



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'.

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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 Blood grouping reagents

Digitally signed by Tricolici Lidia
Date: 2025.08.20 14:35:59 EEST
Reason: MoldSign Signature
Location: Moldova

MOLDOVA EUROPEANĂ



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

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

General Product Name:	Blood grouping reagents
Manufacturer:	Rapid Labs Ltd. Unit 2 & 2a Hall Farm Business Centre, Church road, Little Bentley, Colchester, Essex, CO7 8SD United Kingdom
Variants:	n/a
Intended Use:	To qualitatively determine the presence or absence of the specific antigens on the red cells of blood donors or patients requiring a blood transfusion .
Intended User:	Professional use
IVD Directive Category:	Annex II List A
Notified Body:	Polskie Centrum Badarı i Certyfikacji S.A, 23A Klobucka Street, 02-699 Warsaw, Poland, Notified Body Number 1434.
CE Certificate Reference:	1434-IVDD-031/2022 and 1434-IVDD-032/2022
IVD Directive Assessment Route:	Annex II List A
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2 nd Floor, Tower Street, Swatar BKR 4013 Malta

Name Rowland King

Position Managing Director



Signed _____

Date 23rd May 2023

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

Appendix I – Applicable Standards

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

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

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
BG-A10	Anti-A Monoclonal CE marked	52532
BG-B10	Anti-B Monoclonal CE marked	52538
BG-AB10	Anti-A, B Monoclonal CE marked	46442
BG-D10	Anti-D Monoclonal (IgG + IgM) CE Marked	52647
BG-ABOD10	ABOD Blood grouping Kit CE Marked	43508

Version History

Version	Compiled by	Date	Description
5.0	Emily Swager	08/11/2023	Addition of ABOD blood grouping kit

Monoclonal Blood grouping Reagents

Anti-A
Anti-B
Anti-A,B



1434

RAPID BIOTEC™



CATALOGUE NUMBER

Anti-A: BG-A10, BG-A10X10
Anti-B: BG-B10, BG-B10X10
Anti-A,B: BG-AB10, BG-AB10X10

INTENDED USE

The intended use of Rapid Biotec ABO blood grouping reagents is to be used in a qualitative method to identify the presence or absence of A or B antigens on the surface of red blood cells in donors or patients who require a blood transfusion.

These reagents are suitable for use by the slide, tube and Bio-Rad ID card and are designed for use by operators trained in serological techniques.

INTRODUCTION

The ABO Blood Group System

In 1900, Landsteiner discovered that the serum of some individuals would agglutinate the red cells of others and that this phenomenon could be used to classify individuals into different blood group phenotypes. Four common phenotypes are recognised – O, A, B and AB. Subgroups of the A and B antigens have since been identified. The ABO phenotype of an individual is usually determined by the agglutination reactions of the individual's red cells with Anti-A, Anti-B and Anti-A,B antisera (forward grouping). In testing blood samples from adults, confirmation of the ABO blood group can be provided by the reactions of the individual's serum with standard A and B red cell suspensions (reverse grouping).

PRINCIPLE

When used by the recommended techniques these reagents will cause agglutination (clumping) of red cells carrying the specific antigen (positive test).

Lack of agglutination of the red cells demonstrates the absence of the specific antigen (negative test).

These reagents have been optimised for use by the recommended techniques without further dilution or additions. These products are supplied filtered through 0.2 µm filter.

REAGENTS AND MATERIALS

Blood grouping reagents contain monoclonal murine IgM antibodies in a buffer solution. The solution is a phosphate buffer containing sodium chloride, EDTA and bovine material. This reagent contains <0.1% sodium azide and the following colourants and cell lines:

Reagent	Colour	Dye	Cell line
Anti-A	Blue	Patent blue	BIRMA-1
Anti-B	Yellow	Tartrazine	LB-2
Anti-A,B	Colourless	None	ES-15/ES-4

Materials needed but not provided:

- Microscope slide/Plastic slides
- Plastic stirrers
- Timer
- Isotonic saline/LISS
- Compatible serum/plasma
- Test tubes
- Centrifuge (1000 rcf)
- Bio-Rad ID Cards (NaCl, Enzyme tests and cold agglutinins)
- Bio-Rad ID centrifuge
- Bio-Rad ID cell stab or ID-diluent 2

PRECAUTIONS

- The cell lines used to produce these reagents are of murine origin and have been tested and found to be negative for Mouse Antibody Production (MAP) viruses. Care must be taken in the use and disposal of each container and its contents.
- These reagents contain <0.1% (w/v) sodium azide. Sodium azide may be toxic if ingested and may react with lead and copper plumbing to form highly explosive salts. On disposal, flush with large quantities of water.
- These products have passed through a 0.2µm filter, they should be clear, however, if turbidity appears this may indicate bacterial contamination. These reagents should not be used if a precipitate, fibrin gel or particles are present.

- These reagents are for professional *in vitro* diagnostic use only.
- The bovine materials are obtained from USDA approved sources or from sources for which origin information is available. The donor animals for bovine material have been inspected and certified disease free and are deemed to have low TSE (Transmissible Spongiform Encephalopathy) risk.

DISPOSAL OF REAGENT AND HANDLING A SPILLAGE

For more information of disposal of reagent and decontamination plus handling spillages, please contact sales for a material safety data sheet.

ADVICE TO USERS

- It is recommended that a positive control and a negative control should be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show the expected reactions. It is not required to use a reagent control in parallel with all tests using these reagents.
- Only in typing the red cells of patients known to have auto antibodies or protein abnormalities is the use of a reagent control recommended. This should be tested in parallel with the reagents.
- Once a vial has been opened it can remain viable until the expiry date unless there is visible turbidity or contamination.
- These reagents have been characterised by the procedures recommended in this package insert, their suitability for use in other techniques must be determined by the user.
- Each 10ml vial contains approx number of tests:

Methods	Drop size	No. of tests
Slide & Tube	45µl	<218
	50µl	<200

STORAGE AND STABILITY

Store the unopened products at 2-8°C until the expiry date detailed on the product label. Failure to store the products at the correct temperature, for example, storage at higher temperature or repeated freezing and thawing may result in accelerated loss of reagent activity.

SPECIMEN COLLECTION AND PREPARATION

- Blood samples can be collected into EDTA, citrate, CPDA, Lithium Heparin and Sodium Heparin anticoagulants or as a clotted sample.
- No special preparation of the patient is required prior to specimen collection.
- The specimen should be tested as soon as possible following collection. If a delay in testing should occur, store the specimen at 2- 8°C.
- Specimens displaying gross haemolysis or microbial contamination should not be tested with this reagent.
- Failure to store the specimens at the correct temperature, for example, storage at higher temperature or repeated freezing and thawing may result in false positive or false negative results.
- Specimen collection and preparation should only be conducted by a trained professional or personnel according to the requirements of the country where the reagents are in use.

INSTRUCTIONS FOR USE

SLIDE METHOD:

1. Prepare a 35-50% suspension of test red cells in autologous (or compatible) plasma, serum or in isotonic saline.
2. Add one drop (45-50µl) of either Anti-A, Anti-B or Anti-A,B reagent to a clean, labelled microscope slide.
3. Add one drop (45-50µl) of the suspension of test red cells.
4. Mix the antiserum and cells with plastic stirrers over an area about 2cm in diameter by gently and continuously rocking the slide.
5. Read macroscopically after 1 minute. Do not confuse any drying of the mixture with agglutination

TUBE METHOD (recommended for A_x):

1. Prepare a 3-5% suspension of test red cells in isotonic saline.
2. Add 1 drop (45-50µl) of either Anti-A, Anti-B or Anti- A,B reagent to an appropriately labelled test tube.
3. Add 1 drop (45-50µl) of the suspension of test red cells.
4. Mix and centrifuge at 1000 rcf for 20 seconds.
5. Gently agitate the tube to dislodge the red cells and examine macroscopically for agglutination.
6. Incubate weaker than expected reactions for 1 minute at room temperature and then re-spin.

Monoclonal Blood grouping Reagents
Anti-A
Anti-B
Anti-A,B



1434



BIO-RAD ID MICRO TYPING METHOD:

1. Prepare a 0.8% suspension of red cells in ID- CellStab or ID Diluent
2. Remove aluminium foil from as many microtubes as needed.
3. Place in appropriate microtube: 50µl of test red cell suspension and 25µl of Rapid Biotec Anti-ABO reagent.
4. Centrifuge cassette(s) in an Ortho BioVue System Centrifuge.
5. Read macroscopically for agglutination.

INTERPRETATION OF RESULTS

When used by the recommended techniques these reagents will cause:

• **Positive result:**

Agglutination (clumping) of red cells carrying the specific antigen.

• **Negative result:**

Lack of agglutination of the red cells demonstrates the absence of the specific antigen.

These reagents have been optimised for use by the recommended techniques without further dilution or additions.

LIMITATIONS

- The results of red cell grouping should be confirmed by reverse grouping the individual's serum with known A1 and B red cells.
- No recipient should be given AB blood unless the cells of the recipient are clearly positive with Anti-A and Anti- B and the recipient's serum shown to give negative reactions with A1 and B cells (unless the recipient has been shown to be a subgroup of AB with Anti-A1 in the serum).
- Rapid Biotec Anti-A,B does not detect A3 antigens neither does it detect "Acquired B cells"
- Rapid Biotec Anti-B does not react with "Acquired B cells"
- Anti-A blood grouping reagent is not validated to detect all examples of A_x cells. False positive or false negative results may occur through contamination of test materials or any deviation from the recommended technique.
- ABO antigens are not fully developed at birth therefore weaker reactions may occur with cord or neonatal samples.
- Using the reagent to detect weak B subgroups may give rise to false negative or weaker reactions when using slide, microtitre plates or gel cards.
- Stored blood may give weaker reactions than fresh blood.
- False positive or false negative results may also occur due to:
 - Contamination of test materials
 - Improper storage, cell concentration, incubation time or temperature
 - Improper or excessive centrifugation
 - Deviation from the recommended techniques
 - Cord samples contaminated with Wharton's jelly

PERFORMANCE CHARACTERISTICS

- Reagents will work best by using procedures mentioned in the recommended techniques.
- Every Lot of Rapid Biotec monoclonal blood grouping tested by the recommended techniques against a panel of antigen-positive red cells.
- Anti-A,B can detect A_x antigens however, only through tube technique; see recommended technique in this IFU.
- Specificity of source for monoclonal antibodies is demonstrated by using a panel of antigen-negative cells.
- Potency of these reagents have been tested against the minimum potency reference standards by National Institute of Biological Standards and controls (NIBSC):
 - Anti- A = 03/188
 - Anti- B = 03/164
- Rapid Biotec ABO reagents do not detect crypt antigens such as T, Tn or Cad.
- The reagents comply with the recommendations contained in the latest issue of the Guidelines for the UK Blood Transfusion Services.
- BG-A, BG-B and BG-A,B have been tested by each of the recommended methods with donor, clinical and neonatal specimens collected in either EDTA, citrate, CPDA, Lithium Heparin and Sodium Heparin. The sample population represented all major ABO phenotypes. The sensitivity for Rapid Biotec Anti-A, Anti-B and Anti-A,B is 100% and the specificity is 100%

BIBLIOGRAPHY

1. Moore, S. *et al.* Vox Sang 47: 427-434 (1984). A Mouse Monoclonal Antibody with Anti-A,(B) Specificity which Agglutinates Ax Cells.
2. McDonald, D.F. and Thompson, J.M. Vox Sang 1991;61:53-58. A New Monoclonal Anti-A Antibody BIRMA-1.
3. Issitt, P.D. and Anstee, D.J. Applied Blood Group Serology, 4th Edition, Montgomery Scientific Publications, 1998.
4. Race, R.R. and Sanger, R. Blood Groups in Man 6th Edition Oxford Blackwell Scientific Publishers 1975.
5. Guidelines for the Blood Transfusion Services in the United Kingdom. Current edition.

Index of symbols	
Consult instructions for use	REF Catalogue number
Store between 2-8°C	Manufacturer
IVD For in vitro diagnostic use only	Lot number
Use by	Date of manufacturer

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

Doc Ref: CE ABO RB - 04/2024

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

Monoclonal Blood grouping Reagents

Anti-A
Anti-B
Anti-A,B



1434

RAPID BIOTEC™



CATALOGUE NUMBER

Anti-A: BG-A10, BG-A10X10
Anti-B: BG-B10, BG-B10X10
Anti-A,B: BG-AB10, BG-AB10X10

INTENDED USE

The intended use of Rapid Biotec ABO blood grouping reagents is to be used in a qualitative method to identify the presence or absence of A or B antigens on the surface of red blood cells in donors or patients who require a blood transfusion.

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INTRODUCTION

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PRINCIPLE

When used by the recommended techniques these reagents will cause agglutination (clumping) of red cells carrying the specific antigen (positive test).

Lack of agglutination of the red cells demonstrates the absence of the specific antigen (negative test).

These reagents have been optimised for use by the recommended techniques without further dilution or additions. These products are supplied filtered through 0.2 µm filter.

REAGENTS AND MATERIALS

Blood grouping reagents contain monoclonal murine IgM antibodies in a buffer solution. The solution is a phosphate buffer containing sodium chloride, EDTA and bovine material. This reagent contains <0.1% sodium azide and the following colourants and cell lines:

Reagent	Colour	Dye	Cell line
Anti-A	Blue	Patent blue	BIRMA-1
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Anti-A,B	Colourless	None	ES-15/ES-4

Materials needed but not provided:

- Microscope slide/Plastic slides
- Plastic stirrers
- Timer
- Isotonic saline/LISS
- Compatible serum/plasma
- Test tubes
- Centrifuge (1000 rcf)
- Bio-Rad ID Cards (NaCl, Enzyme tests and cold agglutinins)
- Bio-Rad ID centrifuge
- Bio-Rad ID cell stab or ID-diluent 2

PRECAUTIONS

- The cell lines used to produce these reagents are of murine origin and have been tested and found to be negative for Mouse Antibody Production (MAP) viruses. Care must be taken in the use and disposal of each container and its contents.
- These reagents contain <0.1% (w/v) sodium azide. Sodium azide may be toxic if ingested and may react with lead and copper plumbing to form highly explosive salts. On disposal, flush with large quantities of water.
- These products have passed through a 0.2µm filter, they should be clear, however, if turbidity appears this may indicate bacterial contamination. These reagents should not be used if a precipitate, fibrin gel or particles are present.

- These reagents are for professional *in vitro* diagnostic use only.
- The bovine materials are obtained from USDA approved sources or from sources for which origin information is available. The donor animals for bovine material have been inspected and certified disease free and are deemed to have low TSE (Transmissible Spongiform Encephalopathy) risk.

DISPOSAL OF REAGENT AND HANDLING A SPILLAGE

For more information of disposal of reagent and decontamination plus handling spillages, please contact sales for a material safety data sheet.

ADVICE TO USERS

- It is recommended that a positive control and a negative control should be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show the expected reactions. It is not required to use a reagent control in parallel with all tests using these reagents.
- Only in typing the red cells of patients known to have auto antibodies or protein abnormalities is the use of a reagent control recommended. This should be tested in parallel with the reagents.
- Once a vial has been opened it can remain viable until the expiry date unless there is visible turbidity or contamination.
- These reagents have been characterised by the procedures recommended in this package insert, their suitability for use in other techniques must be determined by the user.
- Each 10ml vial contains approx number of tests:

Methods	Drop size	No. of tests
Slide & Tube	45µl	<218
	50µl	<200

STORAGE AND STABILITY

Store the unopened products at 2-8°C until the expiry date detailed on the product label. Failure to store the products at the correct temperature, for example, storage at higher temperature or repeated freezing and thawing may result in accelerated loss of reagent activity.

SPECIMEN COLLECTION AND PREPARATION

- Blood samples can be collected into EDTA, citrate, CPDA, Lithium Heparin and Sodium Heparin anticoagulants or as a clotted sample.
- No special preparation of the patient is required prior to specimen collection.
- The specimen should be tested as soon as possible following collection. If a delay in testing should occur, store the specimen at 2- 8°C.
- Specimens displaying gross haemolysis or microbial contamination should not be tested with this reagent.
- Failure to store the specimens at the correct temperature, for example, storage at higher temperature or repeated freezing and thawing may result in false positive or false negative results.
- Specimen collection and preparation should only be conducted by a trained professional or personnel according to the requirements of the country where the reagents are in use.

INSTRUCTIONS FOR USE

SLIDE METHOD:

1. Prepare a 35-50% suspension of test red cells in autologous (or compatible) plasma, serum or in isotonic saline.
2. Add one drop (45-50µl) of either Anti-A, Anti-B or Anti-A,B reagent to a clean, labelled microscope slide.
3. Add one drop (45-50µl) of the suspension of test red cells.
4. Mix the antiserum and cells with plastic stirrers over an area about 2cm in diameter by gently and continuously rocking the slide.
5. Read macroscopically after 1 minute. Do not confuse any drying of the mixture with agglutination

TUBE METHOD (recommended for A_x):

1. Prepare a 3-5% suspension of test red cells in isotonic saline.
2. Add 1 drop (45-50µl) of either Anti-A, Anti-B or Anti- A,B reagent to an appropriately labelled test tube.
3. Add 1 drop (45-50µl) of the suspension of test red cells.
4. Mix and centrifuge at 1000 rcf for 20 seconds.
5. Gently agitate the tube to dislodge the red cells and examine macroscopically for agglutination.
6. Incubate weaker than expected reactions for 1 minute at room temperature and then re-spin.

Monoclonal Blood grouping Reagents
Anti-A
Anti-B
Anti-A,B



1434



BIO-RAD ID MICRO TYPING METHOD:

1. Prepare a 0.8% suspension of red cells in ID- CellStab or ID Diluent
2. Remove aluminium foil from as many microtubes as needed.
3. Place in appropriate microtube: 50µl of test red cell suspension and 25µl of Rapid Biotec Anti-ABO reagent.
4. Centrifuge cassette(s) in an Ortho BioVue System Centrifuge.
5. Read macroscopically for agglutination.

INTERPRETATION OF RESULTS

When used by the recommended techniques these reagents will cause:

• **Positive result:**

Agglutination (clumping) of red cells carrying the specific antigen.

• **Negative result:**

Lack of agglutination of the red cells demonstrates the absence of the specific antigen.

These reagents have been optimised for use by the recommended techniques without further dilution or additions.

LIMITATIONS

- The results of red cell grouping should be confirmed by reverse grouping the individual's serum with known A1 and B red cells.
- No recipient should be given AB blood unless the cells of the recipient are clearly positive with Anti-A and Anti- B and the recipient's serum shown to give negative reactions with A1 and B cells (unless the recipient has been shown to be a subgroup of AB with Anti-A1 in the serum).
- Rapid Biotec Anti-A,B does not detect A3 antigens neither does it detect "Acquired B cells"
- Rapid Biotec Anti-B does not react with "Acquired B cells"
- Anti-A blood grouping reagent is not validated to detect all examples of A_x cells. False positive or false negative results may occur through contamination of test materials or any deviation from the recommended technique.
- ABO antigens are not fully developed at birth therefore weaker reactions may occur with cord or neonatal samples.
- Using the reagent to detect weak B subgroups may give rise to false negative or weaker reactions when using slide, microtitre plates or gel cards.
- Stored blood may give weaker reactions than fresh blood.
- False positive or false negative results may also occur due to:
 - Contamination of test materials
 - Improper storage, cell concentration, incubation time or temperature
 - Improper or excessive centrifugation
 - Deviation from the recommended techniques
 - Cord samples contaminated with Wharton's jelly

PERFORMANCE CHARACTERISTICS

- Reagents will work best by using procedures mentioned in the recommended techniques.
- Every Lot of Rapid Biotec monoclonal blood grouping tested by the recommended techniques against a panel of antigen-positive red cells.
- Anti-A,B can detect A_x antigens however, only through tube technique; see recommended technique in this IFU.
- Specificity of source for monoclonal antibodies is demonstrated by using a panel of antigen-negative cells.
- Potency of these reagents have been tested against the minimum potency reference standards by National Institute of Biological Standards and controls (NIBSC):
 - Anti- A = 03/188
 - Anti- B = 03/164
- Rapid Biotec ABO reagents do not detect crypt antigens such as T, Tn or Cad.
- The reagents comply with the recommendations contained in the latest issue of the Guidelines for the UK Blood Transfusion Services.
- BG-A, BG-B and BG-A,B have been tested by each of the recommended methods with donor, clinical and neonatal specimens collected in either EDTA, citrate, CPDA, Lithium Heparin and Sodium Heparin. The sample population represented all major ABO phenotypes. The sensitivity for Rapid Biotec Anti-A, Anti-B and Anti-A,B is 100% and the specificity is 100%

BIBLIOGRAPHY

1. Moore, S. *et al.* Vox Sang 47: 427-434 (1984). A Mouse Monoclonal Antibody with Anti-A,(B) Specificity which Agglutinates Ax Cells.
2. McDonald, D.F. and Thompson, J.M. Vox Sang 1991;61:53-58. A New Monoclonal Anti-A Antibody BIRMA-1.
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	Store between 2-8°C		Manufacturer
IVD	For in vitro diagnostic use only		Lot number
	Use by		Date of manufacturer

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

Doc Ref: CE ABO RB - 04/2024

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



CATALOGUE NUMBER

BG-D10

BG-D10X10

INTENDED USE

Rapid Biotec Anti-D (IgG & IgM) is a blood grouping reagent which is intended to be used to qualitatively determine the presence or absence of the RhD antigen on the red cells of blood donors or patients requiring a blood transfusion when tested in accordance with the recommended techniques stated in this IFU.

INTRODUCTION

The Rh Blood Group System

RhD (D or RH1), originally identified in 1939, was the first clinically important blood group to be found following the discovery of ABO 39 years earlier. A phenotypic relationship between D and an antigen on human red cells detected by antibodies made in rabbits immunized with rhesus monkey red cells, led to D being inappropriately named the Rhesus antigen. A vestige of that term remains in Rh, the name of the blood group system that contains D.

Approximately 15% of Caucasians lack the RhD antigen and are easily stimulated by an RhD positive pregnancy or blood transfusion to produce anti-D. This may cause haemolytic disease of the fetus and newborn or severe haemolytic transfusion reactions.

The frequency of the D+ phenotype is about 85% in Caucasians, around 95% in sub-Saharan Africa, and greater than 99.5% in eastern Asia (Daniels, 2013).

WEAK AND PARTIAL D

Anti-D (-RH1) of the Rh bloodgroup system is clinically important as it causes haemolytic transfusion reactions and haemolytic disease of the foetus and new-born. Although most people are either D+ or D-, there is a plethora of D variants, often categorized as either weak D or partial D. These two types are inadequately defined and the dichotomy is potentially misleading. D^{VI} is the D variant most commonly associated with anti-D production and UK guidelines recommend that patients are tested with anti-D reagents that do not react with D^{VI}.

Rapid Biotec Anti-D (IgG & IgM) reagent will detect most examples of weak D by direct agglutination; see the recommended technique stated in this IFU.

Rapid Biotec Anti-D (IgG & IgM) reagent will detect partial D category D^{VI} by indirect agglutination; see the recommended technique stated in this IFU.

PRINCIPLE

When used by the recommended techniques these reagents will cause direct agglutination (clumping) of red cells carrying the specific antigen (positive test) and indirect agglutination of red cells that are classified as D^{VI} in the antiglobulin phase recommended technique. Lack of agglutination of the red cells demonstrates the absence of the specific antigen (negative test).

These reagents have been optimised for use by the recommended techniques without further dilution or additions.

These products are supplied filtered through 0.2 µm filter.

REAGENTS AND MATERIALS

Blood grouping reagents contain monoclonal human IgM and IgG antibodies in a buffer solution. The solution containing macromolecular chemical potentiators. This reagent contains <0.1% sodium azide and the following colourants and cell lines:

Reagent	Colour	Dye	Cell line
Anti-D (IgG & IgM)	Straw/clear	None	MS-26 & RUM-1

Materials needed but not provided:

Slide technique

- Microscope slide/plastic slides
- Isotonic saline, PBS or compatible plasma/serum
- Plastic stirrers
- Timer

Indirect antiglobulin technique

- Anti-Human globulin reagent
- IgG sensitised red cells (Coombs control cells)

Tube technique

- Test tubes 75 x 12mm (glass)
- Isotonic saline
- 37°C incubator (if needed)
- Timer
- Centrifuge (1000 rcf)

Bio-Rad ID Card technique

- Column agglutination technique Bio-Rad ID Card (NaCl, Enzyme tests and cold agglutinins)
- Bio-Rad ID centrifuge
- Bio-Rad ID cell stab or ID diluent 2

PRECAUTIONS

- These reagents contain <0.1% (w/v) sodium azide. Sodium azide may be toxic if ingested and may react with lead and copper plumbing to form highly explosive salts. On disposal, flush with large quantities of water.
- All blood products should be treated as potential infectious. The human donor or cell line used to produce this reagent has been tested and found to be negative for Anti-HIV, Anti-HCV, HBsAg, EBV. No known tests can guarantee that any products derived from human blood is free from infectious agents. Care must be taken in the use and disposal of each container and its contents.
- These products have passed through a 0.2µm filter, they should be clear, however, if turbidity appears this may indicate bacterial contamination. These reagents should not be used if a precipitate, fibrin gel or particles are present.
- Do not use reagent past the expiration date.
- Protective clothing must be worn when handling reagent, such as, disposable gloves and lab coat.
- These reagents are for professional *in vitro* diagnostic use only.
- The bovine materials are obtained from USDA approved sources or from sources for which origin information is available. The donor animals for bovine material have been inspected and certified disease free and are deemed to have low TSE (Transmissible Spongiform Encephalopathy) risk.
- No known tests can guarantee that products derived from human or animal sources are free from infectious agents. Care must be taken in the use and disposal of each vial and its contents.

DISPOSAL OF REAGENT AND HANDLING A SPILLAGE

For more information of disposal of reagent and decontamination plus handling spillages, please contact sales for a material safety data sheet.

ADVICE TO USERS

- It is recommended that a positive control and a negative control should be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show the expected reactions. It is not required to use a reagent control in parallel with all tests using these reagents.
- The use of the reagent and the interpretation of results must be carried out by properly trained and competent professionals.
- Only in typing the red cells of patients known to have auto antibodies or protein abnormalities is the use of a reagent control recommended. This should be tested in parallel with the reagents.
- Weak and D^{VI} antigens are poorly detected by Bio-Rad ID card and slide techniques. It is recommended that weak D variants should be tested by tube test and D^{VI} should be tested by indirect antiglobulin technique.
- The antiglobulin tube technique can only be considered valid if all negative tests react positively with IgG sensitised red cells.
- Once a vial has been opened it can remain viable until the expiry date unless there is visible turbidity or contamination.
- Before use, let the reagent warm up to room temperature. As soon as the reagent has been used, put the reagent back in storage at 2-8°C.
- Caution should be exercised in the interpretation of results of tests performed at temperatures other than those recommended.
- These reagents have been characterised by the procedures recommended in this package insert, their suitability for use in other techniques must be determined by the user.

STORAGE AND STABILITY

Store the unopened products at 2-8°C until the expiry date detailed on the product label. Failure to store the products at the correct temperature, for example, storage at higher temperature or repeated freezing and thawing may result in accelerated loss of reagent activity.

This reagent has undergone transportation stability studies at 37°C and 2-8°C as described in BS EN ISO 23640:2015.

SPECIMEN COLLECTION AND PREPARATION

- Blood samples can be collected into EDTA, citrate, CPDA, Lithium Heparin and Sodium Heparin anticoagulants or as a clotted sample.
- No special preparation of the patient is required prior to specimen collection.
- The specimen should be tested as soon as possible following collection. If a delay in testing should occur, store the specimen at 2-8°C.
- Specimens displaying gross haemolysis or microbial contamination should not be tested with this reagent.
- Failure to store the specimens at the correct temperature, for example, storage at higher temperature or repeated freezing and thawing may result in false positive or false negative results.

Monoclonal Blood grouping reagents Anti-D (IgG & IgM)



1434

RAPID BIOTEC™



- Specimen collection and preparation should only be conducted by a trained professional or personnel according to the requirements of the country where the reagents are in use.

INSTRUCTIONS FOR USE

SLIDE METHOD:

1. Prepare a 35-50% suspension of test red cells in autologous (or compatible) plasma, serum, isotonic saline or PBS.
2. Add one drop (45-50µl) of Anti-D (IgG & IgM) reagent to a clean, labelled microscope slide.
3. Add one drop (45-50µl) of the suspension of test red cells.
4. Mix the antiserum and cells with plastic stirrers over an area about 2cm in diameter by gently and continuously rocking the slide.
5. Read macroscopically after 1 minute. Do not confuse any drying of the mixture with agglutination.

TUBE METHOD: (recommended for weak D):

1. Prepare a 3-5% suspension of test red cells in isotonic saline.
2. Add 1 drop (45-50µl) of Anti-D (IgG & IgM) reagent to an appropriately labelled glass test tube.
3. Add 1 drop (45-50µl) of the suspension of test red cells.
4. Mix and centrifuge at 1000 rcf for 20 seconds.
5. Gently agitate the tube to dislodge the red cells and examine macroscopically for agglutination.
6. Incubate weaker than expected reactions for 1 minute at room temperature and then re-spin.

BIO-RAD ID MICRO TYPING METHOD:

1. Prepare a 0.8% suspension of red cells in ID- CellStab or ID Diluent
2. Remove aluminium foil from as many microtubes as needed.
3. Place in appropriate microtube: 50µl of test red cell suspension and 25µl of Rapid Biotec Anti-D (IgG & IgM) reagent.
4. Centrifuge cassette(s) in a Bio-Rad gel card centrifuge.
5. Read macroscopically for agglutination.

INDIRECT ANTIGLOBULIN TECHNIQUE (recommended for D^{VI}):

1. Prepare a 3-5% suspension of test red cells in isotonic saline.
2. Add 1 drop (45-50µl) of Anti-D (IgG & IgM) reagent to an appropriately labelled glass test tube.
3. Add 1 drop (45-50µl) of the suspension of test red cells.
4. Mix well and incubate at 37°C for 15 minutes.
5. Wash the cells once with isotonic saline, thoroughly decanting saline.
6. Add 2 drops (80-100µl) of Anti-Human Globulin reagent, mix and centrifuge at 1000 rcf for 20 seconds.
7. Gently agitate the tube to dislodge the red cells and examine macroscopically for agglutination.
8. Confirm validity of negative results with IgG sensitised red cells

INTERPRETATION OF RESULTS

When used by the recommended techniques these reagents will cause:

- **Positive result:**
Agglutination (clumping) of red cells carrying the specific antigen.
- **Negative result:**

Lack of agglutination of the red cells demonstrates the absence of the specific antigen.

LIMITATIONS

- ABO antigens are not fully developed at birth and so weaker reactions may therefore occur with cord or neonatal specimens
- Stored blood may give weaker reactions than fresh blood.
- False positive or false negative results may also occur due to:
 - Contamination of test materials
 - Improper storage, cell concentration, incubation time or temperature
 - Improper or excessive centrifugation
 - Deviation from the recommended techniques
 - Cord samples contaminated with Wharton's jelly

PERFORMANCE CHARACTERISTICS

- Reagents will work optimised best by using procedures mentioned in the recommended techniques.
- Every Lot of Rapid Biotec monoclonal blood grouping reagent is tested by the recommended techniques against a panel of antigen- positive red cells.
- Specificity of source for monoclonal antibodies is demonstrated by using a panel of antigen-negative cells.
- Potency of these reagents have been tested against the minimum potency reference standards by National Institute of Biological Standards and controls (NIBSC): Anti-D = 99/836
- The reagents comply with the recommendations contained in the latest issue of the Guidelines for the UK Blood Transfusion

Services.

- Rapid Biotec Anti-D (IgG & IgM) has been tested by each of the recommended methods with donor, clinical and neonatal specimens collected in either EDTA, citrate, CPDA, Lithium Heparin and Sodium Heparin. The sample population represented all major ABO phenotypes. The sensitivity for Rapid Biotec Anti-D (IgG & IgM) is 100% and the specificity is 100%

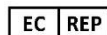
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2. Race RR, Sanger R. Blood Groups in Man 6th Edition, Oxford, Blackwell Scientific Publishers Chapter 2 (1975).
3. Issitt PD. Applied Blood Group Serology, 3rd Edition, Montgomery Scientific, Miami, Chapter 10 (1985).
4. Mollison PL. Blood Transfusion in Clinical Medicine, 8th Edition, Oxford, Blackwell Scientific Publications, Chapter 7 (1987).
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6. Thompson KM, Hughes-Jones NC. Production and characteristics of monoclonal anti-Rh. Bailliere's Clinical Haematology; (1990).
7. Jones J, Scott ML, Voak D. Monoclonal anti-D specificity and Rh D structure: criteria for selection of monoclonal anti-D reagents for routine typing of patients and donors. Transfusion Medicine 5: 171-184 (1995).
8. Guidelines for the Blood Transfusion Service in the United Kingdom. H.M.S.O. Current Edition.
9. Daniels, G. Variants of RhD – Current Testing and Clinical Consequences, British Journal of Haematology; 161: 461-470 (2013).

	Consult instructions for use		For <i>in vitro</i> diagnostic use only
	Catalogue Number		Lot Number
	Store between 2-8°C		Use by
	Manufacturer		Date of manufacture

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

Doc Ref: CE D Blend RB 1 - 04/2024



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



CATALOGUE NUMBER

BG-D10

BG-D10X10

INTENDED USE

Rapid Biotec Anti-D (IgG & IgM) is a blood grouping reagent which is intended to be used to qualitatively determine the presence or absence of the RhD antigen on the red cells of blood donors or patients requiring a blood transfusion when tested in accordance with the recommended techniques stated in this IFU.

INTRODUCTION

The Rh Blood Group System

RhD (D or RH1), originally identified in 1939, was the first clinically important blood group to be found following the discovery of ABO 39 years earlier. A phenotypic relationship between D and an antigen on human red cells detected by antibodies made in rabbits immunized with rhesus monkey red cells, led to D being inappropriately named the Rhesus antigen. A vestige of that term remains in Rh, the name of the blood group system that contains D.

Approximately 15% of Caucasians lack the RhD antigen and are easily stimulated by an RhD positive pregnancy or blood transfusion to produce anti-D. This may cause haemolytic disease of the fetus and newborn or severe haemolytic transfusion reactions.

The frequency of the D+ phenotype is about 85% in Caucasians, around 95% in sub-Saharan Africa, and greater than 99.5% in eastern Asia (Daniels, 2013).

WEAK AND PARTIAL D

Anti-D (-RH1) of the Rh bloodgroup system is clinically important as it causes haemolytic transfusion reactions and haemolytic disease of the foetus and new-born. Although most people are either D+ or D-, there is a plethora of D variants, often categorized as either weak D or partial D. These two types are inadequately defined and the dichotomy is potentially misleading. D^{VI} is the D variant most commonly associated with anti-D production and UK guidelines recommend that patients are tested with anti-D reagents that do not react with D^{VI}.

Rapid Biotec Anti-D (IgG & IgM) reagent will detect most examples of weak D by direct agglutination; see the recommended technique stated in this IFU.

Rapid Biotec Anti-D (IgG & IgM) reagent will detect partial D category D^{VI} by indirect agglutination; see the recommended technique stated in this IFU.

PRINCIPLE

When used by the recommended techniques these reagents will cause direct agglutination (clumping) of red cells carrying the specific antigen (positive test) and indirect agglutination of red cells that are classified as D^{VI} in the antiglobulin phase recommended technique. Lack of agglutination of the red cells demonstrates the absence of the specific antigen (negative test).

These reagents have been optimised for use by the recommended techniques without further dilution or additions.

These products are supplied filtered through 0.2 µm filter.

REAGENTS AND MATERIALS

Blood grouping reagents contain monoclonal human IgM and IgG antibodies in a buffer solution. The solution containing macromolecular chemical potentiators. This reagent contains <0.1% sodium azide and the following colourants and cell lines:

Reagent	Colour	Dye	Cell line
Anti-D (IgG & IgM)	Straw/clear	None	MS-26 & RUM-1

Materials needed but not provided:

Slide technique

- Microscope slide/plastic slides
- Isotonic saline, PBS or compatible plasma/serum
- Plastic stirrers
- Timer

Indirect antiglobulin technique

- Anti-Human globulin reagent
- IgG sensitised red cells (Coombs control cells)

Tube technique

- Test tubes 75 x 12mm (glass)
- Isotonic saline
- 37°C incubator (if needed)
- Timer
- Centrifuge (1000 rcf)

Bio-Rad ID Card technique

- Column agglutination technique Bio-Rad ID Card (NaCl, Enzyme tests and cold agglutinins)
- Bio-Rad ID centrifuge
- Bio-Rad ID cell stab or ID diluent 2

PRECAUTIONS

- These reagents contain <0.1% (w/v) sodium azide. Sodium azide may be toxic if ingested and may react with lead and copper plumbing to form highly explosive salts. On disposal, flush with large quantities of water.
- All blood products should be treated as potential infectious. The human donor or cell line used to produce this reagent has been tested and found to be negative for Anti-HIV, Anti-HCV, HBsAg, EBV. No known tests can guarantee that any products derived from human blood is free from infectious agents. Care must be taken in the use and disposal of each container and its contents.
- These products have passed through a 0.2µm filter, they should be clear, however, if turbidity appears this may indicate bacterial contamination. These reagents should not be used if a precipitate, fibrin gel or particles are present.
- Do not use reagent past the expiration date.
- Protective clothing must be worn when handling reagent, such as, disposable gloves and lab coat.
- These reagents are for professional *in vitro* diagnostic use only.
- The bovine materials are obtained from USDA approved sources or from sources for which origin information is available. The donor animals for bovine material have been inspected and certified disease free and are deemed to have low TSE (Transmissible Spongiform Encephalopathy) risk.
- No known tests can guarantee that products derived from human or animal sources are free from infectious agents. Care must be taken in the use and disposal of each vial and its contents.

DISPOSAL OF REAGENT AND HANDLING A SPILLAGE

For more information of disposal of reagent and decontamination plus handling spillages, please contact sales for a material safety data sheet.

ADVICE TO USERS

- It is recommended that a positive control and a negative control should be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show the expected reactions. It is not required to use a reagent control in parallel with all tests using these reagents.
- The use of the reagent and the interpretation of results must be carried out by properly trained and competent professionals.
- Only in typing the red cells of patients known to have auto antibodies or protein abnormalities is the use of a reagent control recommended. This should be tested in parallel with the reagents.
- Weak and D^{VI} antigens are poorly detected by Bio-Rad ID card and slide techniques. It is recommended that weak D variants should be tested by tube test and D^{VI} should be tested by indirect antiglobulin technique.
- The antiglobulin tube technique can only be considered valid if all negative tests react positively with IgG sensitised red cells.
- Once a vial has been opened it can remain viable until the expiry date unless there is visible turbidity or contamination.
- Before use, let the reagent warm up to room temperature. As soon as the reagent has been used, put the reagent back in storage at 2-8°C.
- Caution should be exercised in the interpretation of results of tests performed at temperatures other than those recommended.
- These reagents have been characterised by the procedures recommended in this package insert, their suitability for use in other techniques must be determined by the user.

STORAGE AND STABILITY

Store the unopened products at 2-8°C until the expiry date detailed on the product label. Failure to store the products at the correct temperature, for example, storage at higher temperature or repeated freezing and thawing may result in accelerated loss of reagent activity.

This reagent has undergone transportation stability studies at 37°C and 2-8°C as described in BS EN ISO 23640:2015.

SPECIMEN COLLECTION AND PREPARATION

- Blood samples can be collected into EDTA, citrate, CPDA, Lithium Heparin and Sodium Heparin anticoagulants or as a clotted sample.
- No special preparation of the patient is required prior to specimen collection.
- The specimen should be tested as soon as possible following collection. If a delay in testing should occur, store the specimen at 2-8°C.
- Specimens displaying gross haemolysis or microbial contamination should not be tested with this reagent.
- Failure to store the specimens at the correct temperature, for example, storage at higher temperature or repeated freezing and thawing may result in false positive or false negative results.

Monoclonal Blood grouping reagents Anti-D (IgG & IgM)



1434

RAPID BIOTEC™



- Specimen collection and preparation should only be conducted by a trained professional or personnel according to the requirements of the country where the reagents are in use.

INSTRUCTIONS FOR USE

SLIDE METHOD:

1. Prepare a 35-50% suspension of test red cells in autologous (or compatible) plasma, serum, isotonic saline or PBS.
2. Add one drop (45-50µl) of Anti-D (IgG & IgM) reagent to a clean, labelled microscope slide.
3. Add one drop (45-50µl) of the suspension of test red cells.
4. Mix the antiserum and cells with plastic stirrers over an area about 2cm in diameter by gently and continuously rocking the slide.
5. Read macroscopically after 1 minute. Do not confuse any drying of the mixture with agglutination.

TUBE METHOD: (recommended for weak D):

1. Prepare a 3-5% suspension of test red cells in isotonic saline.
2. Add 1 drop (45-50µl) of Anti-D (IgG & IgM) reagent to an appropriately labelled glass test tube.
3. Add 1 drop (45-50µl) of the suspension of test red cells.
4. Mix and centrifuge at 1000 rcf for 20 seconds.
5. Gently agitate the tube to dislodge the red cells and examine macroscopically for agglutination.
6. Incubate weaker than expected reactions for 1 minute at room temperature and then re-spin.

BIO-RAD ID MICRO TYPING METHOD:

1. Prepare a 0.8% suspension of red cells in ID- CellStab or ID Diluent
2. Remove aluminium foil from as many microtubes as needed.
3. Place in appropriate microtube: 50µl of test red cell suspension and 25µl of Rapid Biotec Anti-D (IgG & IgM) reagent.
4. Centrifuge cassette(s) in a Bio-Rad gel card centrifuge.
5. Read macroscopically for agglutination.

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3. Add 1 drop (45-50µl) of the suspension of test red cells.
4. Mix well and incubate at 37°C for 15 minutes.
5. Wash the cells once with isotonic saline, thoroughly decanting saline.
6. Add 2 drops (80-100µl) of Anti-Human Globulin reagent, mix and centrifuge at 1000 rcf for 20 seconds.
7. Gently agitate the tube to dislodge the red cells and examine macroscopically for agglutination.
8. Confirm validity of negative results with IgG sensitised red cells

INTERPRETATION OF RESULTS

When used by the recommended techniques these reagents will cause:

- **Positive result:**
Agglutination (clumping) of red cells carrying the specific antigen.

- **Negative result:**
Lack of agglutination of the red cells demonstrates the absence of the specific antigen.

LIMITATIONS

- ABO antigens are not fully developed at birth and so weaker reactions may therefore occur with cord or neonatal specimens
- Stored blood may give weaker reactions than fresh blood.
- False positive or false negative results may also occur due to:
 - Contamination of test materials
 - Improper storage, cell concentration, incubation time or temperature
 - Improper or excessive centrifugation
 - Deviation from the recommended techniques
 - Cord samples contaminated with Wharton's jelly

PERFORMANCE CHARACTERISTICS

- Reagents will work optimised best by using procedures mentioned in the recommended techniques.
- Every Lot of Rapid Biotec monoclonal blood grouping reagent is tested by the recommended techniques against a panel of antigen- positive red cells.
- Specificity of source for monoclonal antibodies is demonstrated by using a panel of antigen-negative cells.
- Potency of these reagents have been tested against the minimum potency reference standards by National Institute of Biological Standards and controls (NIBSC): Anti-D = 99/836
- The reagents comply with the recommendations contained in the latest issue of the Guidelines for the UK Blood Transfusion

Services.

- Rapid Biotec Anti-D (IgG & IgM) has been tested by each of the recommended methods with donor, clinical and neonatal specimens collected in either EDTA, citrate, CPDA, Lithium Heparin and Sodium Heparin. The sample population represented all major ABO phenotypes. The sensitivity for Rapid Biotec Anti-D (IgG & IgM) is 100% and the specificity is 100%

BIBLIOGRAPHY

1. Kholer, G. and Milstein, C. Continuous culture of fused cells secreting antibody of predefined specificity. Nature. 256 : 495-497 (1975).
2. Race RR, Sanger R. Blood Groups in Man 6th Edition, Oxford, Blackwell Scientific Publishers Chapter 2 (1975).
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8. Guidelines for the Blood Transfusion Service in the United Kingdom. H.M.S.O. Current Edition.
9. Daniels, G. Variants of RhD – Current Testing and Clinical Consequences, British Journal of Haematology; 161: 461-470 (2013).

	Consult instructions for use		For <i>in vitro</i> diagnostic use only
	Catalogue Number		Lot Number
	Store between 2-8°C		Use by
	Manufacturer		Date of manufacture

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

Doc Ref: CE D Blend RB 1 - 04/2024

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

Declaration of Conformity

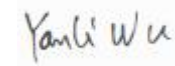
for the

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	Methylenedioxypropyvalerone (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	Mehtaalqualone (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 Cassette (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-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 plasma	58322	B	6
D-CIFT4K40	Free Thyroxine (FT4) Test Kit -human serum or plasma	54413	B	6
D-CIPRLK40	Prolactin Test Kit-human serum or plasma	54335	B	6
D-CICA199K40	Carbohydrate Antigen 199 (CA19-9) Test Kit- human serum and plasma	60976	B	6
D-CIAFPK40	Alpha-fetoprotein (AFP) Test Kit- human serum or plasma	58348	C	3h
D-CICKMBK40	Creatine Kinase MB (CKMB) Test Kit - human whole blood, serum or plasma	61000	C	3j
D-CICRPK40	C-reactive Protein (CRP) Test Kit -human whole blood, serum or plasma	65695	B	6
D-CICTIK40	Cardiac Troponin-I (cTnI) Test Kit -human whole blood, serum or plasma	60780	C	3j
D-CIDDMK40	D-Dimer Test Kit-human whole blood and plasma	60530	C	3k
D-CIINSK40	Insulin (INS) Test Kit-human serum or plasma	54237	B	6
D-CIMYOK40	Myoglobin (MYO) Test Kit-human whole blood, serum or plasma	53952	C	3j

D-CIPCTK40	Procalcitonin (PCT) Test Kit-human whole blood,	58731	B	6
D-CICTNTK40	Cardiac Troponin-T (cTnT) Test Kit -human serum or plasma	54007	B	6
D-CIIL6K40	Interleukin-6 (IL-6) Test Kit-human whole blood,	53858	B	6
D-CIT3K40	Triiodothyronine (T3) Test Kit -human serum or plasma	58330	B	6
D-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-CIPGRP40	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 – Salvia	46994	B	6
D-DOA9M25S	Ketamine (KET) Rapid Test Midstream-Salvia	46994	B	6
D-DOA43D20S	6-Monoacetylmorphine(6-MAM) Rapid Test Device-Saliva	64154	B	6
D-DOA43M25S	6-Monoacetylmorphine (6-MAM) Rapid Test Midstream-salvia	46994	B	6
D-DOA12M20S	Ecstasy (MDMA) Rapid Test Midstream-Saliva	46994	B	6
D-DOA62D25S	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 – Salvia	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. Tramadol 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

H.pylori Antigen Rapid Test Device (Feces)

CATALOGUE NUMBER
D-HPAGD20

A rapid test for the qualitative detection of *Helicobacter pylori* (*H.pylori*) antigens in human feces.
For professional *in vitro* diagnostic use only.

INTENDED USE

The *H.pylori* Antigen Rapid Test Device (Feces) is a rapid chromatographic immunoassay for the qualitative detection of *H.pylori* antigens in human feces to aid in the diagnosis of *H.pylori* infection.

SUMMARY

H.pylori is a small, spiral-shaped bacterium that lives in the surface of the stomach and duodenum. It is implicated in the etiology of a variety of gastrointestinal diseases, including duodenal and gastric ulcer, non-ulcer dyspepsia and active and chronic gastritis.^{1,2} Both invasive and non-invasive methods are used to diagnose *H.pylori* infection in patients with symptoms of gastrointestinal disease. Specimen-dependent and costly invasive diagnostic methods include gastric or duodenal biopsy followed by urease testing (presumptive), culture, and/or histologic staining.³ A very common approach to the diagnosis of *H.pylori* infection is the serological identification of specific antibodies in infected patients. The main limitation of serology test is the inability to distinguish current and past infections. Antibody may be present in the patient's serum long after eradication of the organisms.⁴ HpSA (*H. pylori* Stool Antigen) testing is gaining popularity for diagnosis of *H. pylori* infection and also for monitoring the efficacy of the treatment of *H. pylori* infection. Studies have found that more than 90% of patients with duodenal ulcer and 80% of patients with gastric ulcer are infected with *H.pylori*.⁵

The *H.pylori* Antigen Rapid Test Device (Feces) is a rapid chromatographic immunoassay for the qualitative detection of *H.pylori* antigens in human feces specimens, providing results in 10 minutes. The test utilizes antibodies specific for *H. pylori* antigens to selectively detect *H.pylori* antigens in human feces specimens.

PRINCIPLE

The *H.pylori* Antigen Rapid Test Device (Feces) is a qualitative, lateral flow immunoassay for the detection of *H.pylori* antigens in human feces specimens. In this test, the membrane is pre-coated with anti-*H.pylori* antibodies on the test line region of the test. During testing, the specimen reacts with the particle coated with anti-*H.pylori* antibodies. The mixture migrates upward on the membrane by capillary action to react with anti-*H.pylori* antibodies and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test Device contains monoclonal anti-*H.pylori* antibodies coated particles and monoclonal anti-*H.pylori* antibodies coated on the membrane.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

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

SPECIMEN COLLECTION AND PREPARATION

- The feces specimen must be collected in clean, dry, waterproof container containing no detergents, preservatives or transport media.
- Bring the necessary reagents to room temperature before use.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

MATERIALS

- Test Devices
- Specimen collection tubes with extraction buffer
- Package insert

Materials Provided

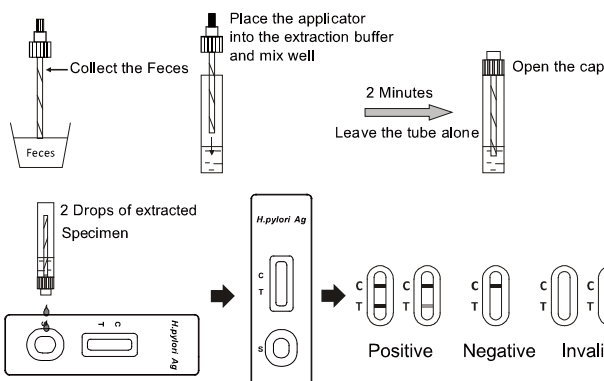
- Specimen collection containers
- Pipette and disposable tips (optional)
- Centrifuge
- Timer
- Droppers

Materials Required But Not Provided

DIRECTIONS FOR USE

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

- To collect fecal specimens:
Collect sufficient quantity of feces (1-2 mL or 1-2 g) in a clean, dry specimen collection container to obtain maximum antigens (if present). Best results will be obtained if the assay is performed within 6 hours after collection. Specimen collected may be stored for 3 days at 2-8°C if not tested within 6 hours. For long term storage, specimens should be kept below -20°C.
- To process fecal specimens:
 - For Solid Specimens:
Unscrew the cap of the specimen collection tube, then randomly **stab the specimen collection applicator into the fecal specimen in at least 3 different sites** to collect approximately 50 mg of feces (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.
 - For Liquid Specimens:
Hold the dropper vertically, aspirate fecal specimens, and then transfer approximately 80 µL into the specimen collection tube containing the extraction buffer.
Tighten the cap onto the specimen collection tube, then **shake the specimen collection tube vigorously** to mix the specimen and the extraction buffer. Leave the tube alone for 2 minutes.
- Bring the pouch to room temperature before opening it. Remove the test Device from the foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
- Hold the specimen collection tube upright and open the cap onto the specimen collection tube. Invert the specimen collection tube and **transfer 2 full drops of the extracted specimen (approximately 80 µL)** to the specimen well (S) of the test Device, then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.
- Read results at 10 minutes after dispensing the specimen. Do not read results after 20 minutes.
Note: If the specimen does not migrate (presence of particles), centrifuge the extracted specimens contained in the extraction buffer vial. Collect 80 µL of supernatant, dispense into the specimen well (S) of a new test Device and start afresh following the instructions mentioned above.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE: Two colored 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).

***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of *H.pylori* antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

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. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal valid procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

- The *H.pylori* Antigen Test Device (Feces) is for *in vitro* diagnostic use only. The test should be used for the detection of *H.pylori* antigens in feces specimens only. Neither the quantitative value nor the rate of increase in *H.pylori* antigens concentration can be determined by this qualitative test.
- The *H.pylori* Antigen Test Device (Feces) will only indicate the presence of *H.pylori* in the specimen and should not be used as the sole criteria for *H.pylori* to be etiologic agent for peptic or duodenal ulcer.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of *H.pylori* infection.
- Following certain antibiotic treatments, the concentration of *H.pylori* antigens may decrease to the concentration below the minimum detection level of the test. Therefore, diagnosis should be made with caution during antibiotic treatment.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The *H.pylori* Antigen Test Device (Feces) has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals. The result shows that the sensitivity of the *H.pylori* Antigen Test Device (Feces) is 98.8% and the specificity is 98.4% relative to Endoscope-based methods.

Method	Endoscope-based method		Total Results
	Positive	Negative	
<i>H.pylori</i> Antigen Test Device (Feces)	Positive	3	171
	Negative	189	191
Total Results	170	192	362

Relative Sensitivity: 98.8% (95%CI*:95.8%-99.9%)

*Confidence Interval

Relative Specificity: 98.4% (95%CI*: 95.5%-99.7%)

Overall Accuracy: 98.6% (95%CI*: 96.8%-99.5%)

Precision

Intra-Assay

Within-run precision has been determined by using 15 replicates of four specimens: negative, low titer positive, middle titer positive and high titer positive specimens. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 15 independent assays on the same four specimens: negative, low titer positive, middle titer positive and high titer positive specimens. Three different lots of the *H.pylori* Antigen Test Device (Feces) have been tested using these specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

Cross reactivity with following organisms has been studied at 1.0E+09 organisms/ml. The following organisms were found negative when tested with the *H.pylori* Antigen Test Device (Feces):

<i>Acinetobacter calcoaceticus</i>	<i>Acinetobacter spp</i>	<i>Branhamella catarrhalis</i>
<i>Candida albicans</i>	<i>Chlamydia trachomatis</i>	<i>Enterococcus faecium</i>
<i>E. coli</i>	<i>Enterococcus faecalis</i>	<i>Gardnerella vaginalis</i>
<i>Group A Streptococcus</i>	<i>Group B Streptococcus</i>	<i>Group C Streptococcus</i>
<i>Hemophilus influenza</i>	<i>Klebsiella pneumonia</i>	<i>Neisseria gonorrhoea</i>
<i>Neisseria meningitides</i>	<i>Proteus mirabilis</i>	<i>Proteus vulgaris</i>
<i>Pseudomonas aeruginosa</i>	<i>Rotavirus</i>	<i>Salmonella choleraesuis</i>
<i>Staphylococcus aureus</i>	<i>Adenovirus</i>	

Interfering Substances

The following potentially Interfering Substances were added to HPG negative and positive specimens.

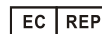
Ascorbic acid: 20mg/dl	Oxalic acid: 60mg/dl	Bilirubin: 100mg/dl
Uric acid: 60mg/dl	Aspirin: 20mg/dl	Urea: 2000mg/dl
Glucose: 2000mg/dl	Caffeine: 40mg/dl	Albumin: 2000mg/dl

BIBLIOGRAPHY

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- Cutler AF. Testing for Helicobacter pylori in clinical practice. Am. J. Med. 1996; 100:35S-41S.
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Index of Symbols

	Consult instructions for use		Contains sufficient for <n> test		Authorized representative in the European Community/European Union
	<i>In vitro</i> 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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Revision 2

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