypox Virus Antigen Rapid Test -Whole Blood/Serum/Plasma	66416	B	6
D-U1MC100AU	Urinalysis Reagent Strips for Urine Analyzer - 1 parameter	63695	B	6
D-U2MC100AU	Urinalysis Reagent Strips for Urine Analyzer - 2 parameters	63695	B	6
D-U3MC100AU	Urinalysis Reagent Strips for Urine Analyzer - 3 parameters	63695	B	6
D-U4MC100AU	Urinalysis Reagent Strips for Urine Analyzer - 4 parameters	63695	B	6
D-U5MC100AU	Urinalysis Reagent Strips for Urine Analyzer - 5 parameters	63695	B	6
D-U6MC100AU	Urinalysis Reagent Strips for Urine Analyzer - 6 parameters	63695	B	6
D-U7MC100AU	Urinalysis Reagent Strips for Urine Analyzer - 7 parameters	63695	B	6
D-U8MC100AU	Urinalysis Reagent Strips for Urine Analyzer - 8 parameters	63695	B	6

D-U9MC100AU	Urinalysis Reagent Strips for Urine Analyzer - 9 parameters	63695	B	6
D-U10MC100AU	Urinalysis Reagent Strips for Urine Analyzer - 10 parameters	63695	B	6
D-U11MC100AU	Urinalysis Reagent Strips for Urine Analyzer - 11 parameters	63695	B	6
D-U12MC100AU	Urinalysis Reagent Strips for Urine Analyzer - 12 parameters	63695	B	6
D-U13MC100AU	Urinalysis Reagent Strips for Urine Analyzer - 13 parameters	63695	B	6
D-U14MC100AU	Urinalysis Reagent Strips for Urine Analyzer - 14 parameters	63695	B	6



Alcohol (ALC) Rapid Test Device (Urine)

CATALOGUE NUMBER D-DOA40D20

A rapid, one step screening test for the semi-quantitative detection of Alcohol in human urine.
For professional in vitro diagnostic use only.

INTENDED USE

The Alcohol (ALC) Rapid Test Device (Urine) is a rapid, highly sensitive method to detect the presence of alcohol in urine and provide an approximation of relative blood alcohol concentration.
This test provides a preliminary screen only. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Clinical consideration and professional judgment should be applied to any test screen result, particularly when preliminary positive screens are indicated.

SUMMARY

Two-thirds of all adults drink alcohol.¹ The blood alcohol concentration at which a person becomes impaired is variable dependent upon the individual. Each individual has specific parameters that affect the level of impairment such as size, weight, eating habits and alcohol tolerance. Inappropriate consumption of alcohol can be a contributing factor to many accidents, injuries, and medical conditions.

PRINCIPLE

It is well established that the concentration of alcohol in urine is comparable to that of blood.^{2,3} The Alcohol (ALC) Rapid Test Device (Urine) consists of a plastic dipstick with a reaction pad attached at the tip. On contact with solutions of alcohol, the reaction pad will rapidly turn colors depending on the concentration of alcohol present. The pad employs a solid-phase chemistry which uses a highly specific enzyme reaction.

REAGENTS

Tetramethylbenzidine
Alcohol Oxidase
Peroxidase
Other additives

PRECAUTIONS

The Alcohol (ALC) Rapid Test Device (Urine) is a visually interpreted test where color matching is used to provide an approximation of relative blood alcohol concentration. Test materials that have been exposed to urine should be treated as potentially infectious. Do not use the Alcohol (ALC) Rapid Test Device (Urine) after the expiration date marked on the foil package.

STORAGE AND STABILITY

The Alcohol (ALC) Rapid Test Device (Urine) is to be stored at 2-30°C (36-86°F) in its sealed foil package. If storage temperatures exceed 30°C, the test performance may degrade. If the product is refrigerated, the Alcohol (ALC) Rapid Test Device (Urine) must be brought to room temperature prior to opening the pouch.

MATERIALS

- Materials Provided

 - Test devices
 - Droppers
 - Package Insert
- Materials Required But Not Provided

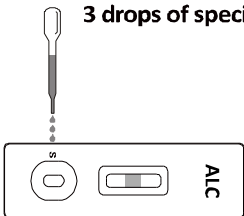
 - Timer

DIRECTIONS FOR USE

Allow the pouched device to equilibrate to room temperature (15-30°C) prior to testing.

- Remove the device from the sealed pouch and use it within 1 hour. Observe the reactive pad on the central window of the device. If the reaction pad has a blue color before applying urine sample, do not use.
- Place the device on a clean and level surface. Hold the dropper vertically and transfer **3 full drops of urine** (approximately 120µL) to the specimen well of the device, and then start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.
- Read the results in 3-5 minutes.** Compare the color of the reaction pad and standard color card to determine the relative blood alcohol concentration.

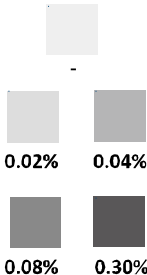
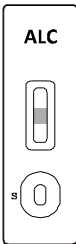
1



3 drops of specimen

2

3-5 Minutes



INTERPRETATION OF RESULTS

Positive: The Alcohol (ALC) Rapid Test Device (Urine) will produce a color change in the presence of urine alcohol. The color will range from light blue color at 0.02% relative blood alcohol concentration to a dark blue color near 0.30% relative blood alcohol concentration. Color pads are provided within this range to allow an approximation of relative blood alcohol concentration. The test may produce colors that appear to be between adjacent color pads.

NOTE: The Alcohol (ALC) Rapid Test Device (Urine) is very sensitive to the presence of alcohol. A blue color that is lighter than the 0.02% color pad should be interpreted as being positive to the presence of alcohol in urine but less than 0.02% relative blood alcohol.

Negative: When the Alcohol (ALC) Rapid Test Device (Urine) shows no color change this should be interpreted as a negative result indicating that alcohol has not been detected.

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

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

LIMITATIONS

- The Alcohol (ALC) Rapid Test Device (Urine) is highly sensitive to the presence of alcohol. Alcohol vapors in the air are sometimes detected by the Alcohol (ALC) Rapid Test Device (Urine). Alcohol vapors are present in many institutions and homes. Alcohol is a component in many household products such as disinfectant, deodorizers, perfumes, and glass cleaners. If the presence of alcohol vapors is suspected, the test should be performed in an area known to be free of vapors.
- Ingestion or general use of over-the-counter medications and products containing alcohol can produce positive results.

PERFORMANCE CHARACTERISTICS

The detection limit on the Alcohol (ALC) Rapid Test Device (Urine) is from 0.02% to 0.30% for approximate relative blood alcohol level. The cutoff level of the Alcohol (ALC) Rapid Test Device (Urine) can vary based on local regulations and laws. Test results can be reference of the color table level standard than color card.

ASSAY SPECIFICITY

The Alcohol (ALC) Rapid Test Device (Urine) will react with methyl, ethyl and allyl alcohols.

INTERFERING SUBSTANCES

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

- Agents which enhance color development
 - Peroxidases
 - Strong oxidizers
- Agents which inhibit color development
 - Reducing agents: Ascorbic acid, Tannic acid, Pyrogallol, Mercaptans and Tosylates, Oxalic acid, Uric Acid.
 - Bilirubin
 - L-dopa
 - L-methyldopa
 - Methamprone

CONTROLS

The Alcohol (ALC) Rapid Test Device (Urine) may be qualitatively verified by using a test solution prepared by adding 5 drops of 80 proof distilled spirits to 8 oz. (1 cup) of water. This solution should produce a color reaction on the pad. The color reaction with alcohol in urine is somewhat slower and less intense than with alcohol in an aqueous solution.

BIBLIOGRAPHY

- Volpicellim, Joseph R., M.D., Ph.D.: Alcohol Dependence: Diagnosis, Clinical Aspects and Biopsychosocial Causes., Substance Abuse Library, University of Pennsylvania, 1997.
- Jones, A.W.: Inter-and intra individual variations in the urine/blood alcohol ratio during ethanol metabolism in man., Clin. Chem. 25, 1394-1398, 1979.
- MacCall, L.E.L., Whiting, B., Moore, M.R. and Goldberg, A.: Correlation of ethanol concentrations in blood and urine., Clin.Sci., 56, 283-286, 1979.

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



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