



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 non-exclusive authorized representative for Orient Gene Brand product in correspondence with the conditions of directive 98/79/EEC.

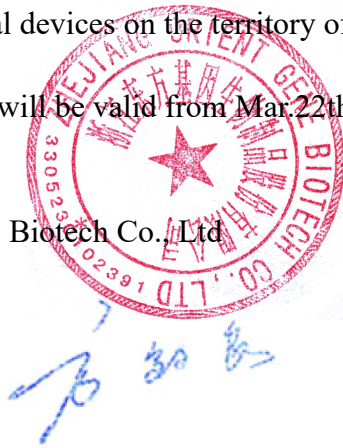
We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

This Statement letter will be valid from Mar.22th,2024 to Mar.21th, 2025.

Zhejiang Orient Gene Biotech Co.,Ltd

General Manager:

Date:2024/3/22



地址：浙江省湖州市安吉县递铺镇阳光大道东段 3787 号
Add: **3787#, East Yangguang Avenue, Dipu Street Anji 313300, Huzhou, Zhejiang, China**
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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](http://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



Product Service

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-OG038
Version 2.0

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)

Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma)	GDTRO-402a
Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma)	GDTRO-402b

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: August 11, 2020

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



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



CE-DOC-OG048
Version 3.0

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)

D-Dimer Rapid Test Cassette (Whole Blood/Plasma)

GDDDI-402b

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: *QARAD BV*

EC Representative's Address: *Cipalstraat 3, 2440 Geel BELGIUM*

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 11, 2021

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

D-Dimer Rapid Test Cassette (Whole Blood/Plasma)

INTENDED USE

The D-Dimer Rapid Test Cassette (Whole Blood/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of D-dimer in human whole blood or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of disseminated intravascular coagulation (DIC), deep vein thrombosis (DVT). Any reactive specimen with the D-Dimer Rapid Test Cassette (Whole Blood/Plasma) must be confirmed with alternative testing method(s) and clinical findings.

INTRODUCTION

During blood coagulation process, fibrinogen is converted to fibrin by the activation of thrombin. The resulting fibrin monomers polymerise to form a soluble gel of non-cross-linked fibrin. This fibrin gel is then converted to cross-linked fibrin by thrombin activated Factor XIII to form an insoluble fibrin clot. Production of plasmin, the major clot-lysing enzyme, is triggered when a fibrin clot is formed. Although fibrinogen and fibrin are both cleared by the fibrinolytic enzyme plasmin to yield degradation products, only degradation products from cross-linked fibrin contain D-dimer and are called cross-linked fibrin degradation products. Therefore, fibrin derivatives in human blood or plasma containing D-dimer are a specific marker of fibrinolysis.

The D-Dimer Rapid Test Cassette (Whole Blood/Plasma) is a rapid test that qualitative detects the presence of D-dimer in whole blood or plasma specimens at the sensitivity of 500 ng/mL. The test utilizes a combination of monoclonal antibodies to selectively detect elevated levels of D-dimer in whole blood or plasma. At the level of claimed sensitivity, the D-Dimer Rapid Test Cassette (Whole Blood/Plasma) shows no cross-reactivity interference from the related Troponin I, Troponin T, CK-MB, Myoglobin or others at high physiological levels.

PRINCIPLE

The D-Dimer Rapid Test Cassette (Whole Blood/Plasma) is immunochromatographic assay including D-Dimer specific monoclonal antibody conjugated to colloidal gold particles, second D-Dimer specific monoclonal antibody on test line and Goat anti-mouse IgG antibody on the control line. When the specimen containing D-Dimer is added to sample pad, it moves to conjugate pad and forms a complex (D-Dimer and antibody-gold conjugate). The complex migrates through a nitrocellulose membrane by capillary action and captured at test line which is second D-Dimer specific monoclonal antibody has been bound. The complex is concentrated at test line and a pink or purple line is showed if the D-Dimer concentration is higher than the clinically established cut-off. Uncaptured gold conjugate continues to flow towards control line which Goat anti-mouse IgG is bound and forms a pink or purple color line, indicating test is working as designed and the result is valid. If the control line does not appear, the test result is not valid.

PRODUCT CONTENTS

The D-Dimer Rapid Test Cassette (Whole Blood/Plasma) containing Anti-D-dimer particles and Anti-D-dimer coated on the membrane.

MATERIALS SUPPLIED

- 25 Sealed pouches each containing a test cassette, a pipette dropper and a desiccant
- 1 Buffer, 4.0 mL
- 1 Package insert

MATERIAL REQUIRED BUT NOT PROVIDED

- Timer
- Lancing device for whole blood test

STORAGE AND STABILITY

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

WARNINGS AND PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or inhale).
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in any area where specimens and kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Do not interchange or mix reagents from different lots. Do not mix solution bottle caps.
- Humidity and temperature can adversely affect results.

SPECIMEN COLLECTION AND PREPARATION

- The D-Dimer Rapid Test Cassette (Whole Blood/Plasma) is intended for use with human whole blood or plasma specimens only.
- Only clear, non-hemolyzed specimens are recommended for use with this test. Whole blood or Plasma should be separated as soon as possible to avoid hemolysis.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Containers containing anticoagulants such as EDTA, citrate, or heparin should be used for whole blood storage.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.

- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.
- Icteric, lipemic, hemolysed, heat treated and contaminated specimens may cause erroneous results.

TEST PROCEDURE

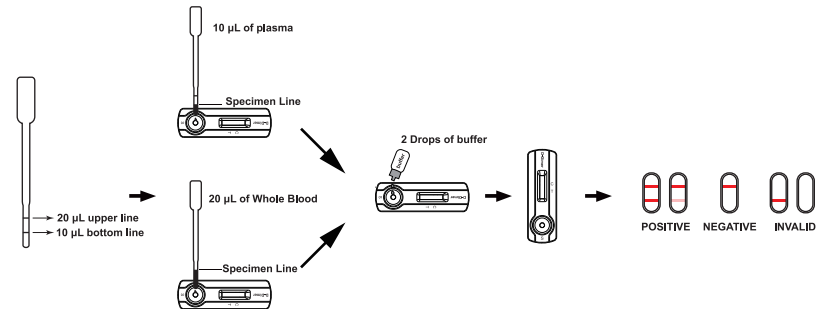
Bring tests, specimens, reagents and/or controls to room temperature (15-30°C) prior to testing.

- 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.
 - Place the test cassette on a clean and level surface.
- For Whole Blood Specimen:** With the 10/20µL mini plastic dropper provided, draw the whole blood specimen to the upper scale line as showed in the following image and then transfer drawn whole blood into the sample well (S) of the test device., then add 2 drops of buffer (approximately 80µL) and start the timer. See illustration below.

For Plasma Specimen: With the 10/20µL mini plastic dropper provided, draw the plasma specimen to the bottom scale line as showed in the following image and then transfer drawn plasma into the sample well (S) of the test device. Then add 2 drops of buffer (approximately 80µL) and start the timer. See illustration below.

Note: Practice a few times prior to testing if you are not familiar with the mini dropper. For better precision, transfer specimen by pipette capable to deliver 10 and 20µL of volume.

- As the test begins to work, color will migrate across the membrane.
- Wait for the colored band(s) to appear. The result should be read in 10 minutes. Do not interpret the result after 15 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. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test Cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this test. However, it is recommended that positive and negative controls are sourced from a local competent authority and tested as a good laboratory practice, to confirm the test procedure and verify the test performance.

LIMITATIONS

- The D-Dimer Rapid Test Cassette (Whole Blood/Plasma) is for *in vitro* diagnostic use only. This test should be used for the detection of D-dimer in whole blood or plasma specimens only. Neither the quantitative value nor the rate of increase in D-dimer can be determined by this qualitative test.
- The D-Dimer Rapid Test Cassette (Whole Blood/Plasma) will only indicate the qualitative level of D-dimer in the specimen and should not be used as the sole criteria for the diagnosis of Disseminated Intravascular Coagulopathy (DIC), Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE).
- During the process of serum is formed, also fibrinogen is converted to fibrin by the activation of thrombin and it also can be detected by D-dimer antibody. So serum specimen can't be used for D-Dimer Rapid Test Device (Whole Blood/Plasma).
- The D-Dimer Rapid Test Cassette (Whole Blood/Plasma) cannot detect less than 500 ng/mL D-dimer in specimens. A negative result at any time does not preclude the possibility of Disseminated Intravascular Coagulopathy (DIC), Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE).
- False negative readings can occur if the sample is taken either too early after thrombus formation, if testing is delayed for several days or if the sample was taken too late after the occurrence of thromboembolic infarction, because the D-dimer concentration may decrease to normal values after one week already. Additionally, a treatment with anti-coagulants prior sample collection can render the test negative because it prevents thrombus extension.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician. E.g. use "Wells score" for DVT resp. PE, Ultrasound, quantitative laboratory D-dimer results etc.
- Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor (RF) may affect expected results. Even if the test results are positive, further clinical evaluation should be considered with other clinical information available to the physician

PERFORMANCE CHARACTERISTICS

1. Sensitivity and Specificity

The D-Dimer Rapid Test Cassette (Whole Blood/Plasma) has been evaluated with a leading commercial D-dimer EIA test using clinical specimens. The results show that the sensitivity of the D-Dimer Rapid Test Cassette (Whole Blood/Plasma) is 98.6% and the specificity is 98.6% relative to the leading EIA test.

Method	EIA			Total Results
	Results	Positive	Negative	
	D-Dimer Rapid Test Cassette	Positive	71	
	Negative	1	211	212
Total Results		72	214	286

Relative Sensitivity: 98.6%

Relative Specificity: 98.6%

Accuracy: 98.6%

2. Precision

Within-run precision has been determined by using 15 replicates of below five specimens: D-dimer specimen levels at 0 ng/mL, 500 ng/mL, 1,000 ng/mL, 1,500 ng/mL and 3,000 ng/mL. The specimens were correctly identified at the prescribed reading time.

3. Inter-Assay

Between-run precision has been determined by 3 independent assays on the same five specimens: 0 ng/mL, 500 ng/mL, 1,000ng/mL, 1,500 ng/mL and 3,000 ng/mL of D-dimer. Three different lots of the D-Dimer Rapid Test Cassette (Whole Blood/Plasma) have been tested using these specimens. The specimens were correctly identified at the prescribed reading time.

4. Cross-reactivity

The D-Dimer Rapid Test Cassette (Whole Blood/Plasma) has been tested with HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, anti-syphilis, anti-HIV, anti-H.pylori, IM heterophile antibodies, anti-CMV, anti-Rubella and anti-Toxoplasma positive specimens. The results showed no cross-reactivity.

5. Interfering Substances

The following potentially interfering substances were added to D-dimer negative and positive specimens, respectively.










Substances	Concentration
Acetaminophen	20 mg/dL
Caffeine	20 mg/dL
Acetylsalicylic Acid	20 mg/dL
Gentisic Acid	20 mg/dL
Ascorbic Acid	20 mg/dL
Albumin	10,500 mg/dL
Creatin	200 mg/dL
Hemoglobin	1,000 mg/dL
Bilirubin	1,000 mg/dL
Oxalic Acid	600 mg/dL
Cholesterol	800 mg/dL
Triglycerides	1,600 mg/dL

None of the substances at the concentration tested interfered in the assay.

REFERENCE

- Gaffney, P.J. D-dimer History of Discovery, Characterisation and Utility of this and other Fibrin Fragments. Fibrinolysis 7 Suppl 2:2-8; 1993
- Lane, D.A. et al. Characterisation of Serum Fibrinogen and Fibrin Fragments Produced During Disseminated Intravascular Coagulation. Haematology. 40: 609-615; 1978.
- Scarvelis, D and Wells, P.S. Diagnosis and Treatment of Deep Vein Thrombosis. Can. Med. Assoc. J. 175 (9):1087-92; 2006
- Bick, R.L. et al. Diagnostic Efficacy of the D-dimer assay in Disseminated Intravascular Coagulation (DIC) Thromb. Res. 65:785-790; 1992.
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- Hunt, F.A. et al. Serum Cross-Linked Fibrin (XDP) and Fibrinogen/Fibrin Degradation Products (FDP) in Disorders Associated with Activation of the Coagulation or Fibrinolytic Systems. Br. J. Haematol. 60: 715-722; 1985.
- Subramanian, R.M. et. al. Does an Immunochromatographic D-dimer exclude acute lower limb deep venous thrombosis? Emer. Med. Austral. 18: 457-463; 2006.
- Runyon, M.S. et. al. Comparison of the Simplify D-dimer assay performed at the bedside with a laboratory based quantitative D-dimer assay for the diagnosis of pulmonary embolism in a low prevalence emergency department population. Emerg. Med. J. 25:70-75; 2008.

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#



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QARAD BV
 Cipalstraat 3, 2440 Geel BELGIUM



GDDDI-402b

Troponin I

Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) Package Insert

A rapid visual immunoassay for the qualitative presumptive detection of cardiac Troponin I in human whole blood, serum, or plasma specimens.
For professional *in vitro* diagnostic use only.

INTENDED USE

The Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid visual immunoassay for the qualitative presumptive detection of cardiac Troponin I in human whole blood, serum, or plasma specimens. This kit is intended to be used as an aid in the diagnosis of myocardial infarction (MI).

SUMMARY

Cardiac Troponin I (cTnI) is a protein found in cardiac muscle with a molecular weight of 22.5 kDa.¹ Troponin I is part of a three subunit complex comprising of Troponin T and Troponin C. Along with tropomyosin, this structural complex forms the main component that regulates the calcium sensitive ATPase activity of actomyosin in striated skeletal and cardiac muscle.² After cardiac injury occurs, Troponin I is released into the blood 4-6 hours after the onset of pain. The release pattern of cTnI is similar to CK-MB, but while CK-MB levels return to normal after 72 hours, Troponin I remains elevated for 6-10 days, thus providing for a longer window of detection for cardiac injury. The high specificity of cTnI measurements for the identification of myocardial damage has been demonstrated in conditions such as the perioperative period, after marathon runs, and blunt chest trauma.³ cTnI release has also been documented in cardiac conditions other than acute myocardial infarction (AMI) such as unstable angina, congestive heart failure, and ischemic damage due to coronary artery bypass surgery.⁴ Because of its high specificity and sensitivity in the myocardial tissue, Troponin I has recently become the most preferred biomarker for myocardial infarction.⁵

PRINCIPLE

The Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) has been designed to detect cardiac Troponin I through visual interpretation of color development in the strip. The membrane was immobilized with anti-cTnI antibodies on the test region. During the test, the specimen is allowed to react with colored anti-cTnI antibodies colloidal gold conjugates, which were precoated on the sample pad of the test. The mixture then moves on the membrane by a capillary action, and interact with reagents on the membrane. If there were enough cTnI in specimens, a colored band will form at the test region of the membrane.

Presence of this colored band indicates a positive result, while its absence indicates a negative result. Appearance of a colored band at the control region serves as a procedural control. This indicates that proper volume of specimen has been added and membrane wicking has occurred.

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Warning: the reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
- Do not use it if the tube/pouch is damaged or broken.
- Test is for single use only. Do not re-use under any circumstances.
- Handle all specimens as if they contain infectious agents. Observe established standard procedure for proper disposal of specimens
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.

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 off the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

SPECIMEN COLLECTION AND PREPARATION

- The Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) is intended only for use with human whole blood, serum, or plasma specimens.
- Only clear, non-hemolyzed specimens are recommended for use with this test.
- Serum or plasma should be separated with soonest possible opportunity to avoid hemolysis.
- Perform the testing immediately after the specimen collection. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- Pack the specimens in compliance with applicable regulations for transportation of etiological agents, in case they need to be shipped.
- Icteric, lipemic, hemolyzed, heat treated and contaminated sera may cause erroneous results.
- There is a slight possibility that some whole blood specimens with very high viscosity or which have been stored for more than 2 days may not run properly on the test device. Repeat the test with a serum or plasma specimen from the same patient using a new test device.

Materials Provided

- Test cassettes
- Disposable Droppers
- Package insert

Materials Required But Not Provided

- Specimen collection containers
- Centrifuge (for plasma only)
- Clock or Timer

DIRECTIONS FOR USE

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

1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. To obtain a best result, the assay should be performed within one hour.

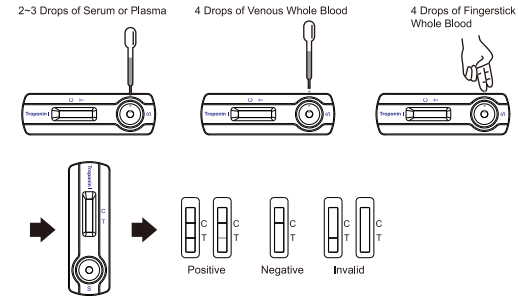
2. Transfer **2-3 drops of serum or plasma** to the specimen well(S) of the device with a disposable pipette provided in the kit, and then start the timer.

OR
Transfer **4 drops of whole blood** specimen to the specimen well(S) of the device with a disposable pipette provided in the kit, and then start the timer.

OR

Allow **4 hanging drops of fingerstick whole blood** specimen to fall into the center of the specimen well (S) of the device, and then start the timer. Avoid trapping air bubbles in the specimen well (S), and do not drop any solution in observation window. As the test begins to work, you will see color move across the membrane.

2. Wait for the colored band(s) to appear. The result should be read at 15 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

NEGATIVE: Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T).

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be discarded.

Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE: Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.

External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

- The Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) is for professional *in vitro* diagnostic use, and should be used for the qualitative detection of cardiac Troponin I only. There is no meaning attributed to linen color intensity or width.
- The Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of Troponin I in the specimen and should not be used as the sole criteria for the diagnosis of tuberculosis.
- If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. The test cannot detect less than 0.5 ng/mL of cTnI in specimens. Thus, a negative result does not at anytime rule out the existence of Troponin I in blood, because the antibodies may be absent or below the minimum detection level of the test.
- Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
- Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor (RF) may affect expected results. Even if the test results are positive, further clinical evaluation should be considered with other clinical information available to the physician.

PERFORMANCE CHARACTERISTICS

Table: Troponin I Rapid Test vs. EIA

Method		Troponin I Rapid Test Cassette		Total Results
		Positive	Negative	
EIA	Positive	138	2	140
	Negative	1	315	316
Total Results		139	317	456

Relative Sensitivity: 98.6% (94.9%-99.8%)*

Relative Specificity: 99.7% (98.3%-99.9%)*

Overall Agreement: 99.3% (98.1%-99.9%)*

*95% Confidence Interval

BIBLIOGRAPHY

- Adams, et al. Biochemical markers of myocardial injury, *Immunoassay Circulation* 88:750-763, 1993.
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- Adams, et al. Diagnosis of Perioperative myocardial infarction with measurements of cardiac troponin I. *N.Eng.J.Med* 330:670, 1994.
- Hossein-Nia M, et al. Cardiac troponin I release in heart transplantation. *Ann. Thorac.Surg.* 61: 227, 1996.
- Alpert JS, et al. Myocardial Infarction Redefined, Joint European Society of Cardiology American College of Cardiology: *J. Am. Coll. Cardio.*, 36(3):959, 2000.



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 Singhal - On behalf of the Schemes Manager





Appendix to Certificate

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

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

A certificate number of 0001, confirms the Client has a single site Certified & the site is their Head Office or Main site in relation to the Certified scope with URS. A certificate number of 0002, or greater (e.g.: xxxx/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

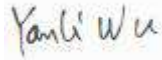
for the

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

D-ZNSD10	Zika NS1 Rapid Test Device -WB/S/P	66467	C	3b
D-ZGMD10	Zika IgG/IgM Rapid Test Device – WB/S/P	63719	B	6
D-ZGMNSD10	Zika IgG/IgM & NS1 Combo Rapid Test Device – WB/S/P	63767	C	3b
D-FILGMD40	Filariasis IgG/IgM rapid Test Device – WB/S/P	52508	B	6
D-TYGMS50	Typhoid Rapid Test Strip – S/P	63976	C	3e
D-PAAGD25	Salmonella paratyphi Antigen Rapid Test Device -Feces	51543	C	3e
D-TYPAGD20	Salmonella typhi and paratyphi Antigen Combo Rapid Test Device – WB/S/P	51512	C	3e
D-MPFS50	Malaria Pf Rapid Test Strip – WB	52336	C	3c
D-HAVGMD25	HAV IgG/IgM Combo Rapid Test Device – WB/S/P	65737	B	6
D-HAVMWBD20	HAVIgM Rapid Test Device – WB/S/P	48270	B	6
D-STRABD20	Strep A Rapid Test Device – Throat Swab	51707	B	6
D-STRARD20	Strep A Rapid Test Device – Throat Swab	51707	B	6
D-LPD25	Legionella pneumophila Rapid Test Device – Urine	51054	C	3c
D-SPAGD10	Streptococcus pneumoniae antigen Rapid Test Device – Urine	51770	C	3c
D-CRAGD10	Cryptococcus Antigen Rapid Test Device – WB/S/P/CSF	65815	C	3b
D-EVGD10	EBV VCA IgG Rapid Test Device – WB/S/P	64773	C	3e
D-ENGD10	EBNA IgG Rapid Test Device – WB/S/P	49689	C	3e
D-EVENGD10	EBV VCA and EBNA IgG Combo Rapid Test Device – WB/S/P	64773	C	3e
D-ADAGD20	Adenovirus Antigen Rapid Test Device – Swab	49856	B	6
D-INFABS20	Influenza A+B Rapid Test Strip-Swab / Nasal Aspirate	49119	B	6
D-HNAGD20	H1N1 Antigen Rapid Test Device – Swab	49150	D	1
D-IHD10	Influenza A/B + H1N1 Combo Rapid Test Device – Swab	49119	D	1
D-RID10	RSV & Influenza A+B Combo Rapid Test Device – Swab/Nasal	64770	B	6
D-ARD10	Adenovirus & RSV Combo Rapid Test Device – Nasopharyngeal Swab	64770	B	6
D-ARID10	Adenovirus, RSV and Influenza A+B Combo Rapid Test Device - Nasopharyngeal Swab	64770	B	6
D-BRUD20	Brucella Abortus Antigen Rapid Test Device – WB/S/P	50611	C	3b
D-SCTD10	Scrub Typhus IgG/IgM Rapid Test Device – WB/S/P	51333	C	3e
D-TBS50	Tuberculosis Rapid Test Strip – WB/S/P	51172	C	3e
D-DOA52D40	AB-PINACA (ABP) Rapid Test Device – Urine	46994	B	6
D-DOA52P40	AB-PINACA (ABP) Rapid Test Panel – Urine	46994	B	6
D-DOA52S50	AB-PINACA (ABP) Rapid Test Strip – Urine	46994	B	6
D-DOA32P40	Acetaminophen (ACE) Rapid Test Panel – Urine	46994	B	6
D-DOA53D40	7-Aminoclonazepam (7-ACL) Rapid Test Device – Urine	46994	B	6
D-DOA53P40	7-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	Fluoketamine (FKET) Rapid Test Device – Urine	46994	B	6
D-DOA48P40	Fluoketamine (FKET) Rapid Test Panel-Urine	46994	B	6
D-DOA48S50	Fluoketamine (FKET) Rapid Test Strip – Urine	46994	B	6
D-DOA59D40	Fluoxetine (FLX) Rapid Test Device – Urine	46994	B	6
D-DOA59P40	Fluoxetine (FLX) Rapid Test Panel – Urine	46994	B	6
D-DOA59S50	Fluoxetine (FLX) Rapid Test Strip – Urine	46994	B	6
D-DOA42P40	Fentanyl (FYL) Rapid Test Panel – Urine	46994	B	6
D-DOA21P40	Gabapentin (GAB) Rapid Test Panel – Urine	46994	B	6
D-DOA9P40	Ketamine (KET) Rapid Test Panel – Urine	46994	B	6
D-DOA36P40	Kratom (KRA) Rapid Test Panel – Urine	46994	B	6
D-DOA29P40	Lysergic Acid Diethylamide (LSD) Rapid Test Panel – Urine	46994	B	6
D-DOA43P40	6-Monoacetylmorphine (6-MAM) Rapid Test Panel – Urine	46994	B	6
D-DOA60D40	Methcathinone (MCAT) Rapid Test Device – Urine	46994	B	6
D-DOA60P40	Methcathinone (MCAT) Rapid Test Panel – Urine	46994	B	6
D-DOA60S50	Methcathinone (MCAT) Rapid Test Strip – Urine	46994	B	6
D-DOA12P40	Ecstasy (MDMA) Rapid Test Panel – Urine	46994	B	6
D-DOA61D40	Tenamfetamine (MDA) Rapid Test Device – Urine	46994	B	6
D-DOA61P40	Tenamfetamine (MDA) Rapid Test Panel – Urine	46994	B	6
D-DOA61S50	Tenamfetamine (MDA) Rapid Test Strip – Urine	46994	B	6

D-DOA62D40	Methylenedioxypropylamphetamine (MDPV) Rapid Test Device – Urine	46994	B	6
D-DOA62P40	Methylenedioxypropylamphetamine (MDPV) Rapid Test Panel – Urine	46994	B	6
D-DOA62S50	Methylenedioxypropylamphetamine (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	Methylenedioxypropylvalerone (MDPV) Rapid Test Device-Saliva	46994	B	6
D-DOA62M25S	Methylenedioxypropylvalerone (MDPV) Rapid Test Midstream-Urine	46994	B	6
D-DOA7M20S	Methadone (MTD) Rapid Test Midstream-Saliva	46994	B	6
D-DOA3M20S	Opiates (OPI) Rapid Test Midstream-Saliva	46994	B	6
D-DOA39D20S	Oxycodone (OXY) Rapid Test Device – Saliva	46994	B	6
D-DOA39M25S	Oxycodone (OXY) Rapid Test Midstream-Saliva	46994	B	6
D-DOA13D20S	Phencyclidine (PCP) Rapid Test Device – Saliva	46994	B	6
D-DOA13M25S	Phencyclidine (PCP) Rapid Test Midstream-Saliva	46994	B	6
D-DOA51D20S	Synthetic Marijuana (K2) Rapid Test Device – Salvia	46994	B	6
D-DOA51M25S	Synthetic Marijuana (K2) Rapid Test Midstream-Salvia	46994	B	6
D-DOA8M25S	Marijuana (THC) Rapid Test Midstream-Saliva	46994	B	6
D-DOA30D20S	Tramadol (TML) Rapid Test Device – Saliva	46994	B	6
D-DOA30M25S	Tramadol(TML) Rapid Test Midstream-Saliva	64161	B	6
D-DOAMM2S	Multi-drug 2 Drugs Rapid Test Midstream-Saliva	46994	B	6
D-DOAMM3S	Multi-drug 3 Drugs Rapid Test Midstream-Saliva	46994	B	6
D-DOAMM4S	Multi-drug 4 Drugs Rapid Test Midstream-Saliva	46994	B	6
D-DOAMM5S	Multi-drug 5 Drugs Rapid Test Midstream-Saliva	46994	B	6
D-DOAMM6S	Multi-drug 6 Drugs Rapid Test Midstream-Saliva	46994	B	6
D-DOAMM7S	Multi-drug 7 Drugs Rapid Test Midstream-Saliva	46994	B	6

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

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

D-HFCD25	H-FABP and 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	Methylenedioxypropylvalerone (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-FICYSD25	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	Methylenedioxypropylone (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	GMDN Code	IVDR CLA	Rule
D-HPVCS25	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-CLOGTD10	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 Biotec)	<i>Yanli Wu</i>		
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-EVENGD10	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-TYGMCD20	Typhoid IgG/IgM Rapid Test -Whole Blood/Serum/Plasma	63976	C	3e
D-TYGMCD20	Typhoid IgG/IgM Rapid Test -Whole Blood/Serum/Plasma	51560	C	3e
D-TYGMCD40	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-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	Legionellapneumophilla & 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-TRFOBD20	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	<i>Yanli Wu</i>		
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-CIAMH40	Anti-mullerian Hormone (AMH) Test Kit-human serum or plasma	64335	B	6
D-CICEA40	Carcinoembryonic Antigen (CEA) Test Kit- human serum or plasma	54615	C	3h
D-CIFSH40	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-CIβHCG40	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-CIPRL40	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 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-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-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 Biotec)	<i>Yanli Wu</i>		
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-MPPFVD20	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	Fluoketamine (FKET) Rapid Test Device – Urine	46994	B	6
D-DOA48P40	Fluoketamine (FKET) Rapid Test Panel-Urine	46994	B	6
D-DOA48S50	Fluoketamine (FKET) Rapid Test Strip – Urine	46994	B	6

D-DOA59D40	Fluoxetine (FLX) Rapid Test Device – Urine	46994	B	6
D-DOA59P40	Fluoxetine (FLX) Rapid Test Panel – Urine	46994	B	6
D-DOA59S50	Fluoxetine (FLX) Rapid Test Strip – Urine	46994	B	6
D-DOA42P40	Fentanyl (FYL) Rapid Test Panel – Urine	46994	B	6
D-DOA21P40	Gabapentin (GAB) Rapid Test Panel – Urine	46994	B	6
D-DOA9P40	Ketamine (KET) Rapid Test Panel – Urine	46994	B	6
D-DOA36P40	Kratom (KRA) Rapid Test Panel – Urine	46994	B	6
D-DOA29P40	Lysergic Acid Diethylamide (LSD) Rapid Test Panel – Urine	46994	B	6
D-DOA43P40	6-Monoacetylmorphine (6-MAM) Rapid Test Panel – Urine	46994	B	6
D-DOA60D40	Methcathinone (MCAT) Rapid Test Device – Urine	46994	B	6
D-DOA60P40	Methcathinone (MCAT) Rapid Test Panel – Urine	46994	B	6
D-DOA60S50	Methcathinone (MCAT) Rapid Test Strip – Urine	46994	B	6
D-DOA12P40	Ecstasy (MDMA) Rapid Test Panel – Urine	46994	B	6
D-DOA61D40	Tenamfetamine (MDA) Rapid Test Device – Urine	46994	B	6
D-DOA61P40	Tenamfetamine (MDA) Rapid Test Panel – Urine	46994	B	6
D-DOA61S50	Tenamfetamine (MDA) Rapid Test Strip – Urine	46994	B	6
D-DOA62D40	Methylenedioxypropylone (MDPV) Rapid Test Device – Urine	46994	B	6
D-DOA62P40	Methylenedioxypropylone (MDPV) Rapid Test Panel – Urine	46994	B	6
D-DOA62S50	Methylenedioxypropylone (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 – 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	Methylenedioxypropylone (MDPV) Rapid Test Device-Saliva	46994	B	6
D-DOA62M25S	Methylenedioxypropylone (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	Methylenedioxypropylvalerone (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 Pane with Adulteration-urine	46994	B	6
D-RDOAPM7A	Multi-Drug 7 Drugs Rapid Test Panel with Adulteration-urine	46994	B	6
D-RDOAPM8A	Multi-Drug 8 Drugs Rapid Test Panel with Adulteration-urine	46994	B	6
D-RDOAPM9A	Multi-Drug 9 Drugs Rapid Test Panel with Adulteration-urine	46994	B	6
D-RDOAPM10A	Multi-Drug 10 Drugs Rapid Test Panel with Adulteration-urine	46994	B	6
D-RDOAPM12A	Multi-Drug 12 Drugs Rapid Test Panel with Adulteration-urine	46994	B	6
D-RDOAM3U	Multi-Drug 3 Drugs Rapid Test Device-urine	46994	B	6
D-RDOAM5U	Multi-Drug 5 Drugs Rapid Test Device-urine	46994	B	6
D-RDOAM6U	Multi-Drug 6 Drugs Rapid Test Device-urine	46994	B	6
D-RDOAM7U	Multi-Drug 7 Drugs Rapid Test Device-urine	46994	B	6
D-RDOAM12U	Multi-Drug 12 Drugs Rapid Test Device-urine	46994	B	6
D-RDOAM3S	Multi-Drug 3 Drugs Rapid Test Device -Saliva	46994	B	6
D-RDOAM4S	Multi-Drug 4 Drugs Rapid Test Device -Saliva	46994	B	6
D-RDOAM5S	Multi-Drug 5 Drugs Rapid Test Device -Saliva	46994	B	6
D-RDOAM6S	Multi-Drug 6 Drugs Rapid Test Device -Saliva	46994	B	6
D-RDOAM7S	Multi-Drug 7 Drugs Rapid Test Device -Saliva	46994	B	6
D-RDOAM8S	Multi-Drug 8 Drugs Rapid Test Device -Saliva	46994	B	6
D-RCFOB10	FOB Rapid Test Device -Feces	54532	B	6
D-RHCGUD40	hCG Pregnancy Rapid Test Device -urine	33819	B	6

D-RCTID10	Cardiac Troponin I Rapid Test Device -WB/S/P	46989	C	3j
D-RNGALD10	NGAL (neutrophil gelatinase-associated lipocalin) Rapid Test Device -WB/S/P	47430	C	3j
D-RCKMBD10	CK-MB Rapid Test Device -WB/S/P	52995	C	3j
D-RMYOD10	Myoglobin Rapid Test Device -WB/S/P	46987	C	3j
D-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-RFSD20	Follicle Stimulating Hormone (FSH) Rapid Test Device -Urine	54188	B	6
D-RTSHD20	TSH Rapid Test Device -WB/S/P	65274	B	6
D-RFED10	Ferritin Rapid test Device -WB/S/P	66124	B	6
D-RTSHSQD20	Thyroid Stimulating Hormone (TSH) Rapid Test Device -WB/S/P	65274	B	6
D-RVDD10	Vitamin D Rapid Test Device -WB/S/P	60955	B	6
D-RPCTCD10	Procalcitonin (PCT) Rapid Test Device -WB/S/P	58305	B	6
D-RCALD10	Calprotectin Rapid Test Device -Feces	60775	B	6
D-RCRD10	CRP Rapid Test Device -WB/S/P	58768	B	6
D-FICEAD20	CEA Test Device -S/P	54616	C	3h
D-FIAFPD20	AFP Test Device -S/P	54060	C	3h
D-FIDIMERD10	D-Dimer Test Device -WB/P	61389	C	3k
D-FICKMBD10	CK-MB Test Device -WB/S/P	61385	C	3j
D-FITROPID20	cTnI Test Device -WB/S/P	54010	C	3j
D-FIMYOD25	Myoglobin Rapid Test Device — WB/S/P	61390	C	3j
D-FIFABD10	H-FABP Test Device -WB/S/P	53365	C	3j
D-FINTPD10	NT-proBNP Test Device -WB/S/P	47352	C	3j
D-FITIMCKD20	Troponin I/Myoglobin/CK-MB (3 in 1) Test Device -WB/S/P	47384	C	3j
D-FITTMCKD20	Troponin T/Myoglobin/CK-MB (3 in 1) Test Device -WB/S/P	47384	C	3j
D-FILHD20	LH Test Device -WB/S/P	65959	B	6
D-FISTRAS20	Strep A Test Device -Swab	63770	B	6
D-FIIABD20	Influenza A+B Test Device -Swab	49117	B	6
D-FIDGMD20	Dengue IgG/IgM Test Device -WB/S/P	48915	B	6
D-FIDAGD25	Dengue NS1 Test Device -WB/S/P	48915	C	3b
D-FIRSVD20	RSV Test Device -Swab	62587	B	6
D-FICDTABD10	Clostridium difficile Toxin A/Toxin B Combo Test Device -Feces	65995	B	6
D-FICDGD10	Clostridium difficile GDH Test Device -Feces	65995	B	6
D-FIADED25	Adenovirus antigen Test Device -Feces	49854	B	6

D-FISPD10	Streptococcus pneumoniae Test Device -urine	63796	C	3c
D-FILPD25	Legionella pneumophila Test Device -urine	63781	C	3c
D-FITPSPD40	Syphilis Test Device -WB/S/P	51814	C	3a
D-FIZAGD10	Zika antigen Test Device -WB/S/P	65994	B	6
D-FIZMD10	Zika IgM Test Device -WB/S/P	66015	B	6
D-FIAMHD10	AMH Test Device -WB/S/P	58410	B	6
D-FIFFD25	Fetal Fibronectin (fFN) Test Device-Swab	53721	B	6
D-FIFSHD20	FSH Test Device -WB/S/P	54188	B	6
D-FIRFSPD20	Rheumatoid Factor IgM Test Device -WB/S/P	55109	B	6
D-FICRPD25	CRP Test Device-WB/S/P	58768	B	6
D-FIPCTD25	PCT Test Device-WB/S/P	54313	B	6
D-FIFOBD25	FOB Test Device-Feces	66044	B	6
D-FIT4D25	T4 Test Device-S/P	63072	B	6
D-FIHCG D25	β-HCG Test Device-S/P	58789	B	6
D-FITSHD25	TSH Test Device-S/P	54384	B	6
D-FIT3D25	T3 Test Device-S/P	63082	B	6
D-FITESD25	Testosterone Test Device-S/P	54184	B	6
D-FIP4D25	Progesterone(P4) Test Device-S/P	54327	B	6
D-FICYSCD25	CysC Test Device-WB/S/P	48177	B	6
D-FI2MGD25	β2MG Test Device-WB/S/P	53930	B	6
D-FINGALD25	N-GAL Test Device-Urine	47426	C	3j
D-FIHBA1CD25	HbA1c Test Device-WB	65958	C	3k
D-FIIGED25	IgE Test Device-WB/S/P	60380	C	3e
D-FIFED25	Ferritin Test Device-S/P	58769	B	6
D-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-CIIGEK40	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-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



Tapentadol (TAP)	Tapentadol	1,000
N,N-Dimethyltryptamine (NND)	N,N-Dimethyltryptamine	1,000
Scopolamine (SCOP)	Scopolamine	500
Mirtazapine (MTZ)	Desmethyilmirtazapine	500
Hydromorphone (HMO)	Hydromorphone	500/300/250
Test	Calibrator	Cut-off
Alcohol (ALC)	Alcohol	0.02%

Multi-Drug X(2-17) Drugs Rapid Test Device with/without Adulteration (Urine)

Instruction Sheet for testing of any combination of the following drugs:
ACE/AMP/BAR/BZO/BUP/COC/THC/MTD/MET/MDMA/MOP/MQL/OP/PCP/PPX/TCA/TML/KET/OXY/COT/EDDP/FYL/K2/6-MAM/MDA/ETG/CLO/LSD/MPD/ZOL/MEP/MDPV/DIA/ZOP/MCAT/CAF/7-ACL/CFYL/CAT/TRO/ALP/PGB/ZAL/MPRD/CNB/GAB/TZD/CAR/ABP(K3)/QTP/FLX/UR-144(K4)/KRA/TLD/α-PVP/MES/PAP/CIT/FKET/OZP/RPD/AP/NND/SCOP/MTZ/HMO/ALC
Including Specimen Validity Tests (S.V.T.) for:
Oxidants/PCC, Specific Gravity, pH, Nitrite, Glutaraldehyde, Creatinine and Bleach

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

INTENDED USE

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

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

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

SUMMARY OF ADULTERATION

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

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

PRINCIPLE (FOR DOA TESTS EXCLUDING ALCOHOL)

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

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

PRINCIPLE OF ADULTERATION

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

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

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

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

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

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

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

PRINCIPLE (FOR ALCOHOL)

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

REAGENTS (FOR DOA TESTS EXCLUDING ALCOHOL)

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

REAGENTS (FOR ALCOHOL)

Tetramethylbenzidine, Alcohol Oxidase, Peroxidase

S.V.T REAGENTS

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

PRECAUTIONS

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

STORAGE AND STABILITY

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

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

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

Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing. When testing cards with S.V.T. or Alcohol storage of urine specimens should not exceed 2 hours at room temperature or 4 hours refrigerated prior to testing.

MATERIALS

Materials Provided

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

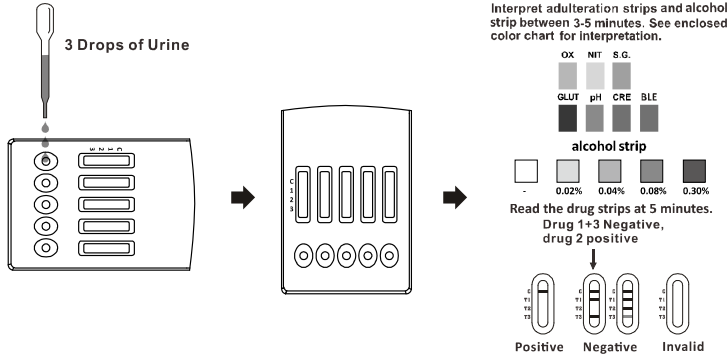
Materials Required But Not Provided

- Timer
- Specimen collection containers

DIRECTIONS FOR USE

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

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



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

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

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

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

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

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

(Please refer to the color chart)

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

INTERPRETATION OF RESULTS (ALCOHOL STRIP)

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

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

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

QUALITY CONTROL

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

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

LIMITATIONS

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

S.V./T/ ADULTERATION LIMITATIONS

1. The adulteration tests included with the product are meant to aid in the determination of abnormal specimens. While comprehensive, these tests are not meant to be an "all-inclusive" representation of possible adulterants.
2. **Oxidants/PCC:** Normal human urine should not contain oxidants or PCC. The presence of high levels of antioxidants in the specimen, such as ascorbic acid, may result in false negative results for the oxidants/PCC pad.
3. **Specific Gravity:** Elevated levels of protein in urine may cause abnormally high specific gravity values.
4. **Nitrite:** Nitrite is not a normal component of human urine. However, nitrite found in urine may indicate urinary tract infections or bacterial infections. Nitrite levels of >20 mg/dL may produce false positive glutaraldehyde results.
5. **Glutaraldehyde:** is not normally found in urine. However certain metabolic abnormalities such as ketoacidosis (fasting, uncontrolled diabetes or high protein diets) may interfere with the test results.
6. **Creatinine:** Normal Creatinine levels are between 20 and 350 mg/dL. Under rare conditions, certain kidney diseases may show dilute urine.
7. **Bleach:** Normal human urine should not contain bleach. The presence of high levels of bleach in the specimen may result in false negative results for the bleach pad.
8. **pH:** Normal pH levels are between 4.0 and 9.0.

PERFORMANCE CHARACTERISTICS

Accuracy

% Agreement with GC/MS

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

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

	MTD 200	MET 1,000	MET 500	MET 300	MDMA 1,000	MDMA 500	MDMA 300	MOP/ OPI 300	MOP/ OPI 100	MQL 300	OPI 2,000
Positive Agreement	98.9%	96.2%	97.6%	97.8%	98.0%	98.1%	98.1%	95.0%	97.0%	89.8%	96.7%
Negative Agreement	98.7%	97.1%	97.0%	97.5%	99.3%	99.3%	99.3%	95.3%	96.6%	93.2%	93.8%
Total Results	98.8%	96.8%	97.2%	97.6%	98.8%	98.8%	98.8%	95.2%	96.8%	92.0%	95.2%

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

	OXY 100	OXY 300	COT 500	COT 200	COT 100	COT 50	COT 10	EDDP 300	EDDP 100	FYL 20	FYL 10
Positive Agreement	97.7%	96.5%	95.7%	96.7%	97.9%	96.7%	97.8%	97.9%	96.9%	98.8%	98.8%
Negative Agreement	99.4%	99.4%	96.1%	97.5%	98.1%	97.5%	98.1%	99.4%	96.7%	99.4%	99.4%
Total Results	98.8%	98.4%	96.0%	97.2%	98.0%	97.2%	98.0%	98.8%	96.8%	99.2%	99.2%

	K2 50	K2 30	6-MAM 10	MDA 500	ETG 500	ETG 1,000	CLO 400	CLO 150	LSD 10	LSD 20	LSD 50
Positive Agreement	97.5%	97.6%	97.7%	98.1%	97.6%	95.3%	97.1%	99.0%	94.3%	94.3%	94.1%
Negative Agreement	98.2%	98.8%	98.1%	97.9%	99.4%	99.4%	99.3%	98.6%	98.5%	98.5%	98.5%
Total Results	98.0%	98.4%	98.0%	98.0%	98.8%	98.0%	98.4%	98.8%	97.0%	97.0%	97.0%

	MPD 300	MPD 1,000	ZOL 50	DIA 300	DIA 200	ZOP 50	MCAT 500	7-ACL 300	7-ACL 200	7-ACL 100	CFYL 500
Positive Agreement	94.6%	94.6%	90.9%	98.4%	98.4%	86.4%	90.9%	94.1%	94.6%	94.7%	94.7%
Negative Agreement	98.4%	98.4%	97.1%	99.2%	99.2%	97.2%	95.0%	97.7%	97.6%	97.5%	98.6%
Total Results	97.0%	97.0%	95.6%	98.8%	98.8%	94.6%	94.1%	96.2%	96.2%	96.2%	97.3%

	CAF 1,000	CAT 150	TRO 350	MDPV 1,000	MDPV 500	MEP 100	ALP 100	ABP/ K3-10	α-PVP 1,000	CNB 500	MPRD 100
Positive Agreement	91.3%	90.5%	92.0%	93.3%	93.1%	90.5%	90.9%	92.0%	92.1%	95.8%	95.0%
Negative Agreement	95.7%	97.3%	97.0%	98.6%	98.3%	97.0%	97.4%	97.1%	96.8%	97.6%	94.2%
Total Results	94.6%	95.8%	95.6%	97.0%	96.6%	95.4%	95.9%	95.8%	95.0%	96.9%	94.4%

	PGB 50,000	TZD 200	UR- 144/K4 25	ZAL 100	MES 100	GAB 2,000	MOP/ OPI 200	ETG 300	α-PVP 500	TLD 50	QTP 1,000
Positive Agreement	90.9%	92.9%	97.1%	95.2%	95.8%	92.3%	95.0%	98.8%	91.9%	97.3%	97.1%
Negative Agreement	97.3%	96.1%	98.4%	97.4%	97.6%	98.5%	96.0%	99.4%	95.2%	98.3%	98.3%
Total Results	95.9%	95.2%	98.0%	96.7%	96.9%	96.7%	95.6%	99.2%	94.0%	97.9%	97.9%

	PAP 500	KRA 300	CAR 2,000	FLX 500	K2 25	CIT 500	FKET 1,000	RPD 150	FYL 100	FYL 200	CFYL 250
Positive Agreement	96.9%	95.7%	95.0%	97.1%	97.6%	93.3%	96.7%	93.3%	98.8%	97.5%	94.7%
Negative Agreement	98.0%	98.3%	94.2%	96.6%	98.2%	95.5%	97.0%	95.5%	99.4%	99.4%	98.6%
Total Results	97.6%	97.6%	94.4%	96.8%	98.0%	94.8%	96.9%	94.8%	99.2%	98.8%	97.3%

Drug Concentration Cut-off Range	LSD 50		ZOL 50		ZOL 25		MDMA 300		THC 200		MOP/OPI 200		MEP 500		MEP 100		MDPV 1,000		ETG 1,500			
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	27	3	26	4	25	5	25	5	26	4	26	4	27	3	27	3	26	4	27	3	27	3
Cut-off	14	16	14	16	15	15	15	15	15	15	15	15	15	17	13	14	16	14	15	15	15	15
+25% Cut-off	3	27	5	25	4	26	3	27	4	26	4	26	4	26	5	25	3	27	3	27	3	27
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
+300% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	MDPV 500		MDPV 300		DIA 300		DIA 200		THC 300		THC 30		K2 25		ZOP 300		ZOP 50		MCAT 500			
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	29	1	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	25	5	26	4	27	3	27	3	26	4	26	4	25	5	28	2	27	3	28	2	28	2
Cut-off	15	15	14	16	15	15	15	15	15	15	14	16	14	16	17	13	17	13	17	13	17	13
+25% Cut-off	3	27	3	27	3	27	3	27	4	26	4	26	3	27	3	27	4	26	3	27	3	27
+50% Cut-off	0	30	0	30	0	30	1	29	0	30	0	30	0	30	0	30	0	30	0	30	0	30
+300% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	7-ACL 300		7-ACL 200		7-ACL 100		CFYL 500		CAF 1,000		CAT 150		TRO 350		ALP 100		α-PVP 1,000	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	26	4	27	3	27	3	25	5	26	4	27	3	27	3	28	2	26	4
Cut-off	14	16	14	16	13	17	14	16	17	13	17	13	15	15	17	13	15	15
+25% Cut-off	5	25	3	27	4	26	6	24	6	24	4	26	3	27	3	27	3	27
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
+300% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	FYL 100		COT 300		TCA 1,000		TCA 500		TCA 300		OPI 1,000		THC 20		CAR 2,000		CAR 1,000		CAR 500			
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	27	3	25	5	25	5	26	4	27	3	27	3	26	4	28	2	27	3	27	3	27	3
Cut-off	15	15	15	15	15	15	14	16	14	16	14	16	14	16	14	16	14	16	14	15	15	15
+25% Cut-off	3	27	4	26	4	26	3	27	3	27	4	26	4	26	3	27	4	26	4	26	4	26
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
+300% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	MPD 150		MPD 300		MPD 1,000		PGB 50,000		PGB 500		GAB 2,000		TZD 200		CNB 500		PAP 500	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	26	4	27	3	26	4	25	5	25	5	28	2	28	2	27	3	29	1
Cut-off	15	15	16	14	16	14	15	15	15	14	16	14	16	14	16	14	15	15
+25% Cut-off	5	25	5	25	5	25	5	25	6	24	3	27	3	27	4	26	1	29
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
+300% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	ABP/K3 10		QTP 1,000		FLX 500		KRA 300		TLD 50		α-PVP 2,000		α-PVP 500		α-PVP 300		LSD 10		HMO 500	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	25	5	29	1	29	1	28	2	29	1	26	4	27	3	27	3	28	2	28	2
Cut-off	15	15	15	15	15	15	14	16	15	15	15	15	15	15	15	14	16	15	15	15
+25% Cut-off	4	26	1	29	2	28	1	29	1	29	3	27	3	27	3	27	3	27	3	27
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
+300% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	COT 500		COT 50		COT 10		CFYL 250		FYL 200		ZAL 100		MPRD 100		TAP 1,000		CIT 500		FKET 1,000		FYL 300	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	26	4	27	3	27	3	25	5	27	3	27	3	27	3	27	3	27	3	27	3	27	3
Cut-off	14	16	16	14	15	15	14	16	15	15	15	15	15	15	15	15	15	15	15	15	17	13
+25% Cut-off	3	27	4	26	4	26	6	24	3	27	4	26	2	28	4	26	4	26	3	27	4	26
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
+300% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	RPD 150		SCOP 500		NND 1,000		MTZ 500		OZP 1,000		MES 300		MES 100		UR-144/K4 25		HMO 250		HMO 300			
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	27	3	26	4	27	3	27	3	27	3	27	3	27	3	28	2	28	2	28	2	28	2
Cut-off	15	15	14	16	15	15	15	15	14	16	14	16	14	16	15	15	15	15	15	15	15	15
+25% Cut-off	4	26	3	27	4	26	4	26	4	26	5	25	4	26	3	27	3	27	2	28	2	28
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
+300% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Analytical Specificity

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

Analytes	conc. (ng/mL)	Analytes	conc. (ng/mL)
ACETAMINOPHEN (ACE 5,000)			
Acetaminophen	5,000		
AMPHETAMINE (AMP 1,000)			
D,L-Amphetamine sulfate	300	Phentermine	1,000
L-Amphetamine	25,000	Maprotiline	50,000
(±) 3,4-Methylenedioxy amphetamine	500	Methoxyphenamine	6,000
		D-Amphetamine	1,000
AMPHETAMINE (AMP 500)			
D,L-Amphetamine sulfate	150	Phentermine	500
L-Amphetamine	12,500	Maprotiline	25,000
(±) 3,4-Methylenedioxy amphetamine	250	Methoxyphenamine	3,000
		D-Amphetamine	500
AMPHETAMINE (AMP 300)			
D,L-Amphetamine sulfate	75	Phentermine	300
L-Amphetamine	10,000	Maprotiline	15,000
(±) 3,4-Methylenedioxy amphetamine	150	Methoxyphenamine	2,000
		D-Amphetamine	300
BARBITURATES (BAR 300)			
Amobarbital	5,000	Alphenol	

Cocaine HCl	200	Ecgonine	30,000
COCAINE (COC 200)			
Benzoyllecgonine	200	Cocaethylene	13,500
Cocaine HCl	135	Ecgonine	20,000
COCAINE (COC 150)			
Benzoyllecgonine	150	Cocaethylene	10,000
Cocaine HCl	120	Ecgonine	15,000
COCAINE (COC 100)			
Benzoyllecgonine	100	Cocaethylene	7,000
Cocaine HCl	80	Ecgonine	10,000
MARIJUANA (THC 300)			
Cannabinol	200,000	Δ^9 -THC	100,000
11-nor- Δ^8 -THC-9 COOH	200	Δ^9 -THC	100,000
11-nor- Δ^9 -THC-9 COOH	300		
MARIJUANA (THC 200)			
Cannabinol	140,000	Δ^9 -THC	68,000
11-nor- Δ^8 -THC-9 COOH	120	Δ^9 -THC	68,000
11-nor- Δ^9 -THC-9 COOH	200		
MARIJUANA (THC 150)			
Cannabinol	100,000	Δ^8 -THC	50,000
11-nor- Δ^8 -THC-9 COOH	100	Δ^9 -THC	50,000
11-nor- Δ^9 -THC-9 COOH	150		
MARIJUANA (THC 50)			
Cannabinol	35,000	Δ^9 -THC	17,000
11-nor- Δ^8 -THC-9 COOH	30	Δ^9 -THC	17,000
11-nor- Δ^9 -THC-9 COOH	50		
MARIJUANA (THC 30)			
Cannabinol	20,000	Δ^8 -THC	10,000
11-nor- Δ^8 -THC-9 COOH	20	Δ^9 -THC	10,000
11-nor- Δ^9 -THC-9 COOH	30		
MARIJUANA (THC 25)			
Cannabinol	17,500	Δ^8 -THC	8,500
11-nor- Δ^8 -THC-9 COOH	15	Δ^9 -THC	8,500
11-nor- Δ^9 -THC-9 COOH	25		
MARIJUANA (THC 20)			
Cannabinol	14,000	Δ^8 -THC	6,800
11-nor- Δ^8 -THC-9 COOH	12	Δ^9 -THC	6,800
11-nor- Δ^9 -THC-9 COOH	20		
METHADONE (MTD 300)			
Methadone	300	Doxylamine	100,000
METHADONE (MTD 200)			
Methadone	200	Doxylamine	65,000
METHADONE (MTD 100)			
Methadone	100	Doxylamine	32,500
METHAMPHETAMINE (MET 1,000)			
p-Hydroxymethamphetamine	25,000	(\pm)-3,4-Methylenedioxy-methamphetamine	12,500
D-Methamphetamine	1,000		
L-Methamphetamine	20,000	Mephentermine	50,000
METHAMPHETAMINE (MET 500)			
p-Hydroxymethamphetamine	12,500	(\pm)-3,4-Methylenedioxy-methamphetamine	6,250
D-Methamphetamine	500		
L-Methamphetamine	10,000	Mephentermine	25,000
METHAMPHETAMINE (MET 300)			
p-Hydroxymethamphetamine	7,500	(\pm)-3,4-Methylenedioxy-methamphetamine	3,750
D-Methamphetamine	300		
L-Methamphetamine	6,000	Mephentermine	15,000
METHAMPHETAMINE (MET 200)			
p-Hydroxymethamphetamine	5,000	(\pm)-3,4-Methylenedioxy-methamphetamine	2,500
D-Methamphetamine	200		
L-Methamphetamine	4,000	Mephentermine	10,000
METHYLENEDIOXYMETHAMPHETAMINE (MDMA 1,000) Ecstasy			
(\pm) 3,4-Methylenedioxy-methamphetamine HCl	1,000	3,4-Methylenedioxyethylamphetamine	600
(\pm) 3,4-Methylenedioxyamphetamine HCl	6,000		
METHYLENEDIOXYMETHAMPHETAMINE (MDMA 500) Ecstasy			
(\pm) 3,4-Methylenedioxy-methamphetamine HCl	500	3,4-Methylenedioxyethylamphetamine	300
(\pm) 3,4-Methylenedioxyamphetamine HCl	3,000		
METHYLENEDIOXYMETHAMPHETAMINE (MDMA 300) Ecstasy			
(\pm) 3,4-Methylenedioxy-methamphetamine HCl	300	3,4-Methylenedioxyethylamphetamine	180
(\pm) 3,4-Methylenedioxyamphetamine HCl	1,800		
MORPHINE (MOP/OPI 300)			
Codeine	200	Norcodeine	6,000
Levorphanol	1,500	Normorphone	50,000
Morphine-3- β -D-Glucuronide	800	Oxycodone	30,000
Ethylmorphine	6,000	Oxymorphone	50,000
Hydrocodone	50,000	Procaine	15,000
Hydromorphone	3,000	Thebaine	6,000
6-Monoacetylmorphine	300	Morphine	300
MORPHINE (MOP/OPI 200)			
Codeine	160	Norcodeine	4,000
Levorphanol	1,000	Normorphone	40,000
Morphine-3- β -D-Glucuronide	600	Oxycodone	20,000
Ethylmorphine	4,000	Oxymorphone	40,000
Hydrocodone	40,000	Procaine	10,000
Hydromorphone	2,000	Thebaine	4,000
6-Monoacetylmorphine	200	Morphine	200
MORPHINE (MOP/OPI 100)			
Codeine	80	Norcodeine	2,000
Levorphanol	500	Normorphone	20,000
Morphine-3- β -D-Glucuronide	300	Oxycodone	10,000
Ethylmorphine	2,000	Oxymorphone	20,000

Hydrocodone	20,000	Procaine	5,000
Hydromorphone	1,000	Thebaine	2,000
6-Monoacetylmorphine	200	Morphine	100
METHAQUALONE (MQL 300)			
Methaqualone	300		
MORPHINE/OPIATE (OPI 2,000)			
Codeine	2,000	Morphine	2,000
Ethylmorphine	3,000	Norcodeine	25,000
Hydrocodone	50,000	Normorphone	50,000
Hydromorphone	15,000	Oxycodone	25,000
Levorphanol	25,000	Oxymorphone	25,000
6-Monoacetylmorphine	3,000	Procaine	50,000
Morphine 3- β -D-glucuronide	2,000	Thebaine	25,000
MORPHINE/OPIATE (OPI 1,000)			
Codeine	1,000	Morphine	1,000
Ethylmorphine	1,500	Norcodeine	12,500
Hydrocodone	25,000	Normorphone	25,000
Hydromorphone	7,500	Oxycodone	12,500
Levorphanol	12,500	Oxymorphone	12,500
6-Monoacetylmorphine	1,500	Procaine	25,000
Morphine 3- β -D-glucuronide	1,000	Thebaine	12,500
MEPERIDINE (MPRD 100)			
Normeperidine	100	Meperidine	100
PHENCYCLIDINE (PCP 50)			
Phencyclidine	50	4-Hydroxyphencyclidine	25,000
PHENCYCLIDINE (PCP 25)			
Phencyclidine	25	4-Hydroxyphencyclidine	12,500
PROPOXYPHENE (PPX 300)			
D-Propoxyphene	300	D-Norpropoxyphene	300
TRICYCLIC ANTIDEPRESSANTS (TCA 1,000)			
Nortriptyline	1,000	Imipramine	400
Nordoxepine	500	Clomipramine	50,000
Trimipramine	3,000	Doxepine	2,000
Amitriptyline	1,500	Maprotiline	2,000
Promazine	3,000	Promethazine	50,000
Desipramine	200	Perphenazine	50,000
Cyclobenzaprine	2,000	Dithiaden	10,000
TRICYCLIC ANTIDEPRESSANTS (TCA 500)			
Nortriptyline	500	Imipramine	200
Nordoxepine	250	Clomipramine	25,000
Trimipramine	1,500	Doxepine	1,000
Amitriptyline	750	Maprotiline	1,000
Promazine	1,500	Promethazine	25,000
Desipramine	100	Perphenazine	25,000
Cyclobenzaprine	1,000	Dithiaden	5,000
TRICYCLIC ANTIDEPRESSANTS (TCA 300)			
Nortriptyline	300	Imipramine	120
Nordoxepine	150	Clomipramine	15,000
Trimipramine	900	Doxepine	600
Amitriptyline	450	Maprotiline	600
Promazine	900	Promethazine	15,000
Desipramine	60	Perphenazine	15,000
Cyclobenzaprine	600	Dithiaden	3,000
TRAMADOL (TML 100)			
n-Desmethyl-cis-tramadol	200	o-Desmethyl-cis-tramadol	10,000
Cis-tramadol	100	Phencyclidine	100,000
Procyclidine	100,000	d,l-O-Desmethyl venlafaxine	50,000
TRAMADOL (TML 200)			
n-Desmethyl-cis-tramadol	400	o-Desmethyl-cis-tramadol	20,000
Cis-tramadol	200	Phencyclidine	200,000
Procyclidine	200,000	d,l-O-Desmethyl venlafaxine	100,000
TRAMADOL (TML 300)			
n-Desmethyl-cis-tramadol	600	o-Desmethyl-cis-tramadol	30,000
Cis-tramadol	300	Phencyclidine	300,000
Procyclidine	300,000	d,l-O-Desmethyl venlafaxine	150,000
TRAMADOL (TML 500)			
n-Desmethyl-cis-tramadol	10,000	o-Desmethyl-cis-tramadol	50,000
Cis-tramadol	500	Phencyclidine	500,000
Procyclidine	500,000	d,l-O-Desmethyl venlafaxine	250,000
KETAMINE (KET 1,000)			
Ketamine	1,000	Benzphetamine	25,000
Dextromethorphan	2,000	(+) Chlorpheniramine	25,000
Methoxyphenamine	25,000	Clonidine	100,000
d-Norpropoxyphene	25,000	EDDP	50,000
Promazine	25,000	4-Hydroxyphencyclidine	50,000
Promethazine	25,000	Levorphanol	50,000
Pentazocine	25,000	MDE	50,000
Phencyclidine	25,000	Meperidine	25,000
Tetrahydrozoline	500	d-Methamphetamine	50,000
Mephentermine	25,000	l-Methamphetamine	50,000
(1R, 2S) (-)-Ephedrine	100,000	3,4-Methylenedioxy-methamphetamine (MDMA)	100,000
Disopyramide	25,000	Thioridazine	50,000
KETAMINE (KET 500)			
Ketamine	500	Benzphetamine	12,500
Dextromethorphan	1,000	(+) Chlorpheniramine	12,500
Methoxyphenamine	12,500	Clonidine	50,000
d-Norpropoxyphene	12,500	EDDP	25,000
Promazine	12,500	4-Hydroxyphencyclidine	25,000
Promethazine	12,500	Levorphanol	25,000
Pentazocine	12,500	MDE	25,000
Phencyclidine	12,500	Meperidine	12,500
Tetrahydrozoline	250	d-Methamphetamine	25,000
Mephentermine	12,500	l-Methamphetamine	25,000
(1R, 2S) (-)-Ephedrine	50,000	3,4-Methylenedioxy-methamphetamine	50,000

		phetamine (MDMA)	
Disopyramide	12,500	Thioridazine	25,000
KETAMINE (KET 300)			
Ketamine	300	Benzphetamine	6,250
Dextromethorphan	600	(+) Chlorpheniramine	6,250
Methoxyphenamine	6,250	Clonidine	30,000
d-Norpropoxyphene	6,250	EDDP	15,000
Promazine	6,250	4-Hydroxyphencyclidine	15,000
Promethazine	6,250	Levorphanol	15,000
Pentazocine	6,250	MDE	15,000
Phencyclidine	6,250	Meperidine	6,250
Tetrahydrozoline	150	d-Methamphetamine	15,000
Mephentermine	6,250	l-Methamphetamine	15,000
(1R, 2S) - (-)-Ephedrine	30,000	3,4-Methylenedioxy-methamphetamine (MDMA)	30,000
Disopyramide	6,250	Thioridazine	15,000
KETAMINE (KET 100)			
Ketamine	100	Benzphetamine	2,000
Dextromethorphan	200	(+) Chlorpheniramine	2,000
Methoxyphenamine	2,000	Clonidine	10,000
d-Norpropoxyphene	2,000	EDDP	5,000
Promazine	2,000	4-Hydroxyphencyclidine	5,000
Promethazine	2,000	Levorphanol	5,000
Pentazocine	2,000	MDE	5,000
Phencyclidine	2,000	Meperidine	2,000
Tetrahydrozoline	50	d-Methamphetamine	5,000
Mephentermine	2,000	l-Methamphetamine	5,000
(1R, 2S) - (-)-Ephedrine	10,000	Thioridazine	5,000
Disopyramide	2,000	3,4-Methylenedioxy-methamphetamine (MDMA)	10,000
OXYCODONE (OXY 300)			
Oxycodone	300	Hydromorphone	150,000
Oxymorphone	900	Naloxone	75,000
Levorphanol	15,000	Naltrexone	75,000
Hydrocodone	75,000		
OXYCODONE (OXY 100)			
Oxycodone	100	Hydromorphone	50,000
Oxymorphone	300	Naloxone	25,000
Levorphanol	50,000	Naltrexone	25,000
Hydrocodone	25,000		
COTININE (COT 300)			
(-)-Cotinine	300	(-)-Nicotine	7,500
COTININE (COT 200)			
(-)-Cotinine	200	(-)-Nicotine	5,000
COTININE (COT 100)			
(-)-Cotinine	100	(-)-Nicotine	2,500
COTININE (COT 500)			
(-)-Cotinine	500	(-)-Nicotine	12,500
COTININE (COT 50)			
(-)-Cotinine	50	(-)-Nicotine	1,250
COTININE (COT 10)			
(-)-Cotinine	10	(-)-Nicotine	250
2-ETHYLIDENE-1,5-DIMETHYL-3,3-DIPHENYLPYRROLIDINE (EDDP 300)			
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)			300
2-ETHYLIDENE-1,5-DIMETHYL-3,3-DIPHENYLPYRROLIDINE (EDDP 100)			
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)			100
FENTANYL (FYL 300)			
Alfentanyl	>600,000	Bupirone	80,000
Norfentanyl	60	Fentanyl	300
Fenfluramine	150,000	Sufentanyl	150,000
FENTANYL (FYL 200)			
Alfentanyl	>600,000	Bupirone	30,000
Fenfluramine	100,000	Fentanyl	200
Norfentanyl	40	Sufentanyl	100,000
FENTANYL (FYL 100)			
Alfentanyl	600,000	Bupirone	15,000
Fenfluramine	50,000	Fentanyl	100
Norfentanyl	20	Sufentanyl	50,000
FENTANYL (FYL 20)			
Alfentanyl	600,000	Bupirone	15,000
Fenfluramine	50,000	Fentanyl	100
Norfentanyl	20	Sufentanyl	50,000
paliperidone	1,250	Risperidone	5,000
FENTANYL (FYL 10)			
Alfentanyl	300,000	Bupirone	8,000
Fenfluramine	25,000	Fentanyl	50
Norfentanyl	10	Sufentanyl	25,000
paliperidone	500	Risperidone	2,500
SYNTHETIC MARIJUANA (K2-50)			
JWH-018 5-Pentanoic acid	50	JWH-073 4-butanoic acid	50
JWH-018 4-Hydroxypentyl	400	JWH-018 5-Hydroxypentyl	500
JWH-073 4-Hydroxybutyl	500		
SYNTHETIC MARIJUANA (K2-30)			
JWH-018 5-Pentanoic acid	30	JWH-073 4-butanoic acid	30
JWH-018 4-Hydroxypentyl	250	JWH-018 5-Hydroxypentyl	300
JWH-073 4-Hydroxybutyl	300		
SYNTHETIC MARIJUANA (K2-25)			
JWH-018 5-Pentanoic acid	25	JWH-073 4-butanoic acid	25
JWH-018 4-Hydroxypentyl	200	JWH-018 5-Hydroxypentyl	250
JWH-073 4-Hydroxybutyl	250		
6-MONOACETYLMORPHINE (6-MAM 10)			
6-Monoacetylmorphine	10	Morphine	100,000
(±) 3, 4-METHYLENEDIOXYAMPHETAMINE (MDA 500)			
(±) 3, 4-Methylenedioxyamphetamine	500	Methoxyphenamine	6,000
		D-Amphetamine	2,000

D,L-Amphetamine sulfate	300	Phentermine	1,000
L-Amphetamine	25,000	Maprotiline	50,000
ETHYL-β-D-GLUCURONIDE (ETG 300)			
Ethyl-β-D-Glucuronide	300	Propyl β-D-glucuronide	30,000
Morphine 3β-glucuronide	60,000	Morphine 6β-glucuronide	60,000
Glucuronic Acid	60,000	Ethanol	>100,000
Methanol	>100,000		
ETHYL-β-D-GLUCURONIDE (ETG 500)			
Ethyl-β-D-Glucuronide	500	Propyl β-D-glucuronide	50,000
Morphine 3β-glucuronide	100,000	Morphine 6β-glucuronide	100,000
Glucuronic Acid	100,000	Ethanol	>100,000
Methanol	>100,000		
ETHYL-β-D-GLUCURONIDE (ETG 1,000)			
Ethyl-β-D-Glucuronide	1,000	Propyl β-D-glucuronide	100,000
Morphine 3β-glucuronide	>100,000	Morphine 6β-glucuronide	>100,000
Glucuronic Acid	>100,000	Ethanol	>100,000
Methanol	>100,000		
ETHYL-β-D-GLUCURONIDE (ETG 1,500)			
Ethyl-β-D-Glucuronide	1,500	Propyl β-D-glucuronide	150,000
Morphine 3β-glucuronide	>100,000	Morphine 6β-glucuronide	>100,000
Glucuronic Acid	>100,000	Ethanol	>100,000
Methanol	>100,000		
CLONAZEPAM (CLO 400)			
Clonazepam	400	Flunitrazepam	300
Alprazolam	200	(±) Lorazepam	1,250
a-hydroxyalprazolam	2,000	RS-Lorazepamglucuronide	250
Bromazepam	1,000	Midazolam	5,000
Chlordiazepoxide	1,000	Nitrazepam	200
Clobazam	250	Norchlordiazepoxide	200
Clorazepatedipotassium	600	Nordiazepam	1,000
Delorazepam	1,000	Oxazepam	350
Desalkylflurazepam	250	Temazepam	150
Diazepam	300	Triazolam	5,000
Estazolam	1,250		
CLONAZEPAM (CLO 150)			
Clonazepam	150	Flunitrazepam	120
Alprazolam	75	(±) Lorazepam	500
a-hydroxyalprazolam	750	RS-Lorazepamglucuronide	100
Bromazepam	400	Midazolam	2,000
Chlordiazepoxide	400	Nitrazepam	75
Clobazam	100	Norchlordiazepoxide	75
Clorazepatedipotassium	250	Nordiazepam	400
Delorazepam	400	Oxazepam	130
Desalkylflurazepam	100	Temazepam	60
Diazepam	120	Triazolam	2,000
Estazolam	500		
LYSERGIC ACID DIETHYLAMIDE (LSD 10)			
Lysergic Acid Diethylamide	10		
LYSERGIC ACID DIETHYLAMIDE (LSD 20)			
Lysergic Acid Diethylamide	20		
LYSERGIC ACID DIETHYLAMIDE (LSD 50)			
Lysergic Acid Diethylamide	50		
METHYLPHENIDATE (MPD 300)			
Methylphenidate (Ritalin)	300	Ritalinic Acid	1,000
METHYLPHENIDATE (MPD 150)			
Methylphenidate (Ritalin)	150	Ritalinic Acid	500
METHYLPHENIDATE (MPD 1,000)			
Methylphenidate (Ritalin)	350	Ritalinic Acid	1,000
ZOLPIDEM (ZOL 50)			
Zolpidem	50		
ZOLPIDEM (ZOL 25)			
Zolpidem	25		
MEPHEDRONE (MEP 500)			
Mephedrone HCl	500	R(+)-Methcathinone HCl	7,500
S(-)-Methcathinone HCl	2,500	3-Fluoromethcathinone HCl	7,500
4-Fluoromethcathinone HCl	1,500	Methoxyphenamine	100,000
MEPHEDRONE (MEP 100)			
Mephedrone HCl	100	R(+)-Methcathinone HCl	1,500
S(-)-Methcathinone HCl	500	3-Fluoromethcathinone HCl	1,500
4-Fluoromethcathinone HCl	300	Methoxyphenamine	100,000
3, 4-METHYLENEDIOXYPYROVALERONE (MDPV 1,000)			
3, 4-methylenedioxyprovalerone	1,000		
3, 4-METHYLENEDIOXYPYROVALERONE (MDPV 500)			
3, 4-methylenedioxyprovalerone	500		
3, 4-METHYLENEDIOXYPYROVALERONE (MDPV 300)			
3, 4-methylenedioxyprovalerone	300		
DIAZEPAM (DIA 300)			
Diazepam	300	Midazolam	6,000
Clobazam	200	Nitrazepam	200
Clonazepam	500	Norchlordiazepoxide	100
Clorazepate dipotassium	500	Nordiazepam	900
Alprazolam	100	Flunitrazepam	200
a-hydroxyalprazolam	1,500	(±) Lorazepam	3,000
Bromazepam	900	RS-Lorazepam glucuronide	200
Chlordiazepoxide	900	Triazolam	3,000
Estazolam	6,000	Temazepam	100
Delorazepam	900	Oxazepam	300
Desalkylflurazepam	200		
DIAZEPAM (DIA 200)			
Diazepam	200	Midazolam	4,000
Clobazam	120	Nitrazepam	120
Clonazepam	300	Norchlordiazepoxide	70
Clorazepate dipotassium	300	Nordiazepam	600
Alprazolam	70	Flunitrazepam	120
a-hydroxyalprazolam	1,000	(±) Lorazepam	2,000

Bromazepam	600	RS-Lorazepam glucuronide	120
Chlordiazepoxide	600	Triazolam	2,000
Estazolam	4,000	Temazepam	70
Delorazepam	600	Oxazepam	200
Desalkylflurazepam	120		
ZOPICLONE (ZOP 300)			
Zopiclone-x-oxide	300	Zopiclone	300
ZOPICLONE (ZOP 50)			
Zopiclone-x-oxide	50	Zopiclone	50
METHCATHINONE (MCAT 500)			
S(-)-Methcathinone HCl	500	R(+)-Methcathinone HCl	1,500
Methoxyphenamine	100,000	3-Fluoromethcathinone HCl	1,500
7-AMINOCLONAZEPAM (7-ACL 300)			
a-hydroxyalprazolam	6,000	Flunitrazepam	3,000
Bromazepam	6,000	RS-Lorazepam glucuronide	2,700
Chlordiazepoxide	6,000	Norchlordiazepoxide	4,500
Clobazam	9,000	Nordiazepam	15,000
Clonazepam	2,400	Temazepam	9,000
Delorazepam	6,000	7-Aminoclonazepam	300
Desalkylflurazepam	6,000		
7-AMINOCLONAZEPAM (7-ACL 200)			
a-hydroxyalprazolam	4,000	Flunitrazepam	2,000
Bromazepam	4,000	RS-Lorazepam glucuronide	1,800
Chlordiazepoxide	4,000	Norchlordiazepoxide	3,000
Clobazam	6,000	Nordiazepam	10,000
Clonazepam	1,600	Temazepam	6,000
Delorazepam	4,000	7-Aminoclonazepam	200
Desalkylflurazepam	4,000		
7-AMINOCLONAZEPAM (7-ACL 100)			
a-hydroxyalprazolam	2,000	Flunitrazepam	1,000
Bromazepam	2,000	RS-Lorazepam glucuronide	900
Chlordiazepoxide	2,000	Norchlordiazepoxide	1,500
Clobazam	3,000	Nordiazepam	5,000
Clonazepam	800	Temazepam	3,000
Delorazepam	2,000	7-Aminoclonazepam	100
Desalkylflurazepam	2,000		
CARFENTANYL (CFYL 500)			
Carfentanyl	500	Fentanyl	100
Sufentanil	50,000	Ramifentanil	10,000
(±)cis-3-Menthylfentanyl	20,000	Butyl fentanyl	150
CARFENTANYL (CFYL 250)			
Carfentanyl	250	Fentanyl	50
Sufentanil	25,000	Ramifentanil	5,000
(±)cis-3-Menthylfentanyl	10,000	Butyl fentanyl	75
CAFFEINE (CAF 1,000)			
Caffeine	1,000		
CATHINE (CAT 150)			
(+)-Norpseudoephedrine HCl (Cathine)	150	(+)-3,4-Methylenedioxyamphetamine (MDA)	100
d/l-Amphetamine	100	p-Hydroxyamphetamine	100
Tryptamine	12,500	Methoxyphenamine	12,500
TROPICAMIDE (TRO 350)			
Tropicamide	350		
ALPRAZOLAM (ALP 100)			
Benzodiazepines	300	Flunitrazepam	200
a-hydroxyalprazolam	1,500	(±) Lorazepam	3,000
Bromazepam	900	RS-Lorazepamglucuronide	200
Chlordiazepoxide	900	Midazolam	6,000
Clobazam	200	Nitrazepam	200
Clonazepam	500	Norchlordiazepoxide	100
Clorazepatedipotassium	500	Nordiazepam	900
Delorazepam	900	Oxazepam	300
Desalkylflurazepam	200	Temazepam	100
Diazepam	300	Triazolam	3,000
Estazolam	6,000	Alprazolam	100
PREGABALIN (PGB 50,000)			
Pregabalin	50,000		
PREGABALIN (PGB 500)			
Pregabalin	500		
ZALEPLON (ZAL 100)			
Zaleplon	100		
CANNABINOL (CNB 500)			
cannabinol	500	Δ ⁹ -THC	10,000
11-nor-Δ ⁹ -THC-9 COOH	300		
GABAPENTIN (GAB 2,000)			
Gabapentin	2,000		
TRAZODONE (TZD 200)			
Trazodone	200		
CARISOPRODOL (CAR 2,000)			
Carisoprodol	2,000		
CARISOPRODOL (CAR 1,000)			
Carisoprodol	1,000		
CARISOPRODOL (CAR 500)			
Carisoprodol	500		
AB-PINACA/K3 (ABP/K3 10)			
AB-PINACA	10	AB-PINACA 5-Pentanoic	10
AB-PINACA 5-hydroxypentyl	10	AB-FUBINACA	10
AB-PINACA 4-hydroxypentyl	10,000	UR-144 5-Pentanoic	5,000
UR-144 5-hydroxypentyl	10,000	UR-144 4-hydroxypentyl	10,000
APINACA 5-hydroxypentyl	10,000	ADB-PINACA Pentanoic Acid	10
ADB-PINACA N-(5-hydroxypentyl)	30	5-fluoro AB-PINACA N-(4-hydroxypentyl)	30
5-fluoro AB-PINACA	25		
UR-144/K4 (25)			
UR-144 5-Pentanoic acid	25	UR-144 4-hydroxypentyl	10,000

UR-144 5-hydroxypentyl	5,000	XLR-11 4-hydroxypentyl	2,000
5-fluoro AB-Pinaca N-(4-hydroxypentyl)	10,000	ADB-PINAC N-(4-hydroxypentyl)	>10,000
AB-PINACA 4-hydroxypentyl	>10,000		
QUETIAPINE (QTP 1,000)			
Quetiapine	1,000	Norquetiapine	10,000
FLUOXETINE (FLX 500)			
Fluoxetine	500		
KRATOM (KRA 300)			
Mitragynine	300	7-hydroxymitragynine	>50,000
TILIDINE (TLD 50)			
Nortilidine	50	Tilidine	100
ALPHA-PYRROLIDINOVALEROPHENONE (α-PVP 2,000)			
Alpha-Pyrrolidinovalerophenone	2,000		
ALPHA-PYRROLIDINOVALEROPHENONE (α-PVP 1,000)			
Alpha-Pyrrolidinovalerophenone	1,000		
ALPHA-PYRROLIDINOVALEROPHENONE (α-PVP 500)			
Alpha-Pyrrolidinovalerophenone	500		
ALPHA-PYRROLIDINOVALEROPHENONE (α-PVP 300)			
Alpha-Pyrrolidinovalerophenone	300		
MESCALINE (MES 100)			
Mescaline	100		
MESCALINE (MES 300)			
Mescaline	300		
PAPAVERINE (PAP 500)			
Papaverine	500	Diflunisal	1,000,000
Methortrexate	65,000	Methedrone	500,000
Pragablin	500,000	Phenelzine	8,000
Quinine	4,000		
TAPENTADOL (TAP 1,000)			
3-((1R,2R)-3-(dimethylamino)-1-ethyl-2-methylpropyl)phenol	1,000		
CITALOPRAM (CIT 500)			
Desmethylcitalopram	500		
F-KETAMINE (FKET 1,000)			
2-(2-fluorophenyl)-2-methylamino-cyclohexanone	1,000		
RISPERIDONE (RPD 150)			
Risperidone	150		
SCOPOLAMINE (SCOP 500)			
Scopolamine	500	Atropine	3,000
N, N-DIMETHYLTRYPTAMINE (NND 1,000)			
N, N-Dimethyltryptamine	1,000		
MIRTAZAPINE (MTZ 500)			
N-Desmethyilmirtazapine	500	Mirtazapine	500
OLANZAPINE (OZP 1,000)			
Olanzapine	1,000		
HYDROMORPHONE (HMO 500)			
Hydromorphone	500	Morphine	200
Codeine	120	Ethylmorphine	120
Hydrocodone	500	Morphine 3-β-D-Glucuronide	250
Levorphanol	2,000	Oxycodone	125,000
Normorphine	125,000	Norcodeine	31,200
Oxymorphone	125,000	Nalorphine	50,000
Thebaine	10,000	Diacetylmorphine (Heroin)	250
6-Monoacetylmorphine	120		
HYDROMORPHONE (HMO 300)			
Hydromorphone	300	Morphine	120
Codeine	75	Ethylmorphine	75
Hydrocodone	300	Morphine 3-β-D-Glucuronide	150
Levorphanol	1,200	Oxycodone	75,000
Normorphine	75,000	Norcodeine	18,700
Oxymorphone	75,000	Nalorphine	30,000
Thebaine	6,000	Diacetylmorphine (Heroin)	150
6-Monoacetylmorphine	75		
HYDROMORPHONE (HMO 250)			
Hydromorphone	250	Morphine	100
Codeine	60	Ethylmorphine	60
Hydrocodone	250	Morphine 3-β-D-Glucuronide	125
Levorphanol	1,000	Oxycodone	62,500
Normorphine	62,500	Norcodeine	15,600
Oxymorphone	62,500	Nalorphine	25,000
Thebaine	5,000	Diacetylmorphine (Heroin)	125
6-Monoacetylmorphine	60		

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high and low specific gravity ranges (1.005-1.045) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The Multi-Drug Rapid Test was tested in duplicate using fifteen drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with the Multi-Drug Rapid Test. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Cross-Reactivity

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

Non Cross-Reacting Compounds

Acetophenetidin	Cortisone	Zomepirac	Quinidine
N-Acetylprocainamide	Creatinine	Ketoprofen	Quinine
Acetylsalicylic acid	Deoxycorticosterone	Labeltalol	Salicylic acid
Aminopyrine	Dextromethorphan	Loperamide	Serotonin
Amoxicillin	Diclofenac	Meprobamate	Sulfamethazine

Ampicillin	Diflunisal	Isoxsuprine	Sulindac
l-Ascorbic acid	Digoxin	d,l-Propranolol	Tetracycline
Apomorphine	Diphenhydramine	Nalidixic acid	Tetrahydrocortisone,
Aspartame	Ethyl-p-aminobenzoate	Naproxen	3-acetate
Atropine	β-Estradiol	Niacinamide	Tetrahydrocortisone
Benzilic acid	Estrone-3-sulfate	Nifedipine	Tetrahydrozoline
Benzoic acid	Erythromycin	Norethindrone	Thiamine
Bilirubin	Fenoprofen	Noscapine	Thioridazine
d,l-Brompheniramine	Furosemide	d,l-Octopamine	d,l-Tyrosine
Cannabidiol	Gentisic acid	Oxalic acid	Tolbutamide
Chloral hydrate	Hemoglobin	Oxolinic acid	Triamterene
Chloramphenicol	Hydralazine	Oxymetazoline	Trifluoperazine
Chlorothiazide	Hydrochlorothiazide	Penicillin-G	Trimethoprim
d,l-Chlorpheniramine	Hydrocortisone	Perphenazine	d,l-Tryptophan
Chlorpromazine	o-Hydroxyhippuric acid	Phenelzine	Uric acid
Cholesterol	3-Hydroxytyramine	Prednisone	Verapamil
Clonidine	d,l-Isoproterenol		

ALCOHOL PERFORMANCE CHARACTERISTICS

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

ALCOHOL ASSAY SPECIFICITY

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

ALCOHOL INTERFERING SUBSTANCES













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

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

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Index of Symbols

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



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