

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
Ministry of Health and Family welfare
(Medical Device and Diagnostic Division)
Market Standing Certificate

Certificate Number : MSC/IVD/2024/000214

Dated : 10/10/2024

This is to certify that M/s. **PARAMCARE LIFE SCIENCES PRIVATE LIMITED** situated at address **G/F-12/13, EVERSHINE-2, SURVEY NO. 307/3/1, BALITHA N.H NO 48, VAPI, Valsad Gujarat, 396191, 9821056409, India** **Valsad Gujarat 396191 9821056409 India** is holding Manufacturing/Import License no. **MFG/IVD/2022/000096** issued on **07-SEP-2022** Under this license, the said firm is permitted to manufacture/import of medical devices as stated in manufacturing/import license.

Name of the products with their product name and dimensions if any mentioned below :

S.NO	Medical Device Details
1	<p>1. Generic Name : Luteinizing Hormone (LH) Rapid Test Kit</p> <p>2. Brand Name : NIL</p> <p>3. Notified Category : Other than above substances In vitro diagnostic device for LH</p> <p>4. Class of Medical Device : Class B</p> <p>5. Shelf life : 24 months</p> <p>6. Sterile/Non-Sterile: Non-Sterilized</p> <p>7. Intended Use : The Luteinizing Hormone (LH) Rapid Test (Urine) is a rapid test that qualitatively detects the presence of LH in urine specimen at the sensitivity of 25 mIU/mL. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of LH in Urine.</p> <p>8. Material of Construction: Nitrocellulose Membrane, Gold Conjugate Pad, Sample Release Pad, Absorbent Pad</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name : NIL</p>
2	<p>1. Generic Name : IgE Rapid Test Kit</p> <p>2. Brand Name : NIL</p> <p>3. Notified Category : Other than above substances In vitro diagnostic device for IgE</p> <p>4. Class of Medical Device : Class B</p> <p>5. Shelf life : 24 months</p> <p>6. Sterile/Non-Sterile: Non-Sterilized</p> <p>7. Intended Use : The Immunoglobulin E (IgE) Rapid Test (Serum/Plasma/Whole blood) is a rapid test that qualitatively detects the presence of IgE in serum/plasma/whole blood specimen at the sensitivity of 100 IU/mL.</p> <p>8. Material of Construction: Nitrocellulose Membrane, Gold Conjugate Pad, Sample Release Pad, Absorbent Pad</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name : NIL</p>
3	<p>1. Generic Name : hCG - Pregnancy Rapid Test Kit</p> <p>2. Brand Name : NIL</p> <p>3. Notified Category : Other than above substances In vitro diagnostic device for hCG</p> <p>4. Class of Medical Device : Class B</p> <p>5. Shelf life : 24 months</p> <p>6. Sterile/Non-Sterile: Non-Sterilized</p> <p>7. Intended Use : The hCG - Pregnancy Rapid Test Kit (Urine) is a rapid test that qualitatively detects the presence of hCG in urine specimen at the sensitivity of 25 mIU/mL. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of HCG in Urine.</p> <p>8. Material of Construction: Nitrocellulose Membrane, Gold Conjugate Pad, Sample Release Pad, Absorbent Pad</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name : NIL</p>

4	<p>1. Generic Name :POTASSIUM TEST KIT</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic device for Potassium</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :It is a colorimetric assay, intended for quantitative determination of Potassium in Serum / Plasma.</p> <p>8. Material of Construction: Sample-20l, Standard-20l, and Reagent-1000l</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>
5	<p>1. Generic Name :SODIUM TEST KIT</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic device for Sodium</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :Sodium Test Kit is intended for Quantitative determination of Sodium in Serum / Plasma.</p> <p>8. Material of Construction: Sample-10l, Standard-10l, and Reagent-1000l</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>
6	<p>1. Generic Name :PHOSPHORUS TEST KIT</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic device for Phosphorus</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :It is a photometric UV method assay, intended for quantitative determination of Phosphorus in Serum / Plasma / Urine.</p> <p>8. Material of Construction: Sample-20l, Standard-20l, and Reagent-1000l</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>
7	<p>1. Generic Name :MAGNESIUM TEST KIT</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic device for Magnesium</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :It is a photometric Xylidile blue method assay, intended for quantitative determination of Magnesium in Serum / Plasma / Urine.</p> <p>8. Material of Construction: Sample-10l, Standard-10l, and Reagent-1000l</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>
8	<p>1. Generic Name :CHLORIDE TEST KIT</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic device for Chloride</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :It is a Photometric test using Mercurous (II) thiocyanate assay, intended for quantitative determination of Chloride in Serum / Plasma / Urine.</p> <p>8. Material of Construction: Sample-10l, Standard-10l, and Reagent-1000l</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>
9	<p>1. Generic Name :ZINC TEST KIT</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic device for Zinc</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :It is a Colorimetric assay, intended for quantitative determination of Zinc in Serum / Plasma / Urine.</p> <p>8. Material of Construction: Sample-50l, Standard-50l, and Reagent-1000l</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>

10	<p>1. Generic Name :HOMOCYSTEINE TEST KIT</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic device for homocysteine</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :It is a enzymatic assay, intended for quantitative determination of Homocysteine in Serum / Plasma.</p> <p>8. Material of Construction: Reagent 1-240l,Reagent 2-65l, Sample-13l, and Calibrator-13l</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>
11	<p>1. Generic Name :AMYLASE TEST KIT</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic device for Amylase</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :It is a Kinetic test, intended for quantitative determination of Amylase in Serum / Plasma / Urine.</p> <p>8. Material of Construction: Serum/Plasma-Sample-20l and Reagent-1000l, Urine-Sample-10l and Reagent-1000l</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>
12	<p>1. Generic Name :CK-MB TEST KIT</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic device for CK-MB</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :It is a Kinetic UV test, intended for quantitative determination of CK-MB in Serum / Plasma.</p> <p>8. Material of Construction: Sample-50l and Reagent-1000l</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>
13	<p>1. Generic Name :CK-NAC TEST KIT</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic device for CK-NAC</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :It is a Kinetic UV test, intended for quantitative determination of CK-NAC in Serum / Plasma.</p> <p>8. Material of Construction: Sample-20l and Reagent-1000l</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>
14	<p>1. Generic Name :COPPER TEST KIT</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic device for Copper.</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :It is a Colorimetric assay, intended for quantitative determination of Copper in Serum / Plasma / Urine.</p> <p>8. Material of Construction: Sample-50l, Standard-50l, and Reagent-1000l</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>

15	<p>1. Generic Name :CALCIUM TEST KIT</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic device for Calcium</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :It is a photometric test using Arsenazo III method assay, intended for quantitative determination of Calcium in Serum / Plasma / Urine.</p> <p>8. Material of Construction: Sample-25l, Standard-25l, and Reagent-1000l</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>
16	<p>1. Generic Name :ALKALINE PHOSPHATASE TEST KIT</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic device for Alkaline Phosphatase</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :It is a Kinetic UV test, intended for quantitative determination of Alkaline phosphatase in Serum / Plasma.</p> <p>8. Material of Construction: Sample-20l and Reagent-1000l</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>
17	<p>1. Generic Name :ADENOSINE DEAMINASE (ADA) TEST KIT</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic device for Adenosine deaminase</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :It is a PNP-XOD Enzymatic test, intended for quantitative determination of Adenosine Deaminase in Serum / Plasma.</p> <p>8. Material of Construction: Reagent 1-400l, Reagent 2-200l and Sample-10l</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>
18	<p>1. Generic Name :BICARBONATE TEST KIT</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic device for Bicarbonate</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :It is a enzymatic assay, intended for quantitative determination of Bicarbonate in Serum / Plasma/Urine.</p> <p>8. Material of Construction: Sample-10l, Standard-10l, and Reagent-1000l</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>
19	<p>1. Generic Name :AMMONIA TEST KIT</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic device for Ammonia</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :It is a UV Kinetic assay, intended for quantitative determination of Ammonia in Serum / Plasma.</p> <p>8. Material of Construction: Sample-100l, Standard-100l, and Reagent-1000l</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>

20	<p>1. Generic Name :LIPASE TEST KIT</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic device for Lipase</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :It is a enzymatic assay, intended for quantitative determination of Lipase in Serum / Plasma.</p> <p>8. Material of Construction: Reagent 1-800I, Reagent 2-200I, Sample-20I and Calibrator-20I</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>
21	<p>1. Generic Name :G6PD (QUANTITATIVE) TEST KIT</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic device for G6PD (Quantitative)</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :It is a enzymatic assay, intended for quantitative determination of G6PD in whole blood</p> <p>8. Material of Construction: Assay Reagent-1000I, Substrate Reagent-2000I and Sample-10I</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>
22	<p>1. Generic Name :LDL CHOLESTEROL TEST KIT</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic device for LDL Cholesterol</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :It is a enzymatic assay, intended for quantitative determination of LDL Cholesterol in Serum / Plasma.</p> <p>8. Material of Construction: Reagent 1-750I, Reagent 2-250I,Calibrator-10I and Sample-10I</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>
23	<p>1. Generic Name :HDL CHOLESTEROL TEST KIT</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic device for HDL Cholesterol</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :It is a enzymatic assay, intended for quantitative determination of HDL Cholesterol in Serum / Plasma.</p> <p>8. Material of Construction: Reagent 1-750I, Reagent 2-250I,Calibrator-10I and Sample-10I</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>
24	<p>1. Generic Name :G6PD (QUALITATIVE) TEST KIT</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic device for G6PD (Qualitative)</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :It is a enzymatic assay, intended for Qualitative determination of G6PD in whole blood</p> <p>8. Material of Construction: Reagent 1 : Substrate Vials, Reagent 2: Buffer Reagent and Reagent 3 : Mineral oil</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>

25	<p>1. Generic Name : Filariasis IgG/IgM Ab Rapid Test Kit</p> <p>2. Brand Name : NIL</p> <p>3. Notified Category : Other than above substances In vitro diagnostic device for Filariasis IgG/IgM Ab</p> <p>4. Class of Medical Device : Class B</p> <p>5. Shelf life : 24 months</p> <p>6. Sterile/Non-Sterile: Non-Sterilized</p> <p>7. Intended Use : Filariasis IgG/IgM Ab Rapid Test Kit (Serum/Plasma/Whole blood) is a rapid test that qualitatively detects the presence of IgG and IgM antibodies to W. bancrofti and B. malayi in human serum/plasma/whole blood. The test utilizes conserved recombinant antigen to simultaneously detect IgG and IgM to the W. bancrofti and B. malayi parasites without the restriction on specimen collection.</p> <p>8. Material of Construction: Nitrocellulose Membrane: The membrane coated with Anti-Human IgG Antibody, Anti-Human IgM Antibody on the test line region of the device and Antibody for Control, Gold Conjugate Pad: Gold conjugated Filariasis Antigen for test and Antibody for control are coated on Glass fiber pad, Sample Release Pad, Absorbent Pad</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name : NIL</p>
26	<p>1. Generic Name : Salmonella Typhi IgG/IgM Ab Rapid Test Kit</p> <p>2. Brand Name : NIL</p> <p>3. Notified Category : Other than above substances In vitro diagnostic device for Salmonella Typhi IgG/IgM Ab</p> <p>4. Class of Medical Device : Class B</p> <p>5. Shelf life : 24 months</p> <p>6. Sterile/Non-Sterile: Non-Sterilized</p> <p>7. Intended Use : S typhi IgG/IgM Ab Rapid Test Kit (Serum/Plasma/Whole blood) is a rapid test that qualitatively detects the presence of IgG and IgM antibodies to S typhi in human serum/plasma/whole blood. The test utilizes a combination of antigens from S typhi monoclonal anti-human IgM and IgG antibodies.</p> <p>8. Material of Construction: Nitrocellulose Membrane: The membrane coated with Anti-Human IgG Antibody, Anti-Human IgM Antibody on the test line region of the device and Antibody for Control, Gold Conjugate Pad: Gold conjugated S typhi Antigen for test and Antibody for control are coated on Glass fiber pad, Sample Release Pad, Absorbent Pad</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name : NIL</p>
27	<p>1. Generic Name : H. Pylori Ab Rapid Test Kit</p> <p>2. Brand Name : NIL</p> <p>3. Notified Category : Other than above substances In vitro diagnostic device for H. Pylori Ab</p> <p>4. Class of Medical Device : Class B</p> <p>5. Shelf life : 24 months</p> <p>6. Sterile/Non-Sterile: Non-Sterilized</p> <p>7. Intended Use : H. Pylori Rapid Test Kit (Serum/Plasma/Whole blood) is a rapid test that qualitatively detects the presence of H. Pylori Ab in human serum/plasma or whole blood specimen. The test utilizes a combination of Recombinants Antigens to detect H. Pylori Ab in human serum/plasma or whole blood.</p> <p>8. Material of Construction: Nitrocellulose Membrane: The membrane coated with Recombinant Ag on the test line region of the device and Antibody for Control, Gold Conjugate Pad: Gold conjugated Recombinant Ag for test and Antibody for control are coated on Glass fiber pad, Sample Release Pad, Absorbent Pad</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name : NIL</p>
28	<p>1. Generic Name : Leptospira IgG/IgM Ab Rapid Test Kit</p> <p>2. Brand Name : NIL</p> <p>3. Notified Category : Other than above substances In vitro diagnostic device for Leptospira IgM Ab</p> <p>4. Class of Medical Device : Class B</p> <p>5. Shelf life : 24 months</p> <p>6. Sterile/Non-Sterile: Non-Sterilized</p> <p>7. Intended Use : Leptospira IgG/IgM Ab Rapid Test Kit (Serum/Plasma/Whole blood) is a rapid test that qualitatively detects the presence of IgG and IgM antibodies to Leptospira interrogans in human serum/plasma/whole blood. The test utilizes a combination of antigens from L. interrogans, monoclonal anti-human IgM and IgG antibodies.</p> <p>8. Material of Construction: Nitrocellulose Membrane: The membrane coated with Anti-Human IgG Antibody, Anti-Human IgM Antibody on the test line region of the device and Antibody for Control, Gold Conjugate Pad: Gold conjugated Leptospira Antigen for test and Antibody for control are coated on Glass fiber pad, Sample Release Pad, Absorbent Pad</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name : NIL</p>

29	<p>1. Generic Name :Chikungunya IgG/IgM Ab Rapid Test Kit</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic device for Chikungunya IgG/IgM Ab</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :Chikungunya IgG/IgM Ab Rapid Test Kit (Serum/Plasma/Whole blood) is a rapid test that qualitatively detects the presence of IgG and IgM antibodies against Chikungunya virus in human Serum/Plasma/Whole Blood. The test utilizes conserved recombinant antigen to simultaneously detect IgG and IgM to the Chikungunya virus without the restriction on specimen collection.</p> <p>8. Material of Construction: Nitrocellulose Membrane: The membrane coated with Anti-Human IgG Antibody, Anti-Human IgM Antibody on the test line region of the device and Antibody for Control, Gold Conjugate Pad: Gold conjugated Chikungunya Antigen for test and Antibody for control are coated on Glass fiber pad , Sample Release Pad, Absorbent Pad</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>
30	<p>1. Generic Name :Japanese encephalitis IgM Ab Rapid Test Kit</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic device for Japanese encephalitis IgM Ab</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :Japanese Encephalitis IgM Ab Rapid Test Kit (Serum/Plasma/Whole blood) is a rapid test that qualitatively detects the presence of IgM antibodies of Japanese encephalitis virus (JEV) in human serum/plasma or whole blood specimen. The test utilizes a combination of Recombinants Antigens and anti-human IgM antibody to detect presence of IgM Ab IgM antibodies of Japanese encephalitis virus (JEV) in human serum/plasma or whole blood.</p> <p>8. Material of Construction: Nitrocellulose Membrane: The membrane coated with Anti-Human IgM antibody on the test line region of the device and Antibody for Control, Gold Conjugate Pad: Gold conjugated Recombinant Ag for test and Antibody for control are coated on Glass fiber pad, Sample Release Pad, Absorbent Pad</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>
31	<p>1. Generic Name :Dengue IgG/IgM Ab Rapid Test Kit</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic device for Dengue IgG/IgM Ab</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :Dengue IgG/IgM Ab Rapid Test Kit (Serum/Plasma/Whole blood) is a rapid test that qualitatively detects the presence of IgG and IgM antibodies to Dengue Virus in human serum/plasma/whole blood. The test utilizes a combination of antigens from Dengue Virus monoclonal anti-human IgM and IgG antibodies.</p> <p>8. Material of Construction: Nitrocellulose Membrane: The membrane coated with Anti-Human IgG Antibody, Anti-Human IgM Antibody on the test line region of the device and Antibody for Control, Gold Conjugate Pad: Gold conjugated Dengue Virus Antigen for test and Antibody for control are coated on Glass fiber pad, Sample Release Pad, Absorbent Pad</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>

32	<p>1. Generic Name :Urine Strips -10 Para (Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocyte)</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic devices for Urine Strips -10 Para</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :Urine Test Strips contains solid phase reagent areas affixed to a plastic stick. They are provided as a dry reagent. Urine Test Strips provide test for the semi-quantitative determinations of Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocyte.</p> <p>8. Material of Construction: Uncut membrane sheet Length- 110 mm and Card Length- 260 mm</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>
33	<p>1. Generic Name :Urine Strips -12 Para (Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, Leukocyte, Micro albumin, and Creatinine)</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic devices for Urine Strips -12 Para</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :Urine Test Strips contains solid phase reagent areas affixed to a plastic stick. They are provided as a dry reagent. Urine Test Strips provide test for the semi-quantitative determinations of Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, Leukocyte, Micro albumin, and Creatinine.</p> <p>8. Material of Construction: Uncut membrane sheet Length- 135 mm and Card Length- 260 mm</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>
34	<p>1. Generic Name :Scrub Typhus IgG/IgM Ab Rapid Test Kit</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic devices for Scrub Typhus</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :Scrub Typhus IgG/IgM Ab Rapid Test Kit (Serum/Plasma/Whole blood) is a rapid test that qualitatively detects the presence of IgG and IgM antibodies to Orientia tsutsugamushi in human serum/plasma/whole blood. The test utilizes a combination of antigens from Orientia tsutsugamushi monoclonal anti-human IgM and IgG antibodies.</p> <p>8. Material of Construction: Nitrocellulose Membrane: The membrane coated with Anti-Human IgG Antibody, Anti-Human IgM Antibody on the test line region of the device and Antibody for Control., Gold Conjugate Pad: Gold conjugated Orientia tsutsugamushi Antigen for test and Antibody for control are coated on Glass fiber pad, Sample Release Pad, Absorbent Pad</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>
35	<p>1. Generic Name :Leishmania IgG/IgM Ab Rapid Test Kit</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic devices for Leishmania</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :Leishmania IgG/IgM Ab Rapid Test Kit (Serum/Plasma/Whole blood) is a rapid test that qualitatively detects the presence of IgG and IgM antibodies to L. donovani in human serum/plasma/whole blood. The test utilizes a combination of antigens from L. donovani monoclonal anti-human IgM and IgG antibodies.</p> <p>8. Material of Construction: Nitrocellulose Membrane: The membrane coated with Anti-Human IgG Antibody, Anti-Human IgM Antibody on the test line region of the device and Antibody for Control, Gold Conjugate Pad: Gold conjugated L. donovani Antigen for test and Antibody for control are coated on Glass fiber pad, Sample Release Pad, Absorbent Pad</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>

36	<p>1. Generic Name :SGPT Test Kit</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic devices for SGPT</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :SGPT Test Kit is intended for Quantitative determination of Alanine transaminase (ALT) in Serum / Plasma.</p> <p>8. Material of Construction: Reagent I : Buffer reagent, Reagent II : Enzyme reagent</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>
37	<p>1. Generic Name :SGOT Test Kit</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic devices for SGOT</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :SGOT Test Kit is intended for Quantitative determination of Aspartate transaminase (AST) in Serum / Plasma.</p> <p>8. Material of Construction: Reagent I : Buffer reagent, Reagent II : Enzyme reagent</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>
38	<p>1. Generic Name :Glucose Hexokinase Test Kit</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic devices for Glucose Hexokinase</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :Glucose Hexokinase Test Kit is intended for Quantitative determination of Glucose in Serum / Plasma / Urine.</p> <p>8. Material of Construction: Reagent 1: Buffer Reagent, Reagent 2: Enzyme Reagent, Standard : 100 mg/dl.</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>
39	<p>1. Generic Name :Bilirubin Total Test Kit</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic devices for Bilirubin Total</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :Bilirubin (Total) Test Kit is intended for Quantitative determination of Total Bilirubin in serum / Plasma.</p> <p>8. Material of Construction: Reagent 1: Bilirubin (Total) , Reagent Reagent 2: Total Nitrite Reagent</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>
40	<p>1. Generic Name :Bilirubin Direct Test Kit</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic devices for Bilirubin Direct</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :Bilirubin (Direct) Test Kit is intended for Quantitative determination of Direct Bilirubin in serum / Plasma.</p> <p>8. Material of Construction: Reagent 1: Bilirubin (Direct) Reagent, Reagent 2: Direct Nitrite Reagent</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>

41	<p>1. Generic Name : Creatinine Enzymatic Test Kit</p> <p>2. Brand Name : NIL</p> <p>3. Notified Category : Other than above substances In vitro diagnostic devices for Creatinine Enzymatic</p> <p>4. Class of Medical Device : Class B</p> <p>5. Shelf life : 24 months</p> <p>6. Sterile/Non-Sterile: Non-Sterilized</p> <p>7. Intended Use : Creatinine (Enzymatic) Test Kit is intended for Quantitative determination of Creatinine in serum / plasma / Urine.</p> <p>8. Material of Construction: Reagent 1: Enzyme Reagent I, Reagent 2: Enzyme Reagent II</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name : NIL</p>
42	<p>1. Generic Name : Creatinine (Alkaline Picrate) Test Kit</p> <p>2. Brand Name : NIL</p> <p>3. Notified Category : Other than above substances In vitro diagnostic devices for Creatinine (Alkaline Picrate)</p> <p>4. Class of Medical Device : Class B</p> <p>5. Shelf life : 24 months</p> <p>6. Sterile/Non-Sterile: Non-Sterilized</p> <p>7. Intended Use : Creatinine (Alkaline Picrate) Test Kit is intended for Quantitative determination of Creatinine in serum / plasma / Urine.</p> <p>8. Material of Construction: Reagent 1: Picrate reagent, Reagent 2: Alkaline Reagent, Creatinine Standard: 2 mg/dl</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name : NIL</p>
43	<p>1. Generic Name : Hemoglobin Test Kit</p> <p>2. Brand Name : NIL</p> <p>3. Notified Category : Other than above substances In vitro diagnostic devices for Hemoglobin</p> <p>4. Class of Medical Device : Class B</p> <p>5. Shelf life : 24 months</p> <p>6. Sterile/Non-Sterile: Non-Sterilized</p> <p>7. Intended Use : Hemoglobin Test Kit is intended for Quantitative determination of Hemoglobin in Whole Blood.</p> <p>8. Material of Construction: Reagent : Hemoglobin reagent</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name : NIL</p>
44	<p>1. Generic Name : Triglycerides Test Kit</p> <p>2. Brand Name : NIL</p> <p>3. Notified Category : Other than above substances In vitro diagnostic devices for Triglycerides</p> <p>4. Class of Medical Device : Class B</p> <p>5. Shelf life : 24 months</p> <p>6. Sterile/Non-Sterile: Non-Sterilized</p> <p>7. Intended Use : Triglycerides Test Kit is intended for Quantitative determination of Triglycerides in Serum / Plasma.</p> <p>8. Material of Construction: Reagent : Triglycerides reagent, Triglycerides Standard : 200 mg/dl</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name : NIL</p>
45	<p>1. Generic Name : Urea (UV) Test Kit</p> <p>2. Brand Name : NIL</p> <p>3. Notified Category : Other than above substances In vitro diagnostic devices for Urea (UV)</p> <p>4. Class of Medical Device : Class B</p> <p>5. Shelf life : 24 months</p> <p>6. Sterile/Non-Sterile: Non-Sterilized</p> <p>7. Intended Use : Urea (UV) Test Kit is intended for Quantitative determination of Urea in Serum / Plasma / Urine.</p> <p>8. Material of Construction: Reagent 1: Buffer reagent, Reagent 2 : Enzyme reagent, Urea Standard : 50 mg/dl</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name : NIL</p>

46	<p>1. Generic Name :Uric Acid Test Kit</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic devices for Uric Acid</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :Uric Acid Test Kit is intended for Quantitative determination of Uric Acid in Serum / Plasma / Urine.</p> <p>8. Material of Construction: Reagent: Uric Acid Reagent, Uric acid Standard: 5 mg/dL</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>
47	<p>1. Generic Name :Sickle Cell Rapid Test Kit</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic devices for Sickle Cell Rapid</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :Sickle Cell Rapid Test Kit is a qualitative screening test for the detection of hemoglobin S and A in blood.</p> <p>8. Material of Construction: Nitrocellulose Membrane: The membrane coated with Sickle cell HbA and HbS Antibodies on the test line region of the device and Goat anti-mouse IgG Antibody for Control, Gold Conjugate Pad: Gold conjugated with Anti Sickle cell HbA and HbS Antibodies for Test, and Mouse IgG Antibody for control are coated on Glass fiber pad, Sample Release Pad , Absorbent Pad</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>
48	<p>1. Generic Name :Urine Strips -2 Para (Glucose, Protein)</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic devices for Urine Strips -2 Para</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :Urine Test Strips contains solid phase reagent areas affixed to a plastic stick. They are provided as a dry reagent. Urine Test Strips provide test for the semi-quantitative determinations of Glucose, Protein. The test results may provide information regarding the status of carbohydrate metabolism, Kidney function, and urinary tract infection.</p> <p>8. Material of Construction: Glucose: 10.54% w/w glucose oxidase (aspergillus, 250 IU), 0.2% w/w Peroxidase (horseradish, 2,500 IU), 0.07% w/w, O-Toluidine and 84.3% non reactive ingredients, Protein: 1.5% w/w tetra bromophenol blue and 98.5% w/w non reactive ingredients</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>
49	<p>1. Generic Name :Urine Strips -3 Para (Glucose, Protein, Ketone)</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic devices for Urine Strips -3 Para</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :Urine Test Strips contains solid phase reagent areas affixed to a plastic stick. They are provided as a dry reagent. Urine Test Strips provide test for the semi-quantitative determinations of Glucose, Protein, and Ketone. The test results may provide information regarding the status of carbohydrate metabolism, Kidney function, liver function, acid Base and urinary tract infection.</p> <p>8. Material of Construction: Glucose: 10.54% w/w glucose oxidase (aspergillus, 250 IU), 0.2% w/w Peroxidase (horseradish, 2,500 IU), 0.07% w/w, O-Toluidine and 84.3% non-reactive ingredients, Ketone: 4.5% w/w sodium nitroprusside and 95.5% w/w buffer, Protein: 1.5% w/w tetrabromophenol blue and 98.5% w/w non-reactive ingredients.</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>

50	<p>1. Generic Name :Albumin Test Kit</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic devices for Albumin</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :An albumin test reagent/kit is a medical device intended for the estimation of albumin in human serum/plasma.</p> <p>8. Material of Construction: Reagent I : BCG reagent , Albumin standard : 4 g/dl (store at 2-8°C)</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>
51	<p>1. Generic Name :Cholesterol Test Kit</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic devices for Cholesterol</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :Cholesterol reagent is intended for Quantitative determination of Cholesterol in serum / plasma.</p> <p>8. Material of Construction: Reagent :Cholesterol reagent, Cholesterol standard :200 mg/dl</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>
52	<p>1. Generic Name :Total Protein Test Kit</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic devices for Total Protein</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :Total Protein Test Kit is intended for Quantitative determination of Total Protein in Serum / Plasma.</p> <p>8. Material of Construction: Reagent I : Biuret reagent, Protein Standard : 6 g/dl</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>
53	<p>1. Generic Name :Sickle Cell Hb S, Hb A and Hb C Rapid Test Kit</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic devices for Sickle Cell</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :Sickle Cell Rapid Test Kit is a qualitative screening test for the detection of hemoglobin A, S and C in blood.</p> <p>8. Material of Construction: • Nitrocellulose Membrane: The membrane coated with Sickle cell HbA and HbS Antibodies on the test line region of the device and Goat anti-mouse IgG Antibody for Control. • Gold Conjugate Pad: Gold conjugated with Anti Sickle cell HbA and HbS Antibodies for Test, and Mouse IgG Antibody for control are coated on Glass fiber pad • Sample Release Pad • Absorbent Pad</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>
54	<p>1. Generic Name :Glucose Test Kit</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic devices for Glucose</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :Glucose Test Kit is intended for Quantitative determination of Glucose in Serum / Plasma / Urine.</p> <p>8. Material of Construction: Reagent I-Glucose Reagent, Glucose standard- 100 mg/dl (5.54 mmol/L)</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>

55	<p>1. Generic Name :Lactate Dehydrogenase (LDH) Test Kit</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic devices for Lactate Dehydrogenase</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :Lactate Dehydrogenase (LDH) (L-P) Test Kit is intended for Quantitative determination of Lactate Dehydrogenase (LDH) in serum / Plasma.</p> <p>8. Material of Construction: Reagent 1-Buffer reagent, Reagent 2-Substrate reagent</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>
56	<p>1. Generic Name :Ferritin Rapid Test Kit</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic devices for Ferritin</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :Ferritin Rapid Test Kit (Serum/Plasma/Whole blood) qualitatively detects the presence of ferritin protein in Whole blood/Serum/Plasma specimens within 15 minutes.</p> <p>8. Material of Construction: Nitrocellulose Membrane: The membrane coated with recombinant Ferritin Antibody on the test line region of the device and Antibody for Control, Gold Conjugate Pad: Gold conjugated recombinant Ferritin Antibody for test and Antibody for control are coated on Glass fiber pad, Sample Release Pad, Absorbent Pad</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>
57	<p>1. Generic Name :Vitamin D Rapid Test Kit</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic devices for Vitamin D</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :Vitamin D Rapid Test Kit (Serum/Plasma/Whole blood) detects the presence of Vitamin D in Whole blood/Serum/Plasma specimens within 15 minutes.</p> <p>8. Material of Construction: Nitrocellulose Membrane, Gold Conjugate Pad, Sample Release Pad, Absorbent Pad</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>

Note: Validity of the Market Satanding will be 1 year from the date of issuance or till validity of licence,whichever is earlier.

Competent Authority