

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

FREE SALE CERTIFICATE

FSC Number : FSC/IVD/2023/000175

Dated : 06/10/2023

This is to certify that M/s. PARAMCARE LIFE SCIENCES PRIVATE LIMITED ,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 is holding Manufacturing License no. MFG/IVD/2022/000096 issued on 07-SEP-2022 Under this license, the said firm is permitted to manufacture the products for their manufacture and sale in domestic market as per Indian Law and for export as per law of importing country (ies):-

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

| S.NO | Medical Device Details  |
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| 1    | 1. Generic Name :Luteinizing Hormone (LH) Rapid Test Kit<br>2. Brand Name :NIL<br>3. Notified Category :Other than above substancesIn vitro diagnostic device for LH<br>4. Class of Medical Device :Class B<br>5. Shelf life :24 months<br>6. Sterile/Non-Sterile:Non-Sterilized<br>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.<br>8. Material of Construction: Nitrocellulose Membrane, Gold Conjugate Pad, Sample Release Pad, Absorbent Pad<br>9. Dimension: NA<br>10. Model/Catalogue No./Name :NIL |
| 2    | 1. Generic Name :IgE Rapid Test Kit<br>2. Brand Name :NIL<br>3. Notified Category :Other than above substancesIn vitro diagnostic device for IgE<br>4. Class of Medical Device :Class B<br>5. Shelf life :24 months<br>6. Sterile/Non-Sterile:Non-Sterilized<br>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.<br>8. Material of Construction: Nitrocellulose Membrane, Gold Conjugate Pad, Sample Release Pad, Absorbent Pad<br>9. Dimension: NA<br>10. Model/Catalogue No./Name :NIL  |

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| 3 | <p>1. Generic Name :hCG - Pregnancy Rapid Test Kit</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn 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>  |

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| 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>   |

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| 13 | 1. Generic Name :CK-NAC TEST KIT<br>2. Brand Name :NIL<br>3. Notified Category :Other than above substancesIn vitro diagnostic device for CK-NAC<br>4. Class of Medical Device :Class B<br>5. Shelf life :24 months<br>6. Sterile/Non-Sterile:Non-Sterilized<br>7. Intended Use :It is a Kinetic UV test, intended for quantitative determination of CK-NAC in Serum / Plasma.<br>8. Material of Construction: Sample-20l and Reagent-1000l<br>9. Dimension: NA<br>10. Model/Catalogue No./Name :NIL  |
| 14 | 1. Generic Name :COPPER TEST KIT<br>2. Brand Name :NIL<br>3. Notified Category :Other than above substancesIn vitro diagnostic device for Copper.<br>4. Class of Medical Device :Class B<br>5. Shelf life :24 months<br>6. Sterile/Non-Sterile:Non-Sterilized<br>7. Intended Use :It is a Colorimetric assay, intended for quantitative determination of Copper in Serum / Plasma / Urine.<br>8. Material of Construction: Sample-50l, Standard-50l, and Reagent-1000l<br>9. Dimension: NA<br>10. Model/Catalogue No./Name :NIL   |
| 15 | 1. Generic Name :CALCIUM TEST KIT<br>2. Brand Name :NIL<br>3. Notified Category :Other than above substancesIn vitro diagnostic device for Calcium<br>4. Class of Medical Device :Class B<br>5. Shelf life :24 months<br>6. Sterile/Non-Sterile:Non-Sterilized<br>7. Intended Use :It is a photometric test using Arsenazo III method assay, intended for quantitative determination of Calcium in Serum / Plasma / Urine.<br>8. Material of Construction: Sample-25l, Standard-25l, and Reagent-1000l<br>9. Dimension: NA<br>10. Model/Catalogue No./Name :NIL           |
| 16 | 1. Generic Name :ALKALINE PHOSPHATASE TEST KIT<br>2. Brand Name :NIL<br>3. Notified Category :Other than above substancesIn vitro diagnostic device for Alkaline Phosphatase<br>4. Class of Medical Device :Class B<br>5. Shelf life :24 months<br>6. Sterile/Non-Sterile:Non-Sterilized<br>7. Intended Use :It is a Kinetic UV test, intended for quantitative determination of Alkaline phosphatase in Serum / Plasma.<br>8. Material of Construction: Sample-20l and Reagent-1000l<br>9. Dimension: NA<br>10. Model/Catalogue No./Name :NIL                            |
| 17 | 1. Generic Name :ADENOSINE DEAMINASE (ADA) TEST KIT<br>2. Brand Name :NIL<br>3. Notified Category :Other than above substancesIn vitro diagnostic device for Adenosine deaminase<br>4. Class of Medical Device :Class B<br>5. Shelf life :24 months<br>6. Sterile/Non-Sterile:Non-Sterilized<br>7. Intended Use :It is a PNP-XOD Enzymatic test, intended for quantitative determination of Adenosine Deaminase in Serum / Plasma.<br>8. Material of Construction: Reagent 1-400l, Reagent 2-200l and Sample-10l<br>9. Dimension: NA<br>10. Model/Catalogue No./Name :NIL |

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| 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 1-800l, Reagent 2-200l, Sample-20l and Calibrator-20l</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-1000l, Substrate Reagent-2000l and Sample-10l</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 1-750l, Reagent 2-250l,Calibrator-10l and Sample-10l</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p> |

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| 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 1-750l, Reagent 2-250l,Calibrator-10l and Sample-10l</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 substancesIn 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 substancesIn 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>  |

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| 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 substancesIn 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 substancesIn 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> |

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| 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>  |



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| 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>   |

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

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| 41 | <p>1. Generic Name :Creatinine Enzymatic Test Kit</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn 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, Standard : 2 mg/d</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>                                   |
| 42 | <p>1. Generic Name :Sickle Cell Assay 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 Assay Kit is a qualitative screening solubility test for the detection of hemoglobin S in blood.</p> <p>8. Material of Construction: R1- Buffer Reagent, R2- Reducing Powder</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p>  |
| 43 | <p>1. Generic Name :Creatinine (Alkaline Picrate) Test Kit</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn 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> |
| 44 | <p>1. Generic Name :Hemoglobin Test Kit</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn 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>  |
| 45 | <p>1. Generic Name :Triglycerides Test Kit</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn 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>  |

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| 46 | <p>1. Generic Name :Urea (UV) Test Kit</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn 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>   |
| 47 | <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>  |
| 48 | <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>  |
| 49 | <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> |

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| 50 | <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> |
| 51 | <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>   |
| 52 | <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>   |
| 53 | <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>  |

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| 54 | <ol style="list-style-type: none"> <li>1. Generic Name :Sickle Cell Hb S, Hb A and Hb C Rapid Test Kit</li> <li>2. Brand Name :NIL</li> <li>3. Notified Category :Other than above substancesIn vitro diagnostic devices for Sickle Cell</li> <li>4. Class of Medical Device :Class B</li> <li>5. Shelf life :24 months</li> <li>6. Sterile/Non-Sterile:Non-Sterilized</li> <li>7. Intended Use :Sickle Cell Rapid Test Kit is a qualitative screening test for the detection of hemoglobin A, S and C in blood.</li> <li>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</li> <li>9. Dimension: NA</li> <li>10. Model/Catalogue No./Name :NIL</li> </ol> |
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Competent Authority