

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/2023/000186

Dated : 09/10/2023

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/2022/000123 issued on 07-NOV-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
1	1. Generic Name :Troponin I Rapid Test Kit 2. Brand Name :NIL 3. Notified Category :Other than above substancesIn vitro diagnostic device for Troponin I 4. Class of Medical Device :Class C 5. Shelf life :24 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Troponin I Rapid Test is a rapid test that qualitatively detects the presence of cTnI in human serum/plasma/whole blood specimen at the sensitivity of 0.5 ng/mL. 8. Material of Construction: Nitrocellulose Membrane, Gold Conjugate Pad, Sample Release Pad, Absorbent Pad 9. Dimension: NA 10. Model/Catalogue No./Name :NIL
2	1. Generic Name :Troponin T Rapid Test Kit 2. Brand Name :NIL 3. Notified Category :Other than above substancesIn vitro diagnostic device for Troponin T 4. Class of Medical Device :Class C 5. Shelf life :24 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Troponin T Rapid Test is a rapid test that qualitatively detects the presence of Cardiac Troponin T (cTnT) in human serum/plasma/whole blood specimen at the sensitivity of 0.5 ng/mL. 8. Material of Construction: Nitrocellulose Membrane, Gold Conjugate Pad, Sample Release Pad, Absorbent Pad 9. Dimension: NA 10. Model/Catalogue No./Name :NIL

3	1. Generic Name :Influenza A+B Rapid Test Kit 2. Brand Name :NIL 3. Notified Category :Other than above substancesIn vitro diagnostic devices for Influenza A+B 4. Class of Medical Device :Class C 5. Shelf life :24 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Influenza A+B Rapid Test Kit is a rapid test that aid in the qualitative detection and differentiation of Influenza A virus (including H5N1 and H1N1), and Influenza B in in nasopharyngeal swab or nasal aspirate specimens. The test utilizes a combination of anti-influenza A +B antibodies. 8. Material of Construction: Influenza A+B Ag Rapid test is a lateral flow immuno-chromatographic assay which utilizes the chemical extraction of viral antigens followed by solid-phase immunoassay technology. The test device is designed to detect antigens from influenza A, and /or influenza B in anterior nasal or nasopharyngeal swab specimens from individuals with signs and symptoms of respiratory infection, suspected of flu by their healthcare provider, within the first five days of onset of symptoms. It is intended to aid in the rapid differential diagnosis of influenza A, and /or influenza B viral infections. 9. Dimension: NA 10. Model/Catalogue No./Name :NIL
4	1. Generic Name :Rapid Drugs (Amphetamine) Screening Test Kit 2. Brand Name :NIL 3. Notified Category :Other than above substancesIn vitro diagnostic devices for Amphetamine 4. Class of Medical Device :Class C 5. Shelf life :24 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :The Rapid Drugs (Amphetamine) Screening Test Kit is a rapid test that qualitatively detects the presence of Amphetamines in human urine specimen at the cut off value of 1000 ng/mL. The test utilizes a combination of monoclonal antibody and BSA conjugated Amphetamines to detect Amphetamines in human urine sample 8. Material of Construction: Nitrocellulose Membrane: The membrane coated with Monoclonal BSA conjugated AMP on the test line region of the device and Antibody for Control, Gold Conjugate Pad: Gold conjugated Monoclonal Anti-AMP Antibodies for test and Antibody for control are coated on Glass fiber pad, Sample Release Pad, Absorbent Pad 9. Dimension: NA 10. Model/Catalogue No./Name :NIL
5	1. Generic Name :Rapid Drugs (Barbiturates) Screening Test Kit 2. Brand Name :NIL 3. Notified Category :Other than above substancesIn vitro diagnostic devices for Barbiturates 4. Class of Medical Device :Class C 5. Shelf life :24 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :The Rapid Drugs (Barbiturates) Screening Test Kit is a rapid test that qualitatively detects the presence of Barbiturates in human urine specimen at the cut off value of 300 ng/mL. The test utilizes a combination of monoclonal antibody and BSA conjugated Barbiturates to detect Barbiturates in human urine sample 8. Material of Construction: Nitrocellulose Membrane: The membrane coated with Monoclonal BSA conjugated BAR on the test line region of the device and Antibody for Control, Gold Conjugate Pad: Gold conjugated Monoclonal Anti-BAR Antibodies for test and Antibody for control are coated on Glass fiber pad, Sample Release Pad, Absorbent Pad 9. Dimension: NA 10. Model/Catalogue No./Name :NIL

6	1. Generic Name :The Rapid Drugs (Benzodiazepines) Screening Test Kit 2. Brand Name :NIL 3. Notified Category :Other than above substancesIn vitro diagnostic devices for Benzodiazepines 4. Class of Medical Device :Class C 5. Shelf life :24 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :The Rapid Drugs (Benzodiazepines) Screening Test Kit is a rapid test that qualitatively detects the presence of Benzodiazepines in human urine specimen at the cut off value of 300 ng/mL. The test utilizes a combination of monoclonal antibody and BSA conjugated Benzodiazepines to detect Benzodiazepines in human urine sample 8. Material of Construction: Nitrocellulose Membrane: The membrane coated with Monoclonal BSA conjugated BZO on the test line region of the device and Antibody for Control, Gold Conjugate Pad: Gold conjugated Monoclonal Anti-BZO Antibodies for test and Antibody for control are coated on Glass fiber pad, Sample Release Pad, Absorbent Pad 9. Dimension: NA 10. Model/Catalogue No./Name :NIL
7	1. Generic Name :Rapid Drugs (Cocaine) Screening Test Kit 2. Brand Name :NIL 3. Notified Category :Other than above substancesIn vitro diagnostic devices for Cocaine 4. Class of Medical Device :Class C 5. Shelf life :24 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :The Rapid Drugs (Cocaine) Screening Test Kit is a rapid test that qualitatively detects the presence of Cocaine in human urine specimen at the cut off value of 300 ng/mL. The test utilizes a combination of monoclonal antibody and BSA conjugated Cocaine to detect Cocaine in human urine sample 8. Material of Construction: Nitrocellulose Membrane: The membrane coated with Monoclonal BSA conjugated COC on the test line region of the device and Antibody for Control, Gold Conjugate Pad: Gold conjugated Monoclonal Anti-COC Antibodies for test and Antibody for control are coated on Glass fiber pad, Sample Release Pad, Absorbent Pad 9. Dimension: NA 10. Model/Catalogue No./Name :NIL
8	1. Generic Name :Rapid Drugs (Opiate (Morphine)) Screening Test Kit 2. Brand Name :NIL 3. Notified Category :Other than above substancesIn vitro diagnostic devices for Opiate (Morphine) 4. Class of Medical Device :Class C 5. Shelf life :24 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :The Rapid Drugs (Opiate (Morphine)) Screening Test Kit is a rapid test that qualitatively detects the presence of Opiate (Morphine) in human urine specimen at the cut off value of 300 ng/mL. The test utilizes a combination of monoclonal antibody and BSA conjugated Opiate (Morphine) to detect Opiate (Morphine) in human urine sample 8. Material of Construction: Nitrocellulose Membrane: The membrane coated with Monoclonal BSA conjugated OPI on the test line region of the device and Antibody for Control, Gold Conjugate Pad: Gold conjugated Monoclonal Anti-OPI Antibodies for test and Antibody for control are coated on Glass fiber pad, Sample Release Pad, Absorbent Pad 9. Dimension: NA 10. Model/Catalogue No./Name :NIL

9	1. Generic Name :Rapid Drugs (Cannabinoids) Screening Test Kit 2. Brand Name :NIL 3. Notified Category :Other than above substancesIn vitro diagnostic devices for Cannabinoids 4. Class of Medical Device :Class C 5. Shelf life :24 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :The Rapid Drugs (Cannabinoids) Screening Test Kit is a rapid test that qualitatively detects the presence of Cannabinoids in human urine specimen at the cut off value of 50 ng/mL. The test utilizes a combination of monoclonal antibody and BSA conjugated Cannabinoids to detect Cannabinoids in human urine sample 8. Material of Construction: Nitrocellulose Membrane: The membrane coated with Monoclonal BSA conjugated THC on the test line region of the device and Antibody for Control, Gold Conjugate Pad: Gold conjugated Monoclonal Anti-THC Antibodies for test and Antibody for control are coated on Glass fiber pad, Sample Release Pad, Absorbent Pad 9. Dimension: NA 10. Model/Catalogue No./Name :NIL
10	1. Generic Name :Rapid Multi Drugs (6 in 1(Cocaine, Amphetamine, Barbiturate, Benzodiazepine, THC, Opiate) Screening Test Kit 2. Brand Name :NIL 3. Notified Category :Other than above substancesIn vitro diagnostic devices for Rapid Multi Drugs 4. Class of Medical Device :Class C 5. Shelf life :24 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Rapid Multi Drugs (6 in 1(Cocaine, Amphetamine, Barbiturate, Benzodiazepine, THC, Opiate) Screening Test Kit is a rapid test that qualitatively detects the presence of Cocaine (300 ng/ml), Amphetamine (1000 ng/ml), Barbiturate (300 ng/ml), Benzodiazepine (300 ng/ml), THC (50 ng/ml) and Opiate (300 ng/ml) in human urine specimen at the cut off value. The test utilizes a combination of monoclonal antibody and BSA conjugated Cocaine, Amphetamine, Barbiturate, Benzodiazepine, THC and Opiate to detect in human urine sample. 8. Material of Construction: Nitrocellulose Membrane: The membrane coated with Monoclonal BSA conjugated AMP, OPI and COC is one membrane and THC, BZO and BAR on another membrane test line region of the device and Antibody for Control, Gold Conjugate Pad: Gold conjugated Monoclonal Anti- COC, AMP, BZO, THC, and OPI Antibodies for test and Antibody for control are coated on Glass fiber pad, Sample Release Pad, Absorbent Pad 9. Dimension: NA 10. Model/Catalogue No./Name :NIL
11	1. Generic Name :Dengue NS 1 Ag Rapid Test Kit 2. Brand Name :NIL 3. Notified Category :Other than above substancesIn vitro diagnostic devices for Dengue NS 1 Ag 4. Class of Medical Device :Class C 5. Shelf life :24 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Dengue NS1 Ag Rapid Test Kit is intended for qualitative determination of NS1 Ag for dengue virus in human Serum/Plasma/Whole Blood. 8. Material of Construction: 1. Nitrocellulose Membrane: The membrane coated with Anti-Dengue NS1 Antibody on the test line region of the device and Antibody for Control. 2. Gold Conjugate Pad: Gold conjugated Anti-Dengue NS1 Antibody for test and Antibody for control are coated on Glass fiber pad 3. Sample Release Pad 4. Absorbent Pad 9. Dimension: NA 10. Model/Catalogue No./Name :NIL

