



## STATEMENT

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

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

Date: March 5th, 2025

Signature:

*Tracy Wu*

**Rapid Labs**  
Rapid Labs Limited

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



# Certificate of Registration

This certificate has been awarded to

## Rapid Labs Limited

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

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

**ISO 13485:2016**

The scope of activities covered by this certificate is defined below

**Please refer to the Appendix**

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

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

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

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

Issued by

Mukesh Singh - On behalf of the Schemes Manager





# Appendix to Certificate

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

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

A certificate number of 0001, confirms the Client has a single site Certified & the site is their Head Office or Main site in relation to the Certified scope with URS. A certificate number of 0002, or greater (e.g.: xxxx/8/0002/UK/En) refers to a client that has more than one site certified with URS, as such, the following statement shall apply - 'The validity of this certificate depends on the validity of the main certificate'.

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Issued by

Mukesh Singh - On behalf of the Schemes Manager



## Declaration of Conformity

for the

### Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 concerning In Vitro Diagnostic Medical Devices

The undersigned, under their sole responsibility, declares that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

|                                            |                                                                                                                                                                                                                                                                                                                                                                                                  |
|--------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>General Product Name:</b>               | Rapid Strips & devices                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Legal Manufacturer: (Name on Label)</b> | <b><u>Rapid Labs Limited</u></b><br>Unit 2 & 2A Hall Farm, Business Centre, Church road, Little Bentley, Colchester, Essex, CO7 8SD United Kingdom                                                                                                                                                                                                                                               |
| <b>SRN:</b>                                | GB-MF-000026335                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Basic UDI-DI:</b>                       | N/A                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Variants:</b>                           | As per Appendix II (This document) – Product Listing/Schedule                                                                                                                                                                                                                                                                                                                                    |
| <b>Intended Purpose:</b>                   | Professional use                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>IVDR Classification:</b>                | As per Appendix II (This document) – Product Listing/Schedule                                                                                                                                                                                                                                                                                                                                    |
| <b>Notified Body:</b>                      | N/A                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>CE Certificate:</b>                     | N/A                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>EU Authorised Representative:</b>       | Advena Limited. Tower Business Centre, 2 <sup>nd</sup> Flr., Tower Street, Swatar, BKR 4013 Malta.                                                                                                                                                                                                                                                                                               |
| <b>EU Authorised Representative SRN:</b>   | MT-AR-000000234                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>IVDR Assessment Route:</b>              | <i>Provide indication of conformity assessment route chosen in accordance with Article 48 of the IVDR.<br/>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.<br/>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<br>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<br>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<br>Pregabalin (PGB) Rapid test Device-Urine<br>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<br>Cocaine (COC) Rapid Test Device - Saliva               | 46994 | B | 6 |
| D-DOA18D20 | Methamphetamine (MET) Rapid Test Midstream- Saliva<br>Methamphetamine (MET) Rapid Test Device- Saliva | 55498 | B | 6 |
| D-DOA19D20 | Opiates (OPI) Test Device- Saliva<br>Opiates (OPI) Test Midstream- Saliva                             | 55701 | B | 6 |
| D-DOA20D20 | Ecstasy (MDMA) Rapid Test Midstream - Saliva<br>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 |

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

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|-------------|---------------------------------------------------------------------------------|-------|---|----|
| 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  | $\alpha$ -Pyrrolidinovalerophenone ( $\alpha$ -PVP ) Rapid Test Device – Urine  | 46994 | B | 6  |
| D-DOA54P40  | $\alpha$ -PVP Rapid Test Panel – Urine                                          | 46994 | B | 6  |
| D-DOA54S50  | $\alpha$ -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  |

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|------------|--------------------------------------------------------------------------|-------|---|---|
| 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 |

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| D-DOA62D40 | Methylenedioxypropyrolone (MDPV) Rapid Test Device – Urine | 46994 | B | 6 |
| D-DOA62P40 | Methylenedioxypropyrolone (MDPV) Rapid Test Panel – Urine  | 46994 | B | 6 |
| D-DOA62S50 | Methylenedioxypropyrolone (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 |

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|------------|---------------------------------------------------|-------|---|---|
| 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 | $\alpha$ -Pyrrolidinovalerophenone ( $\alpha$ -PVP ) Rapid Test Device- Saliva   | 46994 | B | 6 |
| D-DOA54M25S | $\alpha$ -Pyrrolidinovalerophenone ( $\alpha$ -PVP ) Rapid Test Midstream-Saliva | 46994 | B | 6 |
| D-DOA4D20S  | Barbiturates ( BAR) Rapid Test Device – Salvia                                   | 46994 | B | 6 |
| D-DOA4M25S  | Barbiturates (BAR) Rapid Test Midstream-Salvia                                   | 46994 | B | 6 |
| D-DOA11D20S | Buprenorphine (BUP) Rapid Test Device – Saliva                                   | 46994 | B | 6 |
| D-DOA11M25S | Buprenorphine ( BUP) Rapid Test Midstream-Saliva                                 | 46994 | B | 6 |
| D-DOA5D20S  | Benzodiazepine (BZO) Rapid Test Device – Salvia                                  | 46994 | B | 6 |
| D-DOA5M25S  | Benzodiazepine (BZO) Rapid Test Midstream-Salvia                                 | 46994 | B | 6 |
| D-DOA6M25S  | Cocaine (COC) Rapid Test Midstream-Saliva                                        | 46994 | B | 6 |
| D-DOA47D25S | Carfentanyl (CFYL) Rapid Test Device – Salvia                                    | 46994 | B | 6 |
| D-DOA47M25S | Carfentanyl (CFYL) Rapid Test Midstream-Salvia                                   | 46994 | B | 6 |
| D-DOA31M25S | Cotinine (COT) Rapid Test Midstream-Salvia                                       | 46994 | B | 6 |
| D-DOA42D20S | Fentanyl (FYL) Rapid Test Device – Salvia                                        | 46994 | B | 6 |
| D-DOA42M25S | Fentanyl (FYL) Rapid Test Midstream-Salvia                                       | 46994 | B | 6 |
| D-DOA9D20S  | Ketamine (KET) Rapid Test Device – Saliva                                        | 46994 | B | 6 |
| D-DOA9M25S  | Ketamine (KET) Rapid Test Midstream-Salvia                                       | 46994 | B | 6 |
| D-DOA43D20S | 6-Monoacetylmorphine(6-MAM) Rapid Test Device-Saliva                             | 64154 | B | 6 |
| D-DOA43M25S | 6-Monoacetylmorphine (6-MAM) Rapid Test Midstream-salvia                         | 46994 | B | 6 |
| D-DOA12M20S | Ecstasy (MDMA) Rapid Test Midstream-Saliva                                       | 46994 | B | 6 |
| D-DOA62D25S | Methylenedioxypyrovalerone (MDPV) Rapid Test Device-Saliva                       | 46994 | B | 6 |
| D-DOA62M25S | Methylenedioxypyrovalerone (MDPV) Rapid Test Midstream-Urine                     | 46994 | B | 6 |
| D-DOA7M20S  | Methadone (MTD) Rapid Test Midstream-Saliva                                      | 46994 | B | 6 |
| D-DOA3M20S  | Opiates (OPI) Rapid Test Midstream-Saliva                                        | 46994 | B | 6 |
| D-DOA39D20S | Oxycodone (OXY) Rapid Test Device – Saliva                                       | 46994 | B | 6 |
| D-DOA39M25S | Oxycodone (OXY) Rapid Test Midstream-Saliva                                      | 46994 | B | 6 |
| D-DOA13D20S | Phencyclidine (PCP) Rapid Test Device – Saliva                                   | 46994 | B | 6 |
| D-DOA13M25S | Phencyclidine (PCP) Rapid Test Midstream-Saliva                                  | 46994 | B | 6 |
| D-DOA51D20S | Synthetic Marijuana (K2) Rapid Test Device – Salvia                              | 46994 | B | 6 |
| D-DOA51M25S | Synthetic Marijuana (K2) Rapid Test Midstream-Salvia                             | 46994 | B | 6 |
| D-DOA8M25S  | Marijuana (THC) Rapid Test Midstream-Saliva                                      | 46994 | B | 6 |
| D-DOA30D20S | Tramadol (TML) Rapid Test Device – Saliva                                        | 46994 | B | 6 |
| D-DOA30M25S | Tramadol(TML) Rapid Test Midstream-Saliva                                        | 64161 | B | 6 |
| D-DOAMM2S   | Multi-drug 2 Drugs Rapid Test Midstream-Saliva                                   | 46994 | B | 6 |
| D-DOAMM3S   | Multi-drug 3 Drugs Rapid Test Midstream-Saliva                                   | 46994 | B | 6 |
| D-DOAMM4S   | Multi-drug 4 Drugs Rapid Test Midstream-Saliva                                   | 46994 | B | 6 |
| D-DOAMM5S   | Multi-drug 5 Drugs Rapid Test Midstream-Saliva                                   | 46994 | B | 6 |
| D-DOAMM6S   | Multi-drug 6 Drugs Rapid Test Midstream-Saliva                                   | 46994 | B | 6 |
| D-DOAMM7S   | Multi-drug 7 Drugs Rapid Test Midstream-Saliva                                   | 46994 | B | 6 |

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



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|--------------|-----------------------------------------------------------|-------|---|----|
| D-DOA13WBD40 | PCP Rapid Test Device-WB/S/P                              | 30523 | B | 6  |
| D-DOA65WBD40 | PPX Rapid Test Device – WB/S/P                            | 46994 | B | 6  |
| D-DOA51WBD40 | K2 Rapid Test Device-WB/S/P                               | 30519 | B | 6  |
| D-DOA10WBD40 | TCA Rapid Test Device – WB/S/P                            | 30524 | B | 6  |
| D-DOA67WBD40 | THC Rapid Test Device – WB/S/P                            | 46994 | B | 6  |
| D-DOA30WBD20 | TML Rapid Test Device – WB/S/P                            | 46994 | B | 6  |
| D-DOAWBM2    | Multi-drug 2 drugs Rapid Test Device – WB/S/P             | 46994 | B | 6  |
| D-DOAWBM3    | Multi-drug 3 drugs Rapid Test Device – WB/S/P             | 46994 | B | 6  |
| D-DOAWBM4    | Multi-drug 4 drugs Rapid Test Device – WB/S/P             | 46994 | B | 6  |
| D-DOAWBM5    | Multi-drug 5 drugs Rapid Test Device – WB/S/P             | 46994 | B | 6  |
| D-DOAWBM6    | Multi-drug 6 drugs Rapid Test Device – WB/S/P             | 46994 | B | 6  |
| D-DOAWBM7    | Multi-drug 7 drugs Rapid Test Device – WB/S/P             | 46994 | B | 6  |
| D-DOAWBM8    | Multi-drug 8 drugs Rapid Test Device – WB/S/P             | 46994 | B | 6  |
| D-DOAWBM9    | Multi-drug 9 drugs Rapid Test Device – WB/S/P             | 46994 | B | 6  |
| D-DOAWBM10   | Multi-drug 10 drugs Rapid Test Device – WB/S/P            | 46994 | B | 6  |
| D-DOAWBM11   | Multi-drug 11 drugs Rapid Test Device – WB/S/P            | 46994 | B | 6  |
| D-DOAWBM12   | Multi-drug 12 drugs Rapid Test Device – WB/S/P            | 46994 | B | 6  |
| D-DOAWBM13   | Multi-drug 13 drugs Rapid Test Device – WB/S/P            | 46994 | B | 6  |
| D-DOAWBM14   | Multi-drug 14 drugs Rapid Test Device – WB/S/P            | 46994 | B | 6  |
| D-DOAWBM15   | Multi-drug 15 drugs Rapid Test Device – WB/S/P            | 46994 | B | 6  |
| D-DOAWBM16   | Multi-drug 16 drugs Rapid Test Device – WB/S/P            | 46994 | B | 6  |
| D-DOAWBM17   | Multi-drug 17 drugs Rapid Test Device – WB/S/P            | 46994 | B | 6  |
| D-DOA1D20H   | Amphetamine (AMP) Rapid Test Device – Hair                | 46994 | B | 6  |
| D-DOA4D20H   | Barbiturates (BAR) Rapid Test Device – Hair               | 46994 | B | 6  |
| D-DOA11D20H  | Buprenorphine ( BUP) Rapid Test Device – Hair             | 46994 | B | 6  |
| D-DOA5D20H   | Benzodiazepine (BZO) Rapid Test Device – Hair             | 46994 | B | 6  |
| D-DOA6D20H   | Cocaine (COC) Rapid Test Device – Hair                    | 46994 | B | 6  |
| D-DOA31D20H  | Cotinine (COT) Rapid Test Device – Hair                   | 46994 | B | 6  |
| D-DOA9D20H   | Ketamine (KET) Rapid Test Device – Hair                   | 46994 | B | 6  |
| D-DOA43D20H  | 6-Monoacetylmorphine (6-MAM)Rapid Test Device – Hair      | 46994 | B | 6  |
| D-DOA12D20H  | Ecstasy (MDMA) Rapid Test Device – Hair                   | 46994 | B | 6  |
| D-DOA2D20H   | Methamphetamine ( MET) Rapid Test Device – Hair           | 46994 | B | 6  |
| D-DOA38D20H  | Morphine (MOP) Rapid Test Device -Hair                    | 46994 | B | 6  |
| D-DOA39D20H  | Oxycodone (OXY) Rapid Test Device -Hair                   | 46994 | B | 6  |
| D-DOA13D20H  | Phencyclidine (PCP) Rapid Test Device – Hair              | 46994 | B | 6  |
| D-DOAM2H     | Multi-drug 2 drugs Rapid Test Device – Hair               | 46994 | B | 6  |
| D-DOAM3H     | Multi-drug 3 drugs Rapid Test Device – Hair               | 46994 | B | 6  |
| D-DOAM4H     | Multi-drug 4 drugs Rapid Test Device -Hair                | 46994 | B | 6  |
| D-DOAM5H     | Multi-drug 5 drugs Rapid Test Device – Hair               | 46994 | B | 6  |
| D-DOAM6H     | Multi-drug 6 drugs Rapid Test Device – Hair               | 46994 | B | 6  |
| D-DOAM7H     | Multi-drug 7 drugs Rapid Test Device – Hair               | 46994 | B | 6  |
| D-DOAM8H     | Multi-drug 8 drugs Rapid Test Device – Hair               | 46994 | B | 6  |
| D-DOAM9H     | Multi-drug 9 drugs Rapid Test Device – Hair               | 46994 | B | 6  |
| D-CEAD20     | CEA Rapid Test Device – WB/S/P                            | 54617 | C | 3h |
| D-CFOB10     | Calprotectin and FOB Combo Rapid Test Device – Feces      | 66462 | B | 6  |
| D-HBHBD20    | Hb+Hb-Hp Combo Rapid Test Device – Feces                  | 54557 | B | 6  |
| D-TRFOB10    | 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 |

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|-------------|--------------------------------------------------------------------------------|-------|---|----|
| 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 | $\alpha$ -Pyrrolidinovalerophenone ( $\alpha$ -PVP ) Rapid Test Device -Urine  | 46994 | B | 6  |
| D-RDOA4D40  | Barbiturate (BAR) Rapid Test Device-urine                                      | 46994 | B | 6  |
| D-RDOA11D40 | Buprenorphine (BUP) Rapid Test Device -Urine                                   | 65385 | B | 6  |
| D-RDOA5D40  | Benzodiazepines (BZO) Rapid Test Device-urine                                  | 46994 | B | 6  |
| D-RDOA56D40 | Clonazepam (CLO) Rapid Test Device -Urine                                      | 55532 | B | 6  |
| D-RDOA6D40  | COCAINE (COC) Rapid Test Device-urine                                          | 46994 | B | 6  |
| D-RDOA31D40 | Cotinine (COT) Rapid Test Device -Urine                                        | 64155 | B | 6  |
| D-RDOA41D40 | Diazepam (DIA) Rapid Test Device -urine                                        | 64157 | B | 6  |
| D-RDOA57D40 | Ethylenediamine-dimethylphosphinic acid (EDDP) Rapid Test Device -urine        | 42656 | B | 6  |
| D-RDOA58D40 | Ethyl Glucuronide (ETG) Rapid Test Device-urine                                | 60669 | B | 6  |
| D-RDOA42D40 | Fentanyl (FYL) Rapid Test Device -urine                                        | 64153 | B | 6  |
| D-RDOA9D40  | Ketamine (KET)Rapid Test Device-urine                                          | 62130 | B | 6  |
| D-RDOA43D40 | 6-Monoacetylmorphine (6-MAM) Rapid Test Device -urine                          | 64154 | B | 6  |
| D-RDOA12D40 | Ecstasy (MDMA) Rapid Test Device-urine                                         | 55489 | B | 6  |
| D-RDOA61D40 | Tenamfetamine (MDA) Rapid Test Device -urine                                   | 46994 | B | 6  |
| D-RDOA62D40 | Methylenedioxypyrovalerone (MDPV) Rapid Test Device -urine                     | 46994 | B | 6  |
| D-RDOA63D40 | Methylphenidate(MPD) Rapid Test Device -urine                                  | 46994 | B | 6  |
| D-RDOA2D40  | Methamphetamine (MET) Rapid Test Device -urine                                 | 55498 | B | 6  |
| D-RDOA38D40 | Morphine (MOP) Rapid Test Device -urine                                        | 55701 | B | 6  |
| D-RDOA64D40 | Methaqualone (MQL) Rapid Test Device -urine                                    | 55696 | B | 6  |
| D-RDOA7D40  | Methadone (MTD) Rapid Test Device -urine                                       | 30521 | B | 6  |
| D-RDOA3D40  | Opiates (OPI) Rapid Test Device -urine                                         | 55701 | B | 6  |
| D-RDOA39D40 | Oxycodone (OXY) Rapid Test Device -urine                                       | 55734 | B | 6  |
| D-RDOA13D40 | Phencyclidine (PCP) Rapid Test Device -urine                                   | 30523 | B | 6  |
| D-RDOA65D40 | Propoxyphene (PPX) Rapid Test Device -urine                                    | 62324 | B | 6  |

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| 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  | $\beta$ -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   | $\beta$ 2MG Test Device-WB/S/P                                            | 53930 | B | 6  |
| D-FINGALD25  | N-GAL Test Device-Urine                                                   | 47426 | C | 3j |
| D-FIHBA1CD25 | HbA1c Test Device-WB                                                      | 65958 | C | 3k |
| D-FIIGED25   | IgE Test Device-WB/S/P                                                    | 60380 | C | 3e |
| D-FIFED25    | Ferritin Test Device-S/P                                                  | 58769 | B | 6  |
| D-CAND20     | Candida Albicans Rapid Test Device – Swab                                 | 63216 | B | 6  |
| D-CHAGBD20   | Cholera Ag O139 Rapid Test Device – Feces                                 | 51840 | c | 3c |
| D-COVAGD20B  | SARS-CoV-2 Antigen Rapid Test Device – swab                               | 64787 | D | 1  |
| D-COVAGD20H  | COVID-19 Antigen Rapid Test Device – Oral Fluid                           | 64787 | D | 1  |
| D-COVGD25    | COVID-19 IgG Rapid Test Device – WB/S/P                                   | 64831 | D | 1  |
| D-COVID1     | SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test Device – Nasal Swab | 64770 | D | 1  |
| D-COVID20    | SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test Device – Nasal Swab | 64770 | D | 1  |
| D-DOA12D20S  | Ecstasy (MDMA) Rapid Test Device – Saliva                                 | 46994 | B | 6  |
| D-DOA2D20S   | Methamphetamine (MET) Rapid Test Device - Saliva                          | 46994 | B | 6  |
| D-DOA31D20S  | Cotinine (COT) Rapid Test Device – Salvia                                 | 46994 | B | 6  |
| D-DOA3D20S   | Opiates (OPI) Rapid Test Device – Saliva                                  | 46994 | B | 6  |
| D-DOA43D20D  | 6-Monoacetylmorphine (6-MAM) Rapid Test Device – Salvia                   | 46994 | B | 6  |
| D-DOA50D40   | Pregabalin (PGB) Rapid Test Device – Urine                                | 46994 | B | 6  |
| D-DOA50S50   | Pregabalin (PGB) Rapid Test Strip – Urine                                 | 46994 | B | 6  |
| D-DOA51D20   | Synthetic Marijuana (K2) Rapid Test Device – Urine                        | 46994 | B | 6  |
| D-DOA51S50   | Synthetic Marijuana (K2) Rapid Test Strip – Urine                         | 46994 | B | 6  |
| D-DOA58S40   | Ethyl Glucuronide (ETG) Rapid Test Strip – Urine                          | 46994 | B | 6  |
| D-DOA62S25S  | Methylenedioxypyrovalerone (MDPV) Rapid Test Device – Saliva              | 46994 | B | 6  |
| D-DOA6D20S   | Cocaine (COC) Rapid Test Device – Saliva                                  | 46994 | B | 6  |
| D-DOA7D20S   | Methadone (MTD) Rapid Test Device – Saliva                                | 46994 | B | 6  |
| D-DOAS50     | Methadone (MTD) Rapid Test Strip – Urine                                  | 46994 | B | 6  |
| D-DOA8D20S   | Marijuana (THC) Rapid Test Device – Saliva                                | 46994 | B | 6  |
| D-DOAM10UT   | Multi- Drug 10 drugs inc. T ramadol Rapid Test Device – Urine             | 46994 | B | 6  |
| D-GL10D      | Giardia Lamblia Rapid Test Device – Feces                                 | 52249 | B | 6  |
| D-GONOD20    | Gonorrhea Rapid Test Device – Swab                                        | 51228 | C | 3a |
| D-HBAC1CD10  | HbA1c Rapid Test Device – WB                                              | 65322 | C | 3k |
| D-HCGS0      | (hCG) Rapid Test Device plain/no box – Urine/S/P                          | 66850 | B | 6  |
| D-HPD20      | H.pylori Rapid Test Device – WB/S/P                                       | 30825 | B | 6  |
| D-HPD40      | H.pylori Antibody Rapid Test Device – WB/S/P                              | 30825 | B | 6  |
| D-HPVD20     | HPV Antigen Rapid Test Device – Cervical Swab                             | 63733 | B | 6  |

|              |                                                                   |       |   |    |
|--------------|-------------------------------------------------------------------|-------|---|----|
| D-INFABS50   | Influenza A+B Rapid Test Strip – Swab/Nasal Aspirate              | 49119 | B | 6  |
| D-LACFD20    | Lactoferrin Rapid Test Device – Feces                             | 53910 | B | 6  |
| D-MASQS50    | Micro-Albumin Semi-Quantitative Rapid Test Strip – Urine          | 60471 | B | 6  |
| D-MCKTMD40   | Myoglobin/CK-MB/Troponin I Combo Rapid Test Device – WB/S/P       | 61295 | C | 3j |
| D-TETD20     | Tetanus Rapid Test Device – WB/S/P                                | 50867 | B | 6  |
| D-TPS100     | Syphilis Rapid Test Strip – WB/S/P                                | 51788 | C | 3a |
| D-TRFOBHB    | Transferrin, FOB, Hb+Hb+Hp Rapid Test Device – Feces              | 65270 | B | 6  |
| D-TROPQD20   | Troponin I (cTNI) Semi Quantitative Test Rapid Test Device –      | 46989 | C | 3j |
| D-TRVAD10    | Trichomonas Vaginalis Rapid Test Device – Swab                    | 52471 | C | 3a |
| D-TYGMCD40   | Typhoid Rapid Test Device – WB/S/P                                | 63976 | C | 3e |
| D-TYGMCD40   | Typhoid Rapid Test Device – S/P                                   | 63976 | C | 3e |
| D-COVAGD25H  | SARS-CoV-2 Antigen Rapid Test Device – Oral Fluid                 | 64787 | D | 1  |
| D-DOA30DM25S | Tramadol (TML) Rapid Test Device – Midstream Saliva               | 46994 | B | 6  |
| D-SHID20     | Shigella Rapid Test Device – Faeces                               | 64874 | C | 3b |
| D-FICOVID10  | COVID-19 Antigen Rapid Test Device – Nasopharyngeal Swab          | 64787 | D | 1  |
| D-HAVMD20    | HAV IgM Rapid Test S/P                                            | 48270 | B | 6  |
| D-NGALD10    | NGAL Rapid test WB/S/P                                            | 47427 | C | 3j |
| D-COVD25B    | SARS-CoV-2 IgG/ IgM Rapid Test Device (WB/S/P)                    | 64756 | D | 1  |
| D-CHAGS50    | Cholera Ag Rapid test - Faeces                                    | 51840 | C | 3c |
| D-RDOA40D40  | Alcohol(ALC) Rapid Test Casette (for Reader)-Urine                | 64159 | B | 6  |
| D-RDOA6725S  | Marijuana (THC) Rapid Test device (for Reader)-Saliva             | 30519 | B | 6  |
| D-RDOA1M25S  | Amphetamine (AMP) Rapid Test Midstream (for Reader)-Saliva        | 46994 | B | 6  |
| D-RDOA4M25S  | Barbiturate (BAR) Rapid Test Midstream (for Reader)-Saliva        | 46994 | B | 6  |
| D-RDOA11M25S | Buprenorphine (BUP) Rapid Test Midstream (for Reader)-Saliva      | 65385 | B | 6  |
| D-RDOA5M20S  | Benzodiazepines (BZO) Rapid Test Midstream (for Reader)-Saliva    | 46994 | B | 6  |
| D-RDOA6M25S  | COCAINE (COC) Rapid Test Midstream (for Reader)-Saliva            | 46994 | B | 6  |
| D-RDOA2M25S  | Methamphetamine (MET) Rapid Test Midstream (for Reader)-Saliva    | 55498 | B | 6  |
| D-RDOA7M25S  | Methadone (MTD) Rapid Test Midstream (for Reader)-Saliva          | 30521 | B | 6  |
| D-RDOA3M25S  | Opiates (OPI) Rapid Test Midstream (for Reader)-Saliva            | 55701 | B | 6  |
| D-RDOA13M25S | Phencyclidine (PCP) Rapid Test Midstream (for Reader)-Saliva      | 30523 | B | 6  |
| D-RDOA51M25S | Synthetic Marijuana (K2) Rapid Test Midstream (for Reader)-Saliva | 30519 | B | 6  |
| D-FIMAD25    | Micro-albumin Test device(for Analyzer)-urine                     | 53479 | B | 6  |
| D-LEIGID20   | Legionella Antigen Rapid Test Device – T hroat Swab               | 51054 | C | 3c |
| D-LEIGID40   | Legionella Antigen Rapid Test Device – Throat Swab                | 51054 | C | 3c |
| D-TBSPD10    | Tuberculosis (TB) Rapid Test Device – WB/S/P                      | 65814 | C | 3e |
| D-TBSPD20    | Tuberculosis (TB) Rapid Test Device – WB/S/P                      | 65814 | C | 3e |
| D-MPPFVBD20  | Malaria P.f./P.v. Rapid Test Device -WB/S/P                       | 63331 | C | 3c |
| D-DGMCMD20   | Dengue + Chik (IgG/IgM-Chik IgM) Test<br>– WB/S/P                 | 63970 | B | 6  |

## Annex

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

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

## ANNEX II

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

| Date of Update        | Update made                                                   | Signature |            |      |
|-----------------------|---------------------------------------------------------------|-----------|------------|------|
| 10/04/2024            | New Brand Addition (Rapid Biotech)                            | Yanli Wu  |            |      |
| Part/Catalogue Number | Description/Name                                              | GMDN Code | IVDR CLASS | Rule |
| D-ADAGD20             | Adenovirus pneumoniae Antigen Rapid Test -Swab                | 49856     | B          | 6    |
| D-ARD10               | Adenovirus & RSV Combo Rapid Test -Nasal Swab                 | 64770     | B          | 6    |
| D-ARID10              | Adenovirus, RSV & Influenza A+B Combo Rapid Test -Nasal Swab  | 64770     | B          | 6    |
| D-EVGD10              | EBV VCA IgG Rapid Test -Whole Blood/Serum/Plasma              | 64773     | C          | 3e   |
| D-ENGD10              | EBNA IgG Rapid Test -Whole Blood/Serum/Plasma                 | 49689     | C          | 3e   |
| D-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-TYGMD20             | Typhoid IgG/IgM Rapid Test -Serum/Plasma                      | 63976     | C          | 3e   |
| D-TYGMCD20            | Typhoid IgG/IgM Rapid Test -Whole Blood/Serum/Plasma          | 51560     | C          | 3e   |
| D-TYGMD40             | Typhoid IgG/IgM Rapid Test -Serum/Plasma                      | 63976     | C          | 3e   |
| D-TYGMCD40            | Typhoid IgG/IgM Rapid Test -Whole Blood/Serum/Plasma          | 63976     | C          | 3e   |
| D-TYGMS50             | Typhoid IgG/IgM Rapid Test -Whole Blood/Serum/Plasma          | 63976     | C          | 3e   |



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

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

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

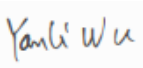
|                  |                                                                                                            |       |   |    |
|------------------|------------------------------------------------------------------------------------------------------------|-------|---|----|
| D-CA199D10       | CA19-9 Rapid Test -Whole Blood/Serum/Plasma                                                                | 64536 | C | 3h |
| D-TRFOB20        | Transferrin/FOB Rapid Test -Faeces                                                                         | 65270 | B | 6  |
| D-TRFOBHB        | Transferrin/FOB & Hb+Hb-Hp Rapid Test -Faeces                                                              | 65270 | B | 6  |
| D-TRFOBHBD20     | Transferrin/FOB and Hb-Hp Combo Rapid Test -Faeces                                                         | 65270 | B | 6  |
| D-TROPD20        | Cardiac Troponin I Rapid Test -Whole Blood/Serum/Plasma                                                    | 46989 | C | 3j |
| D-CTTD10         | Cardiac Troponin T Rapid Test -Whole Blood/Serum/Plasma                                                    | 46989 | C | 3j |
| D-CRPD10         | C-reactive protein (CRP) Rapid Test -Whole Blood/Serum/Plasma                                              | 58395 | B | 6  |
| D-CRPSQD10       | C-reactive protein (CRP) (Semi-Quantitative) Rapid Test -Whole Blood/Serum/Plasma                          | 58395 | B | 6  |
| D-CRPS10         | C-reactive protein (CRP) Rapid Test -Whole Blood/Serum/Plasma                                              | 58395 | B | 6  |
| D-CRPSQS10       | C-reactive protein (CRP) (Semi-Quantitative) Rapid Test -Whole Blood/Serum/Plasma                          | 58395 | B | 6  |
| D-DIMERD10       | D-Dimer Rapid Test -Whole Blood/Serum/Plasma                                                               | 47343 | C | 3k |
| D-FABD10         | H-FABP Rapid Test -Whole Blood/Serum/Plasma                                                                | 66449 | C | 3j |
| D-HFCD25         | H-FABP & cTnI Combo Rapid Test -Whole Blood/Serum/Plasma                                                   | 61295 | C | 3j |
| D-HMCKCTD10      | H-FABP & Myoglobin & CK-MB & CTNI Combo Rapid Test -Whole Blood/Serum/Plasma                               | 61295 | C | 3j |
| D-NTPD10         | NT-proBNP rapid test Whole Blood/Serum/Plasma                                                              | 47041 | C | 3j |
| D-MCKTMD20       | Myoglobin & CK-MB & Troponin I Combo Rapid Test -Whole Blood/Serum/Plasma                                  | 61295 | C | 3j |
| D-MYOD10         | Myoglobin Test – whole blood/serum/plasma                                                                  | 46987 | C | 3j |
| D-PCTD40         | Procalcitonin (PCT) Rapid Test -Serum/Plasma                                                               | 58305 | B | 6  |
| D-PCTD10         | Procalcitonin (PCT) Rapid Test -Serum/Plasma                                                               | 58305 | B | 6  |
| D-CKMBD10        | CK-MB Rapid Test -Whole Blood/Serum/Plasma                                                                 | 52995 | C | 3j |
| D-COVD25         | 2019-nCoV IgG/IgM Rapid Test (Self Testing) -Whole Blood/Serum/Plasma                                      | 64756 | D | 1  |
| D-COVAGIFD25     | COVID-19 and Influenza A+B Antigen Combo Rapid Test (Self Testing) -Swab                                   | 64770 | D | 1  |
| D-COVAGD25B      | SARS-CoV-2 Antigen Rapid Test -Nasal Swab                                                                  | 64787 | D | 1  |
| D-COVAGD20N      | SARS-CoV-2 Antigen Rapid Test -Nasal Swab                                                                  | 64787 | D | 1  |
| D-COVID1         | SARS-CoV-2 & Influenza A+B Antigen Rapid Test -Nasal Swab                                                  | 64770 | D | 1  |
| D-COVID20        | SARS-CoV-2 & Influenza A+B Antigen Rapid Test -Nasal Swab                                                  | 64770 | D | 1  |
| D-COVGD25        | COVID-19 IgG Rapid Test -Whole Blood/Serum/Plasma                                                          | 64831 | D | 1  |
| D-COVIRCS20      | COVID-19,Flu A+B & RSV Combo Rapid Test -Nasopharyngeal swab                                               | 64770 | D | 1  |
| D-SCIABRSVAPNS20 | SARS-CoV-2 & Influenza A+B & RSV & Adenovirus & M.pneumoniae Antigen Combo Rapid Test -Nasopharyngeal swab | 64770 | D | 1  |

|            |                                                                   |       |   |    |
|------------|-------------------------------------------------------------------|-------|---|----|
| D-HBA1CD10 | HbA1c Rapid Test -Faeces                                          | 65322 | C | 3k |
| D-IGED10   | IgE Rapid Test -Whole Blood/Serum/Plasma                          | 65991 | C | 3e |
| D-LACFD10  | Lactoferrin Rapid Test -Faeces                                    | 53910 | B | 6  |
| D-CALD10   | Calprotectin Rapid Test -Faeces                                   | 60775 | B | 6  |
| D-CALAD10  | Calprotectin & Lactoferrin Rapid test - Faeces                    | 60775 | B | 6  |
| D-FESQD10  | Ferritin Rapid Test (Semi-Quantitative) -Whole Blood/Serum/Plasma | 66124 | B | 6  |
| D-FED10    | Ferritin Rapid Test -Whole Blood/Serum/Plasma                     | 66124 | B | 6  |
| D-VDD10    | Vitamin D Rapid Test -Whole Blood                                 | 60955 | B | 6  |
| D-DOAM2U   | DOA Multi 2 Parameters Rapid Test -Urine                          | 46994 | B | 6  |
| D-DOAM3U   | DOA Multi 3 Parameters Rapid Test -Urine                          | 46994 | B | 6  |
| D-DOAM4U   | DOA Multi 4 Parameters Rapid Test -Urine                          | 46994 | B | 6  |
| D-DOAM5U   | DOA Multi 5 Parameters Rapid Test -Urine                          | 46994 | B | 6  |
| D-DOAM6U   | DOA Multi 6 Parameters Rapid Test -Urine                          | 46994 | B | 6  |
| D-DOAM7U   | DOA Multi 7 Parameters Rapid Test -Urine                          | 46994 | B | 6  |
| D-DOAM8U   | DOA Multi 8 Parameters Rapid Test -Urine                          | 46994 | B | 6  |
| D-DOAM9U   | DOA Multi 9 Parameters Rapid Test -Urine                          | 46994 | B | 6  |
| D-DOAM10U  | DOA Multi 10 Parameters Rapid Test -Urine                         | 46994 | B | 6  |
| D-DOAM11U  | DOA Multi 11 Parameters Rapid Test -Urine                         | 46994 | B | 6  |
| D-DOAM12U  | DOA Multi 12 Parameters Rapid Test -Urine                         | 46994 | B | 6  |
| D-DOAM13U  | DOA Multi 13 Parameters Rapid Test -Urine                         | 46994 | B | 6  |
| D-DOAM14U  | DOA Multi 14 Parameters Rapid Test -Urine                         | 46994 | B | 6  |
| D-DOAM15U  | DOA Multi 15 Parameters Rapid Test -Urine                         | 46994 | B | 6  |
| D-DOAM16U  | DOA Multi 16 Parameters Rapid Test -Urine                         | 46994 | B | 6  |
| D-DOAM17U  | DOA Multi 17 Parameters Rapid Test -Urine                         | 46994 | B | 6  |
| D-DOACM2   | DOA Multi 2 Parameters -1 Step Urine Cup                          | 46994 | B | 6  |
| D-DOACM3   | DOA Multi 3 Parameters -1 Step Urine Cup                          | 46994 | B | 6  |
| D-DOACM4   | DOA Multi 4 Parameters -1 Step Urine Cup                          | 46994 | B | 6  |
| D-DOACM5   | DOA Multi 5 Parameters -1 Step Urine Cup                          | 46994 | B | 6  |
| D-DOACM6   | DOA Multi 6 Parameters -1 Step Urine Cup                          | 46994 | B | 6  |
| D-DOACM7   | DOA Multi 7 Parameters -1 Step Urine Cup                          | 46994 | B | 6  |
| D-DOACM8   | DOA Multi 8 Parameters -1 Step Urine Cup                          | 46994 | B | 6  |
| D-DOACM9   | DOA Multi 9 Parameters -1 Step Urine Cup                          | 46994 | B | 6  |
| D-DOACM10  | DOA Multi 10 Parameters -1 Step Urine Cup                         | 46994 | B | 6  |
| D-DOACM11  | DOA Multi 11 Parameters -1 Step Urine Cup                         | 46994 | B | 6  |
| D-DOACM12  | DOA Multi 12 Parameters -1 Step Urine Cup                         | 46994 | B | 6  |
| D-DOACM13  | DOA Multi 13 Parameters -1 Step Urine Cup                         | 46994 | B | 6  |
| D-DOACM14  | DOA Multi 14 Parameters -1 Step Urine Cup                         | 46994 | B | 6  |
| D-DOACM15  | DOA Multi 15 Parameters -1 Step Urine Cup                         | 46994 | B | 6  |
| D-DOACM16  | DOA Multi 16 Parameters -1 Step Urine Cup                         | 46994 | B | 6  |
| D-DOACM17  | DOA Multi 17 Parameters -1 Step Urine Cup                         | 46994 | B | 6  |
| D-DOACM18  | DOA Multi 18 Parameters -1 Step Urine Cup                         | 46994 | B | 6  |
| D-DOACM19  | DOA Multi 19 Parameters -1 Step Urine Cup                         | 46994 | B | 6  |
| D-DOACM20  | DOA Multi 20 Parameters -1 Step Urine Cup                         | 46994 | B | 6  |
| D-DOACM21  | DOA Multi 21 Parameters -1 Step Urine Cup                         | 46994 | B | 6  |
| D-DOACM22  | DOA Multi 22 Parameters -1 Step Urine Cup                         | 46994 | B | 6  |
| D-DOACM2S  | DOA Multi 2 Parameters -1 Step Saliva Cup                         | 46994 | B | 6  |
| D-DOACM3S  | DOA Multi 3 Parameters -1 Step Saliva Cup                         | 46994 | B | 6  |
| D-DOACM4S  | DOA Multi 4 Parameters -1 Step Saliva Cup                         | 46994 | B | 6  |
| D-DOACM5S  | DOA Multi 5 Parameters -1 Step Saliva Cup                         | 46994 | B | 6  |
| D-DOACM6S  | DOA Multi 6 Parameters -1 Step Saliva Cup                         | 46994 | B | 6  |

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

## ANNEX III

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

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

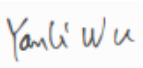
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|-----------------|----------------------------------------------------------------------------------------|-------|---|----|
| D-CIPCTK40      | Procalcitonin (PCT) Test Kit-human whole blood,                                        | 58731 | B | 6  |
| D-CICTNTK40     | Cardiac Troponin-T (cTnT) Test Kit -human serum or plasma                              | 54007 | B | 6  |
| D-CIIL6K40      | Interleukin-6 (IL-6) Test Kit-human whole blood,                                       | 53858 | B | 6  |
| D-CIT3K40       | Triiodothyronine (T3) Test Kit -human serum or plasma                                  | 58330 | B | 6  |
| D-CISAAK40      | Serum Amyloid A Protein (SAA) Test Kit-human whole blood, serum or plasma              | 65690 | B | 6  |
| D-CIHFABPK40    | Heart-fatty Acid-binding Protein (H-FABP) Test Kit- human whole blood, serum or plasma | 53377 | C | 3j |
| D-CIBNPK40      | Brain Natriuretic Peptide (BNP)Test Kit-human plasma                                   | 47351 | C | 3k |
| D-CIsST2K40     | Growth Stimulation Expressed Gene 2 (ST2) Test Kit- human whole blood, serum or plasma | 66516 | C | 3k |
| D-CICPEK40      | C-Peptide (CP) Test Kit-human serum and plasma                                         | 54130 | B | 6  |
| D-CICA125K40    | Cancer Antigen 125 (CA125) Test Kit -human serum or plasma                             | 54588 | C | 3h |
| D-CICYFRA211K40 | Cytokeratin-19-fragment (CYFRA21-1) Test Kit-human serum or plasma                     | 54612 | B | 6  |
| D-CISCKK40      | Squamous Cell Carcinoma Antigen (SCC) Test Kit-human serum or plasma                   | 61418 | B | 6  |
| D-CIPGIK40      | Pepsinogen I (PG I) Test Kit-human serum or plasma                                     | 61414 | B | 6  |
| D-CIPGIK40      | Pepsinogen II (PG II) Test Kit -human serum or plasma                                  | 61415 | B | 6  |
| D-CIPGRPK40     | Gastrin Releasing Peptide Precursor (ProGRP) Test Kit- human serum or plasma           | 54660 | B | 6  |
| D-CIFT3K40      | Free Triiodothyronine (FT3) Test Kit-human serum or plasma                             | 54417 | B | 6  |
| D-CIHBAK40      | Glycated Hemoglobin (HbA1c) Test Kit-human whole blood                                 | 61010 | C | 3k |
| D-CITGK40K40    | Thyroglobulin (TG) Test Kit-human serum or plasma                                      | 54375 | B | 6  |
| D-CICA153K40    | Cancer Antigen 15-3 (CA15-3) Test Kit-human serum or plasma                            | 60975 | C | 3h |
| D-CIFAK40       | Folic Acid (FA) Test Kit- human serum                                                  | 60982 | B | 6  |
| D-CIhsCTIK40    | High Sensitive Cardiac Troponin-I (hs-cTnI) Test Kit- human serum or plasma            | 60780 | C | 3j |
| D-CIPROGK40     | Progesterone Test Kit-human serum or plasma                                            | 54322 | B | 6  |
| D-CICA242K40    | Cancer Antigen 242 (CA242) Test Kit-human serum or plasma                              | 66062 | B | 6  |



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

## ANNEX IV

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

| Date of Update        | Update made                                                                                      | Signature                                                                           |            |      |
|-----------------------|--------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|------------|------|
| 15/07/2024            | New Brand Addition (Rapid Biotech)                                                               |  |            |      |
| Part/Catalogue Number | Description/Name                                                                                 | GMDN Code                                                                           | IVDR CLASS | Rule |
| D-CHIKWBD40           | Chikungunya IgG/IgM Rapid Test Device – WB/S/P                                                   | 63970                                                                               | B          | 6    |
| D-HCGUS25             | hCG Pregnancy Rapid Test Cannister Strip – Urine                                                 | 66850                                                                               | B          | 6    |
| D-HPS50               | H.pylori Antibody Rapid Test Strip – WB/S/P                                                      | 30825                                                                               | B          | 6    |
| D-DGMD20              | Dengue Rapid Test Device – WB/S/P                                                                | 63238                                                                               | B          | 6    |
| D-DAGD20              | Dengue NS1 Rapid Test Device – WB/S/P                                                            | 62946                                                                               | C          | 3b   |
| D-CHIKMD20            | Chikungunya IgG/IgM Rapid Test Device– WB/S/P                                                    | 60870                                                                               | B          | 6    |
| D-FILGMD20            | Filariasis IgG/IgM Rapid Test Device – WB/S/P                                                    | 52508                                                                               | B          | 6    |
| D-INFS20              | Influenza A Rapid Test Strip - Swab/Nasal Aspirate<br>Influenza A Rapid Test Device - Swab/Nasal | 49150                                                                               | B          | 6    |
| D-COVAGD25            | COVID-19 Antigen Rapid Test Strip -<br>Nasopharyngeal Swab                                       | 64787                                                                               | D          | 1    |
| D-MPPFPVD20           | Malaria P.f./P.v. Rapid Test Device - WB                                                         | 52311                                                                               | C          | 3c   |
| D-TYPGMD20            | Typhoid Rapid Test Strip - WB/S/P<br>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    |

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|------------|----------------------------------------------------------------------------------------------------------------------------------|-------|---|---|
| D-DOA38D40 | Pregabalin (PGB) Rapid test Strip- Urine<br>Pregabalin (PGB) Rapid test Device-Urine<br>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 |

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|-------------|-------------------------------------------------------------------------------------------------------|-------|---|----|
| 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<br>Cocaine (COC) Rapid Test Device - Saliva               | 46994 | B | 6  |
| D-DOA18D20  | Methamphetamine (MET) Rapid Test Midstream- Saliva<br>Methamphetamine (MET) Rapid Test Device- Saliva | 55498 | B | 6  |
| D-DOA19D20  | Opiates (OPI) Test Device- Saliva<br>Opiates (OPI) Test Midstream- Saliva                             | 55701 | B | 6  |
| D-DOA20D20  | Ecstasy (MDMA) Rapid Test Midstream - Saliva<br>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 | $\alpha$ -Pyrrolidinovalerophenone ( $\alpha$ -PVP ) Rapid Test Device – Urine | 46994 | B | 6 |
| D-DOA54P40 | $\alpha$ -PVP Rapid Test Panel – Urine                                         | 46994 | B | 6 |
| D-DOA54S50 | $\alpha$ -PVP Rapid Test Strip – Urine                                         | 46994 | B | 6 |
| D-DOA4P40  | Barbiturate (BAR) Rapid Test Panel – Urine                                     | 46994 | B | 6 |
| D-DOA11P40 | Buprenorphine (BUP) Rapid Test Panel – Urine                                   | 46994 | B | 6 |
| D-DOA5P40  | Benzodiazepines (BZO) Rapid Test Panel – Urine                                 | 46994 | B | 6 |
| D-DOA45D20 | Cathine (CAT) Rapid Test Device – Urine                                        | 46994 | B | 6 |
| D-DOA45P40 | Cathine (CAT) Rapid Test Panel – Urine                                         | 46994 | B | 6 |
| D-DOA45S50 | Cathine (CAT) Rapid Test Strip – Urine                                         | 46994 | B | 6 |
| D-DOA46D20 | Caffeine (CAF) Rapid Test Device – Urine                                       | 46994 | B | 6 |
| D-DOA46P40 | Caffeine (CAF) Rapid Test Panel – Urine                                        | 46994 | B | 6 |
| D-DOA46S50 | Caffeine (CAF) Rapid Test Strip – Urine                                        | 46994 | B | 6 |
| D-DOA37P40 | Carisoprodol (CAR) Rapid Test Panel – Urine                                    | 46994 | B | 6 |
| D-DOA55D40 | Cannabinol (CNB) Rapid Test Device – Urine                                     | 46994 | B | 6 |
| D-DOA55P40 | Cannabinol (CNB) Rapid Test Panel – Urine                                      | 46994 | B | 6 |
| D-DOA55S50 | Cannabinol (CNB) Rapid Test Strip – Urine                                      | 46994 | B | 6 |
| D-DOA47D20 | Carfentanyl (CFYL) Rapid Test Device – Urine                                   | 46994 | B | 6 |
| D-DOA47P40 | Carfentanyl (CFYL) Rapid Test Panel – Urine                                    | 46994 | B | 6 |
| D-DOA47S50 | Carfentanyl (CFYL) Rapid Test Strip – Urine                                    | 46994 | B | 6 |
| D-DOA56D40 | Clonazepam (CLO) Rapid Test Device – Urine                                     | 46994 | B | 6 |
| D-DOA56P40 | Clonazepam (CLO) Rapid Test Panel – Urine                                      | 46994 | B | 6 |
| D-DOA56S50 | Clonazepam (CLO) Rapid Test Strip – Urine                                      | 46994 | B | 6 |
| D-DOA6P40  | Cocaine (COC) Rapid Test Panel – Urine                                         | 46994 | B | 6 |
| D-DOA31D20 | Cotinine (COT) Rapid Test Device – Urine                                       | 46994 | B | 6 |
| D-DOA31P40 | Cotinine (COT) Rapid Test Panel – Urine                                        | 46994 | B | 6 |
| D-DOA31S50 | Cotinine (COT) Rapid Test Strip – Urine                                        | 46994 | B | 6 |
| D-DOA41P40 | Diazepam (DIA) Rapid Test Panel – Urine                                        | 46994 | B | 6 |
| D-DOA57D40 | Ethylenediamine-dimethylphosphinic acid (EDDP) Rapid Test Device – Urine       | 46994 | B | 6 |
| D-DOA57P40 | Ethylenediamine-dimethylphosphinic acid (EDDP) Rapid Test Panel – Urine        | 46994 | B | 6 |
| D-DOA57S50 | Ethylenediamine-dimethylphosphinic acid (EDDP) Rapid Test Strip – Urine        | 46994 | B | 6 |
| D-DOA58D40 | Ethyl Glucuronide (ETG) Rapid Test Device – Urine                              | 46994 | B | 6 |
| D-DOA58P40 | Ethyl Glucuronide (ETG) Rapid Test Panel – Urine                               | 46994 | B | 6 |
| D-DOA58S50 | Ethyl Glucuronide (ETG) Rapid Test strip-Urine                                 | 60669 | B | 6 |
| D-DOA48D20 | Fluorketamine (FKET) Rapid Test Device – Urine                                 | 46994 | B | 6 |
| D-DOA48P40 | Fluorketamine (FKET) Rapid Test Panel-Urine                                    | 46994 | B | 6 |
| D-DOA48S50 | Fluorketamine (FKET) Rapid Test Strip – Urine                                  | 46994 | B | 6 |

|            |                                                             |       |   |   |
|------------|-------------------------------------------------------------|-------|---|---|
| D-DOA59D40 | Fluoxetine (FLX) Rapid Test Device – Urine                  | 46994 | B | 6 |
| D-DOA59P40 | Fluoxetine (FLX) Rapid Test Panel – Urine                   | 46994 | B | 6 |
| D-DOA59S50 | Fluoxetine (FLX) Rapid Test Strip – Urine                   | 46994 | B | 6 |
| D-DOA42P40 | Fentanyl (FYL) Rapid Test Panel – Urine                     | 46994 | B | 6 |
| D-DOA21P40 | Gabapentin (GAB) Rapid Test Panel – Urine                   | 46994 | B | 6 |
| D-DOA9P40  | Ketamine (KET) Rapid Test Panel – Urine                     | 46994 | B | 6 |
| D-DOA36P40 | Kratom (KRA) Rapid Test Panel – Urine                       | 46994 | B | 6 |
| D-DOA29P40 | Lysergic Acid Diethylamide (LSD) Rapid Test Panel – Urine   | 46994 | B | 6 |
| D-DOA43P40 | 6-Monoacetylmorphine (6-MAM) Rapid Test Panel – Urine       | 46994 | B | 6 |
| D-DOA60D40 | Methcathinone (MCAT) Rapid Test Device – Urine              | 46994 | B | 6 |
| D-DOA60P40 | Methcathinone (MCAT) Rapid Test Panel – Urine               | 46994 | B | 6 |
| D-DOA60S50 | Methcathinone (MCAT) Rapid Test Strip – Urine               | 46994 | B | 6 |
| D-DOA12P40 | Ecstasy (MDMA) Rapid Test Panel – Urine                     | 46994 | B | 6 |
| D-DOA61D40 | Tenamfetamine (MDA) Rapid Test Device – Urine               | 46994 | B | 6 |
| D-DOA61P40 | Tenamfetamine (MDA) Rapid Test Panel – Urine                | 46994 | B | 6 |
| D-DOA61S50 | Tenamfetamine (MDA) Rapid Test Strip – Urine                | 46994 | B | 6 |
| D-DOA62D40 | Methylenedioxypyrovalerone (MDPV) Rapid Test Device – Urine | 46994 | B | 6 |
| D-DOA62P40 | Methylenedioxypyrovalerone (MDPV) Rapid Test Panel – Urine  | 46994 | B | 6 |
| D-DOA62S50 | Methylenedioxypyrovalerone (MDPV) Rapid Test Strip – Urine  | 46994 | B | 6 |
| D-DOA2P40  | Methamphetamine (MET) Rapid Test Panel – Urine              | 46994 | B | 6 |
| D-DOA23P40 | Mephedrone HCl (MEP) Rapid Test Panel – Urine               | 46994 | B | 6 |
| D-DOA24P40 | Mescaline (MES) Rapid Test Panel – Urine                    | 46994 | B | 6 |
| D-DOA38P40 | Morphine (MOP) Rapid Test Panel – Urine                     | 46994 | B | 6 |
| D-DOA63D40 | Methylphenidate (MPD) Rapid Test Device – Urine             | 46994 | B | 6 |
| D-DOA63P40 | Methylphenidate (MPD) Rapid Test Panel – Urine              | 46994 | B | 6 |
| D-DOA63S50 | Methylphenidate (MPD) Rapid Test Strip – Urine              | 46994 | B | 6 |
| D-DOA22P40 | Meperidine (MPRD) Rapid Test Panel – Urine                  | 46994 | B | 6 |
| D-DOA64D40 | Methaqualone (MQL) Rapid Test Device – Urine                | 46994 | B | 6 |
| D-DOA64P40 | Methaqualone (MQL) Rapid Test Panel – Urine                 | 46994 | B | 6 |
| D-DOA64S50 | Methaqualone (MQL) Rapid Test Strip – Urine                 | 46994 | B | 6 |
| D-DOA7P40  | Methadone (MTD) Rapid Test Panel – Urine                    | 46994 | B | 6 |
| D-DOA3P40  | Opiates (OPI) Rapid Test Panel – Urine                      | 46994 | B | 6 |
| D-DOA3S50  | Opiates (OPI) Rapid Test Strip – Urine                      | 46994 | B | 6 |
| D-DOA39P40 | Oxycodone (OXY) Rapid Test Panel – Urine                    | 46994 | B | 6 |
| D-DOA49D20 | Olanzapine (OZP) Rapid Test Device - Urine                  | 46994 | B | 6 |
| D-DOA49P40 | Olanzapine (OZP) Rapid Test Panel – Urine                   | 46994 | B | 6 |
| D-DOA49S50 | Olanzapine (OZP) Rapid Test Strip – Urine                   | 46994 | B | 6 |
| D-DOA35P40 | Papaverine (PAP) Rapid Test Panel – Urine                   | 46994 | B | 6 |
| D-DOA13P40 | Phencyclidine (PCP) Rapid Test Panel – Urine                | 46994 | B | 6 |
| D-DOA50P40 | Pregabalin (PGB) Rapid Test Panel – Urine                   | 46994 | B | 6 |
| D-DOA65D40 | Propoxyphene (PPX) Rapid Test Device – Urine                | 46994 | B | 6 |

|            |                                                          |       |   |   |
|------------|----------------------------------------------------------|-------|---|---|
| D-DOA65P40 | Propoxyphene (PPX) Rapid Test Panel – Urine              | 46994 | B | 6 |
| D-DOA65S50 | Propoxyphene (PPX) Rapid Test Strip – Urine              | 46994 | B | 6 |
| D-DOA34P40 | Quetiapine (QTP) Rapid Test Panel – Urine                | 46994 | B | 6 |
| D-DOA66D40 | Risperidone (RPD) Rapid Test Device-Urine                | 46994 | B | 6 |
| D-DOA66P40 | Risperidone (RPD) Rapid Test Panel-Urine                 | 46994 | B | 6 |
| D-DOA66S50 | Risperidone (RPD) Rapid Test strip-Urine                 | 46994 | B | 6 |
| D-DOA51P40 | Synthetic Marijuana (K2) Rapid Test Panel – Urine        | 46994 | B | 6 |
| D-DOA10P40 | Tricyclic Antidepressants (TCA) Rapid Test Panel – Urine | 30524 | B | 6 |
| D-DOA8P40  | Marijuana (THC) Rapid Test Panel – Urine                 | 46994 | B | 6 |
| D-DOA33P40 | Tilidine (TLD) Rapid Test Panel – Urine                  | 46994 | B | 6 |
| D-DOA33S50 | Tilidine (TLD) Rapid Test Strip – Urine                  | 46994 | B | 6 |
| D-DOA30P40 | Tramadol (TML) Rapid Test Panel – Urine                  | 46994 | B | 6 |
| D-DOA25P40 | Tropicamide (TRO) Rapid Test Panel – Urine               | 46994 | B | 6 |
| D-DOA26P40 | Trazodone (TZD) Rapid Test Panel – Urine                 | 46994 | B | 6 |
| D-DOA27P40 | UR-144 Rapid Test Panel – Urine                          | 46994 | B | 6 |
| D-DOA28P40 | Zaleplon (ZAL) Rapid Test Panel – Urine                  | 46994 | B | 6 |
| D-DOA68D40 | Zolpidem (ZOL) Rapid Test Device – Urine                 | 46994 | B | 6 |
| D-DOA68P40 | Zolpidem (ZOL) Rapid Test Panel – Urine                  | 46994 | B | 6 |
| D-DOA68S50 | Zolpidem (ZOL) Rapid Test Strip – Urine                  | 46994 | B | 6 |
| D-DOA69D40 | Zopiclone (ZOP) Rapid Test Device – Urine                | 46994 | B | 6 |
| D-DOA69P40 | Zopiclone (ZOP) Rapid Test Panel – Urine                 | 46994 | B | 6 |
| D-DOA69S50 | Zopiclone (ZOP) Rapid Test Strip – Urine                 | 46994 | B | 6 |
| D-DOAPM2   | Multi-drug 2 drugs Rapid Test Panel – Urine              | 46994 | B | 6 |
| D-DOAPM3   | Multi-drug 3 drugs Rapid Test Panel – Urine              | 46994 | B | 6 |
| D-DOAPM4   | Multi-drug 4 drugs Rapid Test Panel – Urine              | 46994 | B | 6 |
| D-DOAPM5   | Multi-drug 5 drugs Rapid Test Panel – Urine              | 46994 | B | 6 |
| D-DOAPM6   | Multi-drug 6 drugs Rapid Test Panel – Urine              | 46994 | B | 6 |
| D-DOAPM7   | Multi-drug 7 drugs Rapid Test Panel – Urine              | 46994 | B | 6 |
| D-DOAPM8   | Multi-drug 8 drugs Rapid Test Panel – Urine              | 46994 | B | 6 |
| D-DOAPM9   | Multi-drug 9 drugs Rapid Test Panel – Urine              | 46994 | B | 6 |
| D-DOAPM10  | Multi-drug 10 drugs Rapid Test Panel – Urine             | 46994 | B | 6 |
| D-DOAPM11  | Multi-drug 11 drugs Rapid Test Panel – Urine             | 46994 | B | 6 |
| D-DOAPM12  | Multi-drug 12 drugs Rapid Test Panel – Urine             | 46994 | B | 6 |
| D-DOAPM13  | Multi-drug 13 drugs Rapid Test Panel – Urine             | 46994 | B | 6 |
| D-DOAPM14  | Multi-drug 14 drugs Rapid Test Panel – Urine             | 46994 | B | 6 |
| D-DOAPM15  | Multi-drug 15 drugs Rapid Test Panel – Urine             | 46994 | B | 6 |
| D-DOAPM16  | Multi-drug 16 drugs Rapid Test Panel – Urine             | 46994 | B | 6 |
| D-DOAPM17  | Multi-drug 17 drugs Rapid Test Panel – Urine             | 46994 | B | 6 |
| D-DOAPM18  | Multi-drug 18 drugs Rapid Test Panel – Urine             | 46994 | B | 6 |
| D-DOAPM19  | Multi-drug 19 drugs Rapid Test Panel – Urine             | 46994 | B | 6 |
| D-DOAPM20  | Multi-drug 20 drugs Rapid Test Panel – Urine             | 46994 | B | 6 |
| D-DOACM2K  | Multi-Drug 2 Drugs Rapid Test 2-Step Cup - Urine         | 46994 | B | 6 |
| D-DOACM3K  | Multi-Drug 3 Drugs Rapid Test 2-Step Cup - Urine         | 46994 | B | 6 |
| D-DOACM4K  | Multi-Drug 4 Drugs Rapid Test 2-Step Cup - Urine         | 46994 | B | 6 |
| D-DOACM5K  | Multi-Drug 5 Drugs Rapid Test 2-Step Cup - Urine         | 46994 | B | 6 |

|             |                                                                                  |       |   |   |
|-------------|----------------------------------------------------------------------------------|-------|---|---|
| D-DOACM6K   | Multi-Drug 6 Drugs Rapid Test 2-Step Cup - Urine                                 | 46994 | B | 6 |
| D-DOACM7K   | Multi-Drug 7 Drugs Rapid Test 2-Step Cup - Urine                                 | 46994 | B | 6 |
| D-DOACM8K   | Multi-Drug 8 Drugs Rapid Test 2-Step Cup - Urine                                 | 46994 | B | 6 |
| D-DOACM9K   | Multi-Drug 9 Drugs Rapid Test 2-Step Cup - Urine                                 | 46994 | B | 6 |
| D-DOACM10K  | Multi-Drug 10 Drugs Rapid Test 2-Step Cup - Urine                                | 46994 | B | 6 |
| D-DOACM11K  | Multi-Drug 11 Drugs Rapid Test 2-Step Cup - Urine                                | 46994 | B | 6 |
| D-DOACM12K  | Multi-Drug 12 Drugs Rapid Test 2-Step Cup - Urine                                | 46994 | B | 6 |
| D-DOACM13K  | Multi-Drug 13 Drugs Rapid Test 2-Step Cup - Urine                                | 46994 | B | 6 |
| D-DOACM14K  | Multi-Drug 14 Drugs Rapid Test 2-Step Cup - Urine                                | 46994 | B | 6 |
| D-DOACM15K  | Multi-Drug 15 Drugs Rapid Test 2-Step Cup - Urine                                | 46994 | B | 6 |
| D-DOACM16K  | Multi-Drug 16 Drugs Rapid Test 2-Step Cup - Urine                                | 46994 | B | 6 |
| D-DOACM17K  | Multi-Drug 17 Drugs Rapid Test 2-Step Cup - Urine                                | 46994 | B | 6 |
| D-DOACM18K  | Multi-Drug 18 Drugs Rapid Test 2-Step Cup - Urine                                | 46994 | B | 6 |
| D-DOA1D20S  | Amphetamine (AMP) Rapid Test Device – Saliva                                     | 46994 | B | 6 |
| D-DOA1M25S  | Amphetamine (AMP) Rapid Test Midstream-Saliva                                    | 46994 | B | 6 |
| D-DOA54D25S | $\alpha$ -Pyrrolidinovalerophenone ( $\alpha$ -PVP ) Rapid Test Device- Saliva   | 46994 | B | 6 |
| D-DOA54M25S | $\alpha$ -Pyrrolidinovalerophenone ( $\alpha$ -PVP ) Rapid Test Midstream-Saliva | 46994 | B | 6 |
| D-DOA4D20S  | Barbiturates ( BAR) Rapid Test Device – Salvia                                   | 46994 | B | 6 |
| D-DOA4M25S  | Barbiturates (BAR) Rapid Test Midstream-Salvia                                   | 46994 | B | 6 |
| D-DOA11D20S | Buprenorphine (BUP) Rapid Test Device – Saliva                                   | 46994 | B | 6 |
| D-DOA11M25S | Buprenorphine ( BUP) Rapid Test Midstream-Saliva                                 | 46994 | B | 6 |
| D-DOA5D20S  | Benzodiazepine (BZO) Rapid Test Device – Salvia                                  | 46994 | B | 6 |
| D-DOA5M25S  | Benzodiazepine (BZO) Rapid Test Midstream-Salvia                                 | 46994 | B | 6 |
| D-DOA6M25S  | Cocaine (COC) Rapid Test Midstream-Saliva                                        | 46994 | B | 6 |
| D-DOA47D25S | Carfentanyl (CFYL) Rapid Test Device – Salvia                                    | 46994 | B | 6 |
| D-DOA47M25S | Carfentanyl (CFYL) Rapid Test Midstream-Salvia                                   | 46994 | B | 6 |
| D-DOA31M25S | Cotinine (COT) Rapid Test Midstream-Salvia                                       | 46994 | B | 6 |
| D-DOA42D20S | Fentanyl (FYL) Rapid Test Device – Salvia                                        | 46994 | B | 6 |
| D-DOA42M25S | Fentanyl (FYL) Rapid Test Midstream-Salvia                                       | 46994 | B | 6 |
| D-DOA9D20S  | Ketamine (KET) Rapid Test Device – Salvia                                        | 46994 | B | 6 |
| D-DOA9M25S  | Ketamine (KET) Rapid Test Midstream-Salvia                                       | 46994 | B | 6 |
| D-DOA43D20S | 6-Monoacetylmorphine(6-MAM) Rapid Test Device-Saliva                             | 64154 | B | 6 |
| D-DOA43M25S | 6-Monoacetylmorphine (6-MAM) Rapid Test Midstream-salvia                         | 46994 | B | 6 |
| D-DOA12M20S | Ecstasy (MDMA) Rapid Test Midstream-Saliva                                       | 46994 | B | 6 |
| D-DOA62D25S | Methylenedioxypyrovalerone (MDPV) Rapid Test Device-Saliva                       | 46994 | B | 6 |
| D-DOA62M25S | Methylenedioxypyrovalerone (MDPV) Rapid Test Midstream-Urine                     | 46994 | B | 6 |
| D-DOA7M20S  | Methadone (MTD) Rapid Test Midstream-Saliva                                      | 46994 | B | 6 |
| D-DOA3M20S  | Opiates (OPI) Rapid Test Midstream-Saliva                                        | 46994 | B | 6 |
| D-DOA39D20S | Oxycodone (OXY) Rapid Test Device – Saliva                                       | 46994 | B | 6 |
| D-DOA39M25S | Oxycodone (OXY) Rapid Test Midstream-Saliva                                      | 46994 | B | 6 |



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| 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 |

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| 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 |

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|--------------|-------------------------------------------------------------------------------|-------|---|---|
| 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  | $\alpha$ -Pyrrolidinovalerophenone ( $\alpha$ -PVP ) Rapid Test Device -Urine | 46994 | B | 6 |
| D-RDOA4D40   | Barbiturate (BAR) Rapid Test Device-urine                                     | 46994 | B | 6 |
| D-RDOA11D40  | Buprenorphine (BUP) Rapid Test Device -Urine                                  | 65385 | B | 6 |
| D-RDOA5D40   | Benzodiazepines (BZO) Rapid Test Device-urine                                 | 46994 | B | 6 |
| D-RDOA56D40  | Clonazepam (CLO) Rapid Test Device -Urine                                     | 55532 | B | 6 |
| D-RDOA6D40   | COCAINE (COC) Rapid Test Device-urine                                         | 46994 | B | 6 |
| D-RDOA31D40  | Cotinine (COT) Rapid Test Device -Urine                                       | 64155 | B | 6 |
| D-RDOA41D40  | Diazepam (DIA) Rapid Test Device -urine                                       | 64157 | B | 6 |
| D-RDOA57D40  | Ethylenediamine-dimethylphosphinic acid (EDDP) Rapid Test Device -urine       | 42656 | B | 6 |
| D-RDOA58D40  | Ethyl Glucuronide (ETG) Rapid Test Device-urine                               | 60669 | B | 6 |
| D-RDOA42D40  | Fentanyl (FYL) Rapid Test Device -urine                                       | 64153 | B | 6 |
| D-RDOA9D40   | Ketamine (KET)Rapid Test Device-urine                                         | 62130 | B | 6 |
| D-RDOA43D40  | 6-Monoacetylmorphine (6-MAM) Rapid Test Device -urine                         | 64154 | B | 6 |
| D-RDOA12D40  | Ecstasy (MDMA) Rapid Test Device-urine                                        | 55489 | B | 6 |
| D-RDOA61D40  | Tenamfetamine (MDA) Rapid Test Device -urine                                  | 46994 | B | 6 |
| D-RDOA62D40  | Methylenedioxypyrovalerone (MDPV) Rapid Test Device -urine                    | 46994 | B | 6 |
| D-RDOA63D40  | Methylphenidate(MPD) Rapid Test Device -urine                                 | 46994 | B | 6 |
| D-RDOA2D40   | Methamphetamine (MET) Rapid Test Device -urine                                | 55498 | B | 6 |
| D-RDOA38D40  | Morphine (MOP) Rapid Test Device -urine                                       | 55701 | B | 6 |
| D-RDOA64D40  | Methaqualone (MQL) Rapid Test Device -urine                                   | 55696 | B | 6 |
| D-RDOA7D40   | Methadone (MTD) Rapid Test Device -urine                                      | 30521 | B | 6 |
| D-RDOA3D40   | Opiates (OPI) Rapid Test Device -urine                                        | 55701 | B | 6 |
| D-RDOA39D40  | Oxycodone (OXY) Rapid Test Device -urine                                      | 55734 | B | 6 |
| D-RDOA13D40  | Phencyclidine (PCP) Rapid Test Device -urine                                  | 30523 | B | 6 |
| D-RDOA65D40  | Propoxyphene (PPX) Rapid Test Device -urine                                   | 62324 | B | 6 |
| D-RDOA51D40  | Synthetic Marijuana (K2) Rapid Test Device-urine                              | 30519 | B | 6 |
| D-RDOA10D40  | Tricyclic Antidepressants (TCA) Rapid Test Device -urine                      | 55712 | B | 6 |
| D-RDOA8D40   | Marijuana (THC) Rapid Test Device-urine                                       | 30519 | B | 6 |
| D-RDTMLD40   | Tramadol (TML) Rapid Test Device -urine                                       | 64161 | B | 6 |
| D-RDOA29D40  | Lysergic Acid Diethylamide (LSD) Rapid Test Device -urine                     | 64156 | B | 6 |
| D-RDOA68D40  | Zolpidem(ZOL) Rapid Test Device -urine                                        | 46994 | B | 6 |
| D-RDOA1D25S  | Amphetamine (AMP) Rapid Test Device -Saliva                                   | 46994 | B | 6 |
| D-RDOA4D25S  | Barbiturate (BAR) Rapid Test Device -Saliva                                   | 46994 | B | 6 |
| D-RDOA11D25S | Buprenorphine (BUP) Rapid Test Device -Saliva                                 | 65385 | B | 6 |
| D-RDOA5D20S  | Benzodiazepines (BZO) Rapid Test Device -Saliva                               | 46994 | B | 6 |

|              |                                                              |       |   |   |
|--------------|--------------------------------------------------------------|-------|---|---|
| D-RDOA6D25S  | COCAINE (COC) Rapid Test Device -Saliva                      | 46994 | B | 6 |
| D-RDOA2D25S  | Methamphetamine (MET) Rapid Test Device -Saliva              | 55498 | B | 6 |
| D-RDOA7D25S  | Methadone (MTD) Rapid Test Device -Saliva                    | 30521 | B | 6 |
| D-RDOA3D25S  | Opiates (OPI) Rapid Test Device -Saliva                      | 55701 | B | 6 |
| D-RDOA13D25S | Phencyclidine (PCP) Rapid Test Device -Saliva                | 30523 | B | 6 |
| D-RDOA51D25S | Synthetic Marijuana (K2) Rapid Test Device -Saliva           | 30523 | B | 6 |
| D-RDOAPM3    | Multi-Drug 3 Drugs Rapid Test Panel-urine                    | 46994 | B | 6 |
| D-RDOAPM4    | Multi-Drug 4 Drugs Rapid Test Panel-urine                    | 46994 | B | 6 |
| D-RDOAPM5    | Multi-Drug 5 Drugs Rapid Test Panel-urine                    | 46994 | B | 6 |
| D-RDOAPM6    | Multi-Drug 6 Drugs Rapid Test Panel-urine                    | 46994 | B | 6 |
| D-RDOAPM7    | Multi-Drug 7 Drugs Rapid Test Panel-urine                    | 46994 | B | 6 |
| D-RDOAPM8    | Multi-Drug 8 Drugs Rapid Test Panel-urine                    | 46994 | B | 6 |
| D-RDOAPM9    | Multi-Drug 9 Drugs Rapid Test Panel-urine                    | 46994 | B | 6 |
| D-RDOAPM10   | Multi-Drug 10 Drugs Rapid Test Panel-urine                   | 46994 | B | 6 |
| D-RDOAPM12   | Multi-Drug 12 Drugs Rapid Test Panel-urine                   | 46994 | B | 6 |
| D-RDOAPM3A   | Multi-Drug 3 Drugs Rapid Test Panel with Adulteration-urine  | 46994 | B | 6 |
| D-RDOAPM4A   | Multi-Drug 4 Drugs Rapid Test Panel with Adulteration-urine  | 46994 | B | 6 |
| D-RDOAPM5A   | Multi-Drug 5 Drugs Rapid Test Panel with Adulteration-urine  | 46994 | B | 6 |
| D-RDOAPM6A   | Multi-Drug 6 Drugs Rapid Test Panel with Adulteration-urine  | 46994 | B | 6 |
| D-RDOAPM7A   | Multi-Drug 7 Drugs Rapid Test Panel with Adulteration-urine  | 46994 | B | 6 |
| D-RDOAPM8A   | Multi-Drug 8 Drugs Rapid Test Panel with Adulteration-urine  | 46994 | B | 6 |
| D-RDOAPM9A   | Multi-Drug 9 Drugs Rapid Test Panel with Adulteration-urine  | 46994 | B | 6 |
| D-RDOAPM10A  | Multi-Drug 10 Drugs Rapid Test Panel with Adulteration-urine | 46994 | B | 6 |
| D-RDOAPM12A  | Multi-Drug 12 Drugs Rapid Test Panel with Adulteration-urine | 46994 | B | 6 |
| D-RDOAM3U    | Multi-Drug 3 Drugs Rapid Test Device-urine                   | 46994 | B | 6 |
| D-RDOAM5U    | Multi-Drug 5 Drugs Rapid Test Device-urine                   | 46994 | B | 6 |
| D-RDOAM6U    | Multi-Drug 6 Drugs Rapid Test Device-urine                   | 46994 | B | 6 |
| D-RDOAM7U    | Multi-Drug 7 Drugs Rapid Test Device-urine                   | 46994 | B | 6 |
| D-RDOAM12U   | Multi-Drug 12 Drugs Rapid Test Device-urine                  | 46994 | B | 6 |
| D-RDOAM3S    | Multi-Drug 3 Drugs Rapid Test Device -Saliva                 | 46994 | B | 6 |
| D-RDOAM4S    | Multi-Drug 4 Drugs Rapid Test Device -Saliva                 | 46994 | B | 6 |
| D-RDOAM5S    | Multi-Drug 5 Drugs Rapid Test Device -Saliva                 | 46994 | B | 6 |
| D-RDOAM6S    | Multi-Drug 6 Drugs Rapid Test Device -Saliva                 | 46994 | B | 6 |
| D-RDOAM7S    | Multi-Drug 7 Drugs Rapid Test Device -Saliva                 | 46994 | B | 6 |
| D-RDOAM8S    | Multi-Drug 8 Drugs Rapid Test Device -Saliva                 | 46994 | B | 6 |
| D-RCFOB10    | FOB Rapid Test Device -Feces                                 | 54532 | B | 6 |
| D-RHCGUD40   | hCG Pregnancy Rapid Test Device -urine                       | 33819 | B | 6 |

|              |                                                                             |       |   |    |
|--------------|-----------------------------------------------------------------------------|-------|---|----|
| D-RCTID10    | Cardiac Troponin I Rapid Test Device -WB/S/P                                | 46989 | C | 3j |
| D-RNGALD10   | NGAL (neutrophil gelatinase-associated lipocalin) Rapid Test Device -WB/S/P | 47430 | C | 3j |
| D-RCKMBD10   | CK-MB Rapid Test Device -WB/S/P                                             | 52995 | C | 3j |
| D-RMYOD10    | Myoglobin Rapid Test Device -WB/S/P                                         | 46987 | C | 3j |
| D-RHPAGD25   | H. pylori Antigen Rapid Test Device -Feces                                  | 30825 | B | 6  |
| D-RMONOD25   | MONO Rapid Test Device -WB/S/P                                              | 49689 | C | 3e |
| D-RINFAD20   | Influenza A Rapid Test Device -Swab/Nasal Aspirate                          | 49119 | B | 6  |
| D-RSTRAS20   | Strep A Rapid Test Device -Throat Swab                                      | 51707 | B | 6  |
| D-RTPD40     | Syphilis Rapid Test Device -S/P                                             | 63969 | C | 3a |
| D-RDGMD20    | Dengue IgG/IgM Rapid Test Device -WB/S/P                                    | 63238 | B | 6  |
| D-RDAGD20    | Dengue NS1 Rapid Test Device-WB/S/P                                         | 62946 | C | 3b |
| D-RFFD25     | Fetal Fibronectin (fFN) Rapid Test Device -Vaginal Discharge                | 53721 | B | 6  |
| D-RFSDH20    | Follicle Stimulating Hormone (FSH) Rapid Test Device -Urine                 | 54188 | B | 6  |
| D-RTSHD20    | TSH Rapid Test Device -WB/S/P                                               | 65274 | B | 6  |
| D-RFED10     | Ferritin Rapid test Device -WB/S/P                                          | 66124 | B | 6  |
| D-RTSHSQD20  | Thyroid Stimulating Hormone (TSH) Rapid Test Device -WB/S/P                 | 65274 | B | 6  |
| D-RVDD10     | Vitamin D Rapid Test Device -WB/S/P                                         | 60955 | B | 6  |
| D-RPCTCD10   | Procalcitonin (PCT) Rapid Test Device -WB/S/P                               | 58305 | B | 6  |
| D-RCALD10    | Calprotectin Rapid Test Device -Feces                                       | 60775 | B | 6  |
| D-RCRD10     | CRP Rapid Test Device -WB/S/P                                               | 58768 | B | 6  |
| D-FICEAD20   | CEA Test Device -S/P                                                        | 54616 | C | 3h |
| D-FIAFPD20   | AFP Test Device -S/P                                                        | 54060 | C | 3h |
| D-FIDIMERD10 | D-Dimer Test Device -WB/P                                                   | 61389 | C | 3k |
| D-FICKMBD10  | CK-MB Test Device -WB/S/P                                                   | 61385 | C | 3j |
| D-FITROPID20 | cTnI Test Device -WB/S/P                                                    | 54010 | C | 3j |
| D-FIMYOD25   | Myoglobin Rapid Test Device — WB/S/P                                        | 61390 | C | 3j |
| D-FIFABD10   | H-FABP Test Device -WB/S/P                                                  | 53365 | C | 3j |
| D-FINTPD10   | NT-proBNP Test Device -WB/S/P                                               | 47352 | C | 3j |
| D-FITIMCKD20 | Troponin I/Myoglobin/CK-MB (3 in 1 ) Test Device -WB/S/P                    | 47384 | C | 3j |
| D-FITTMCKD20 | Troponin T/Myoglobin/CK-MB (3 in 1 ) Test Device -WB/S/P                    | 47384 | C | 3j |
| D-FILHD20    | LH Test Device -WB/S/P                                                      | 65959 | B | 6  |
| D-FISTRAS20  | Strep A Test Device -Swab                                                   | 63770 | B | 6  |
| D-FIIABD20   | Influenza A+B Test Device -Swab                                             | 49117 | B | 6  |
| D-FIDGMD20   | Dengue IgG/IgM Test Device -WB/S/P                                          | 48915 | B | 6  |
| D-FIDAGD25   | Dengue NS1 Test Device -WB/S/P                                              | 48915 | C | 3b |
| D-FIRSVD20   | RSV Test Device -Swab                                                       | 62587 | B | 6  |
| D-FICDTABD10 | Clostridium difficile Toxin A/Toxin B Combo Test Device -Feces              | 65995 | B | 6  |
| D-FICDGD10   | Clostridium difficile GDH Test Device -Feces                                | 65995 | B | 6  |
| D-FIADED25   | Adenovirus antigen Test Device -Feces                                       | 49854 | B | 6  |

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|--------------|---------------------------------------------------------------|-------|---|----|
| D-FISPD10    | Streptococcus pneumoniae Test Device -urine                   | 63796 | C | 3c |
| D-FILPD25    | Legionella pneumophila Test Device -urine                     | 63781 | C | 3c |
| D-FITSPD40   | Syphilis Test Device -WB/S/P                                  | 51814 | C | 3a |
| D-FIZAGD10   | Zika antigen Test Device -WB/S/P                              | 65994 | B | 6  |
| D-FIZMD10    | Zika IgM Test Device -WB/S/P                                  | 66015 | B | 6  |
| D-FIAMHD10   | AMH Test Device -WB/S/P                                       | 58410 | B | 6  |
| D-FIFFD25    | Fetal Fibronectin (fFN) Test Device-Swab                      | 53721 | B | 6  |
| D-FIFSHD20   | FSH Test Device -WB/S/P                                       | 54188 | B | 6  |
| D-FIRFSPD20  | Rheumatoid Factor IgM Test Device -WB/S/P                     | 55109 | B | 6  |
| D-FICRPD25   | CRP Test Device-WB/S/P                                        | 58768 | B | 6  |
| D-FIPCTD25   | PCT Test Device-WB/S/P                                        | 54313 | B | 6  |
| D-FIFOBD25   | FOB Test Device-Feces                                         | 66044 | B | 6  |
| D-FIT4D25    | T4 Test Device-S/P                                            | 63072 | B | 6  |
| D-FIHCG D25  | β-HCG Test Device-S/P                                         | 58789 | B | 6  |
| D-FITSHD25   | TSH Test Device-S/P                                           | 54384 | B | 6  |
| D-FIT3D25    | T3 Test Device-S/P                                            | 63082 | B | 6  |
| D-FITESD25   | Testosterone Test Device-S/P                                  | 54184 | B | 6  |
| D-FIP4D25    | Progesterone(P4) Test Device-S/P                              | 54327 | B | 6  |
| D-FICYSD25   | CysC Test Device-WB/S/P                                       | 48177 | B | 6  |
| D-FI2MGD25   | β2MG Test Device-WB/S/P                                       | 53930 | B | 6  |
| D-FINGALD25  | N-GAL Test Device-Urine                                       | 47426 | C | 3j |
| D-FIHBA1CD25 | HbA1c Test Device-WB                                          | 65958 | C | 3k |
| D-FIIGED25   | IgE Test Device-WB/S/P                                        | 60380 | C | 3e |
| D-FIFED25    | Ferritin Test Device-S/P                                      | 58769 | B | 6  |
| D-CHAGBD20   | Cholera Ag O139 Rapid Test Device – Feces                     | 51840 | c | 3c |
| D-COVAGD20B  | SARS-CoV-2 Antigen Rapid Test Device – swab                   | 64787 | D | 1  |
| D-COVAGD20H  | COVID-19 Antigen Rapid Test Device – Oral Fluid               | 64787 | D | 1  |
| D-DOA12D20S  | Ecstasy (MDMA) Rapid Test Device – Saliva                     | 46994 | B | 6  |
| D-DOA2D20S   | Methamphetamine (MET) Rapid Test Device -                     | 46994 | B | 6  |
| D-DOA31D20S  | Cotinine (COT) Rapid Test Device – Salvia                     | 46994 | B | 6  |
| D-DOA3D20S   | Opiates (OPI) Rapid Test Device – Saliva                      | 46994 | B | 6  |
| D-DOA43D20D  | 6-Monoacetylmorphine (6-MAM) Rapid Test Device – Salvia       | 46994 | B | 6  |
| D-DOA50D40   | Pregabalin (PGB) Rapid Test Device – Urine                    | 46994 | B | 6  |
| D-DOA50S50   | Pregabalin (PGB) Rapid Test Strip – Urine                     | 46994 | B | 6  |
| D-DOA51D20   | Synthetic Marijuana (K2) Rapid Test Device – Urine            | 46994 | B | 6  |
| D-DOA51S50   | Synthetic Marijuana (K2) Rapid Test Strip – Urine             | 46994 | B | 6  |
| D-DOA58S40   | Ethyl Glucuronide (ETG) Rapid Test Strip – Urine              | 46994 | B | 6  |
| D-DOA62S25S  | Methylenedioxypyrovalerone (MDPV) Rapid Test Device – Saliva  | 46994 | B | 6  |
| D-DOA6D20S   | Cocaine (COC) Rapid Test Device – Saliva                      | 46994 | B | 6  |
| D-DOA7D20S   | Methadone (MTD) Rapid Test Device – Saliva                    | 46994 | B | 6  |
| D-DOAS50     | Methadone (MTD) Rapid Test Strip – Urine                      | 46994 | B | 6  |
| D-DOA8D20S   | Marijuana (THC) Rapid Test Device – Saliva                    | 46994 | B | 6  |
| D-DOAM10UT   | Multi- Drug 10 drugs inc. T ramadol Rapid Test Device – Urine | 46994 | B | 6  |

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|--------------|---------------------------------------------------------------------|-------|---|----|
| 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  |

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|--------------|-----------------------------------------------------------------------------------------------|-------|---|----|
| D-LEIGID20   | Legionella Antigen Rapid Test Device – Throat                                                 | 51054 | C | 3c |
| D-LEIGID40   | Legionella Antigen Rapid Test Device – Throat                                                 | 51054 | C | 3c |
| D-TBSPD10    | Tuberculosis (TB) Rapid Test Device – WB/S/P                                                  | 65814 | C | 3e |
| D-TBSPD20    | Tuberculosis (TB) Rapid Test Device – WB/S/P                                                  | 65814 | C | 3e |
| D-DGMCMD20   | Dengue + Chik (IgG/IgM-Chik IgM) Test – WB/S/P                                                | 63970 | B | 6  |
| D-HPVCSD25   | HPV Antigen Rapid Test -Cervical Swab                                                         | 49993 | C | 3a |
| D-HEMS50     | HB Hemoglobin Strip                                                                           | 63089 | B | 6  |
| D-DOA70D40   | Tapentadol (TAP) Rapid Test -Urine                                                            | 46994 | B | 6  |
| D-DOA70P40   | Tapentadol (TAP) Rapid Test -Urine                                                            | 46994 | B | 6  |
| D-DOA70S50   | Tapentadol (TAP) Rapid Test -Urine                                                            | 46994 | B | 6  |
| D-DOA40SS50  | Alcohol Rapid Test Dipstick(Saliva)                                                           | 64159 | B | 6  |
| D-DOA40D25   | Alcohol (ALC) Oral Fluid Cassette                                                             | 64159 | B | 6  |
| D-DOA40BBD15 | Breath Alcohol Test (With Blow bag) Cassette                                                  | 64159 | B | 6  |
| D-DOA40BBD20 | Breath Alcohol Test (Without Blow bag) Cassette                                               | 64159 | B | 6  |
| D-U12100     | Urinalysis Strips 12 Parameter                                                                | 63695 | B | 6  |
| D-U13100     | Urinalysis Strips 13 Parameter                                                                | 63695 | B | 6  |
| D-U14100     | Urinalysis Strips 14 Parameter                                                                | 63695 | B | 6  |
| D-HSV1D20    | HSV-1 IgG/IgM Rapid Test -WB/S/P                                                              | 49556 | C | 3a |
| D-HSV2D20    | HSV-2 IgG/IgM Rapid Test -WB/S/P                                                              | 49556 | C | 3a |
| D-CLOSGTD10  | C. difficile GDH+ Toxin A +Toxin B Combo Rapid Test -Faeces                                   | 50831 | B | 6  |
| D-CIIGE40    | Total IgE (T-IgE) Test Kit-human serum or plasma                                              | 60380 | C | 3e |
| D-CIFERK40   | Ferritin Test Kit-whole blood, serum or plasma                                                | 61078 | B | 6  |
| D-CIAMHK40   | Anti-mullerian Hormone (AMH) Test Kit-human serum or plasma                                   | 64335 | B | 6  |
| D-CICEAK40   | Carcinoembryonic Antigen (CEA) Test Kit- human serum or plasma                                | 54615 | C | 3h |
| D-CIFSHK40   | FSH Test Kit-human serum or plasma                                                            | 54187 | B | 6  |
| D-CILHK40    | LH Test Kit-human serum or plasma                                                             | 54254 | B | 6  |
| D-CINBNPK40  | N-Terminal pro-B-type Natriuretic Peptide (NT-proBNP) Test Kit - whole blood, serum or plasma | 47351 | C | 3j |
| D-CITSHK40   | Thyroid Stimulating Hormone (TSH) Test Kit-human serum or plasma                              | 54386 | B | 6  |
| D-CIVDK40    | 25 OH Vitamin D (25-OH VD) Test Kit -whole blood, serum or plasma                             | 60922 | B | 6  |
| D-CIβHCGK40  | β-human Chorionic Gonadotropin (β-HCG) Test Kit -human serum or plasma                        | 54215 | B | 6  |
| D-CIT4K40    | Thyroxine (T4) Test Kit-human serum or                                                        | 58322 | B | 6  |
| D-CIFT4K40   | Free Thyroxine (FT4) Test Kit -human serum or plasma                                          | 54413 | B | 6  |
| D-CIPRLK40   | Prolactin Test Kit-human serum or plasma                                                      | 54335 | B | 6  |
| D-CICA199K40 | Carbohydrate Antigen 199 (CA19-9) Test Kit- human serum and plasma                            | 60976 | B | 6  |



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

|               |                                                                                |       |   |    |
|---------------|--------------------------------------------------------------------------------|-------|---|----|
| D-CIHBK40     | Glycated Hemoglobin (HbA1c)<br>Test Kit-human whole blood                      | 61010 | C | 3k |
| D-CITGK40K40  | Thyroglobulin (TG) Test Kit-human<br>serum or plasma                           | 54375 | B | 6  |
| D-CICA153K40  | Cancer Antigen 15-3 (CA15-3)<br>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)<br>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)<br>Test Kit-human serum or plasma                   | 66062 | B | 6  |
| D-CICA724K40  | Cancer Antigen 72-4 (CA72-4)<br>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)<br>Test Kit-human serum or plasma             | 56656 | B | 6  |
| D-CINSEK40    | Neuron-specific Enolase (NSE)<br>Test Kit-human serum                          | 64542 | B | 6  |
| D-CIPLGFK40   | Placental Growth Factor (PLGF)<br>Test Kit- human serum                        | 56616 | C | 3j |
| D- CIsFLT1K40 | Soluble fms-like Tyrosine Kinase-1 (sFlt-1)<br>Test Kit-human serum            | 61081 | C | 3j |
| D-MPOXD25     | Monkeypox Virus Antibody Rapid Test<br>-Whole Blood/Serum/Plasma               | 66498 | B | 6  |
| D-MPOXAGD25   | Monkeypox Virus Antigen Rapid Test<br>-Whole Blood/Serum/Plasma                | 66416 | B | 6  |
| D-U1MC100AU   | Urinalysis Reagent Strips for Urine Analyzer<br>- 1 parameter                  | 63695 | B | 6  |
| D-U2MC100AU   | Urinalysis Reagent Strips for Urine Analyzer<br>- 2 parameters                 | 63695 | B | 6  |
| D-U3MC100AU   | Urinalysis Reagent Strips for Urine Analyzer<br>- 3 parameters                 | 63695 | B | 6  |
| D-U4MC100AU   | Urinalysis Reagent Strips for Urine Analyzer<br>- 4 parameters                 | 63695 | B | 6  |
| D-U5MC100AU   | Urinalysis Reagent Strips for Urine Analyzer<br>- 5 parameters                 | 63695 | B | 6  |
| D-U6MC100AU   | Urinalysis Reagent Strips for Urine Analyzer<br>- 6 parameters                 | 63695 | B | 6  |
| D-U7MC100AU   | Urinalysis Reagent Strips for Urine Analyzer<br>- 7 parameters                 | 63695 | B | 6  |
| D-U8MC100AU   | Urinalysis Reagent Strips for Urine Analyzer<br>- 8 parameters                 | 63695 | B | 6  |

|              |                                                                 |       |   |   |
|--------------|-----------------------------------------------------------------|-------|---|---|
| D-U9MC100AU  | Urinalysis Reagent Strips for Urine Analyzer<br>- 9 parameters  | 63695 | B | 6 |
| D-U10MC100AU | Urinalysis Reagent Strips for Urine Analyzer<br>- 10 parameters | 63695 | B | 6 |
| D-U11MC100AU | Urinalysis Reagent Strips for Urine Analyzer<br>- 11 parameters | 63695 | B | 6 |
| D-U12MC100AU | Urinalysis Reagent Strips for Urine Analyzer<br>- 12 parameters | 63695 | B | 6 |
| D-U13MC100AU | Urinalysis Reagent Strips for Urine Analyzer<br>- 13 parameters | 63695 | B | 6 |
| D-U14MC100AU | Urinalysis Reagent Strips for Urine Analyzer<br>- 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.<sup>1,2</sup> 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.<sup>3</sup> 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.<sup>4</sup> 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*.<sup>5</sup>

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 on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

### 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 Required But Not Provided

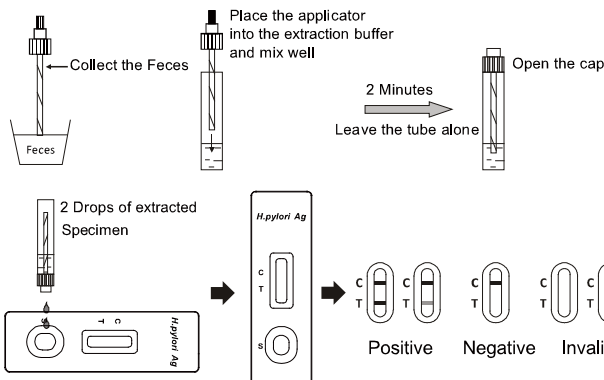
- Specimen collection containers
- Pipette and disposable tips (optional)
- Centrifuge
- Timer
- Droppers

### 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 etiological 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 |               |
|                                      | 168                    | 3        | 171           |
| H.pylori Antigen Test Device (Feces) | Results                |          |               |
|                                      | Positive               | 2        | 189           |
| Total Results                        | Negative               | 170      | 192           |

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</i> spp     | <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 gonorrhea</i>     |
| <i>Neisseria meningitidis</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  |

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- Cutler AF. Testing for Helicobacter pylori in clinical practice. Am J. Med. 1996; 100:35S-41S.
- Anand BS, Raed AK, Malaty HM, et al. Loe point prevalence of peptic ulcer in normal individual with Helicobacter pylori infection. Am J Gastroenterol. 1996;91:1112-1115.

#### Index of Symbols

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



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Revision 2

29/04/2024

## Calprotectin Rapid Test Device (Feces)

### CATALOGUE NUMBER D-CALD10

A rapid, one step test for the qualitative detection of Calprotectin in human feces specimen.  
For professional *in vitro* diagnostic use only.

#### INTENDED USE

The Calprotectin Rapid Test Device (Feces) is a rapid chromatographic immunoassay for the qualitative detection of Calprotectin in human feces specimen which might be useful for the diagnosis of inflammatory gastrointestinal disorders.

#### SUMMARY

Calprotectin is a 24 kDa dimer of calcium binding proteins S100A8 and S100A9.<sup>1</sup> The complex accounts for up to 60% of the soluble protein content of the neutrophil cytosol.<sup>2</sup> Calprotectin becomes available in the intestinal lumen via leukocyte shedding,<sup>3</sup> active secretion,<sup>2</sup> cell disturbance, and cell death.<sup>3</sup> This results in elevated faecal calprotectin levels, which can be detected in the stool.<sup>3</sup> Elevated faecal calprotectin levels therefore indicate migration of neutrophils into the intestinal mucosa, which occurs during intestinal inflammation.<sup>4</sup> Faecal calprotectin has been used to detect intestinal inflammation, and can serve as a marker for inflammatory bowel diseases.<sup>5</sup> Calprotectin is useful as a marker, as it is resistant to enzymatic degradation, and can be easily measured in faeces.<sup>6</sup>

#### PRINCIPLE

The Calprotectin Rapid Test Device (Feces) is a qualitative, lateral flow immunoassay for the detection of Calprotectin in human feces specimen. The membrane is precoated with anti-Calprotectin antibody on the test line region of the test. During testing, the specimen reacts with the particle coated with Calprotectin antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-Calprotectin antibody on the membrane and generate a colored line. The presence of this colored line in the test line 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 the proper volume of specimen has been added and membrane wicking has occurred.

#### REAGENTS

The test contains anti-Calprotectin antibody particles and anti-Calprotectin antibody coated on the membrane.

#### PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after 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.

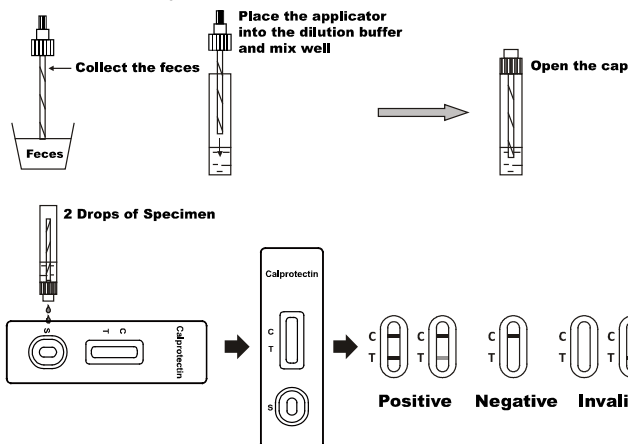
#### MATERIALS

- |                                  | Materials Provided                                 |
|----------------------------------|----------------------------------------------------|
| • Test Devices                   | • Specimen collection tubes with extraction buffer |
| • Package insert                 |                                                    |
|                                  | Materials Required But Not Provided                |
| • Specimen collection containers | • Timer • Droppers                                 |

#### DIRECTIONS FOR USE

Allow the test, specimen, buffer and/or control 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 2 drops (approximately 80 µL) into the specimen collection tube containing the extraction buffer.
- Tighten the cap onto the specimen collection tube, and 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 5 minutes after dispensing the specimen.** Do not read results after 10 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 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 Calprotectin 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 Calprotectin Rapid Test Device (Feces) is for *in vitro* diagnostic use only.
- The Calprotectin Rapid Test Device (Feces) will only indicate the presence of Calprotectin, the detail concentration of Calprotectin was not confirmed with the rapid test.
- As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
- Other clinically available tests are required if questionable results are obtained.

#### PERFORMANCE CHARACTERISTICS

##### Accuracy

The Calprotectin Rapid Test Device (Feces) has been compared with another leading commercial rapid test using clinical specimens.

| Calprotectin Rapid Test Device (Feces) | Method        | Other Rapid Test |          | Total Results |
|----------------------------------------|---------------|------------------|----------|---------------|
|                                        | Results       | Positive         | Negative |               |
|                                        |               | 133              | 2        | 135           |
|                                        | Positive      | 133              | 2        | 135           |
|                                        | Negative      | 3                | 198      | 201           |
|                                        | Total Results | 136              | 200      | 336           |

Relative sensitivity: 97.8% (95%CI\*: 93.7%~99.5%);

Relative specificity: 99.0% (95%CI\*: 96.4%~99.9%);

Accuracy: 98.5% (95%CI\*: 96.6%~99.5%).

\*Confidence Intervals

##### Sensitivity

The Calprotectin Rapid Test Device (Feces) can detect levels of Calprotectin as low as 50 µg/g or 140 ng/mL feces.

##### Precision

###### Intra-Assay

Within-run precision has been determined by using 15 replicates of three specimens: 140ng/mL, 500ng/mL and 10µg/mL 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 three specimens: 140ng/mL, 500ng/mL and 10µg/mL positive specimens. Three different lots of the Calprotectin Rapid Test Device (Feces) have been tested using these specimens. The specimens were correctly identified >99% of the time.

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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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Revision2

29/04/2024