

Laboratory QPS Bioserve India Pvt. Ltd., 6-56/6/1A, Balanagar, Hyderabad, Telangana

Accreditation Standard ISO 15189: 2012

Field Medical Testing **Issue Date** 21.12.2015

Certificate Number M-0843 **Valid Until** 20.12.2017

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| S.No. | Product / Material of Test | Specific Test Performed | Test Method | Range of Testing / Limits of Detection | CV% |
|-----------|-------------------------------------|---------------------------|---|--|-----|
| I. | <u>CLINICAL BIOCHEMISTRY</u> | | | | |
| 1. | SERUM | Glucose | GOD/POD, Colorimetric | 20 - 625.0 mg/dL | 2.5 |
| 2. | SERUM | Blood Urea Nitrogen (BUN) | Urease with Indicator Dye | 2.0 - 120.0 mg/dL | 2.8 |
| 3. | SERUM | Creatinine | Enzymatic (Creatinine Amidohydrolase) | 0.05 - 14.0 mg/dL | 3.1 |
| 4. | SERUM | Total Bilirubin | Azobilirubin/dyphylline | 0.10 - 27.0 mg/dL | 7.9 |
| 5. | SERUM | ALT / SGPT | Kinetic With Pyridoxal 5 Phosphate - (Lactate dehydrogenase / NADH) | 6.0 - 1000.0 U/L | 8.6 |
| 6. | SERUM | AST / SGOT | Kinetic (leuco dye) with Pyridoxal 5 Phosphate (Visible method) | 3.0 - 750.0 U/L | 6.5 |
| 7. | SERUM | Cholesterol | Enzymatic (CHE/CHO/POD) | 50.0 - 325.0 mg/dL | 3.2 |
| 8. | SERUM | Total Protein | Biuret (Alkaline Cupric Sulfate) | 1.0 - 12.0 g/dL | 4.4 |
| 9. | SERUM | Sodium | Direct Ion Selective Electrode | 75.0 - 250.0 mmol/L | 1.7 |

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| 10. | SERUM | Potassium | Direct Ion Selective Electrode | 1.0 - 14.0 mmol/L | 1.3 |
| II. <u>CLINICAL PATHOLOGY</u> | | | | | |
| 1. | URINE | Colour | Physical Examination | NA | NA |
| | | Appearance | Physical Examination | NA | NA |
| | | pH | Double Indicator Principle using Photometric Method | 5.0 - 8.5 | NA |
| | | Specific Gravity | Photometric Method | 1.000 - 1.030 | NA |
| | | Proteins | Protein-error-of-indicators Principle using Photometric Method | Negative (Trace) < 30 mg/dL (+) 30 mg/dL (++) 100 mg/dL (+++) 300 mg/dL (++++) over 2000 mg/dL | NA |
| | | Glucose | Double sequential enzyme reaction using Photometric Method | Negative (Trace) < 1/10 g/dL (+) 1/4 g/dL (++) 1.2 g/dL (+++) 1 g/dL (++++) 2 g/dL or more | NA |

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| | | Ketone | Photometry principle using Photometric Method | Negative (Trace) 5 mg/dL (Small) 15 mg/dL (Moderate) 40 mg/dL (Large) 80 mg/dL (Large) 160 mg/dL | NA |
| | | Bilirubin | Coupling principle using Photometric Method | Negative (+) Small (++) Moderate (+++ Large) | NA |
| | | Urobilinogen | Ethrich reaction using Photometric Method | 0.2 - 8.0 EU/dL | NA |
| | | Pregnancy/hCG | Rapid Chromatographic immunoassay | NA | NA |
| III. <u>HAEMATOLOGY & IMMUNOHAEMATOLOGY</u> | | | | | |
| 1. | K₂ EDTA WHOLE BLOOD | Total Leukocyte Count (WBC Count) | Impedance Method | 0.4 - 106.6 x 10 ³ /mm ³ | 5.1 |
| 2. | K₂ EDTA WHOLE BLOOD | Total Erythrocyte Count (RBC Count) | Impedance Method | 0.2 - 8.1 x 10 ⁶ /mm ³ | 2.7 |
| 3. | K₂ EDTA WHOLE BLOOD | Hemoglobin | Cyanide (Potassium Cyanide) | 0.68 - 26 g/dL | 3.1 |

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| 4. | K ₂ EDTA WHOLE BLOOD | HCT (PCV) | Impedance Method | 2.0 - 80 % | 4.0 |
| 5. | K ₂ EDTA WHOLE BLOOD | MCV | Calculated | 1.1 - 300 μm ³ | 3.8 |
| 6. | K ₂ EDTA WHOLE BLOOD | MCH | Calculated | 0.4 - 99.9 pg | 3.5 |
| 7. | K ₂ EDTA WHOLE BLOOD | MCHC | Calculated | 0.4 - 99.9 g/dL | 3.4 |
| 8. | K ₂ EDTA WHOLE BLOOD | Platelet Count | Impedance Method | 10 – 2200 x 10 ³ /mm ³ | 12.3 |
| 9. | K ₂ EDTA WHOLE BLOOD | Lymphocytes | Impedance + Specific Lyse Action | 0 - 100 % | 5.5 |
| 10. | K ₂ EDTA WHOLE BLOOD | Monocytes | Impedance + Specific Lyse Action | 0 - 100 % | 9.7 |
| 11. | K ₂ EDTA WHOLE BLOOD | Granulocytes | Impedance + Specific Lyse Action | 0 - 100 % | 7.2 |

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| IV. MICROBIOLOGY & SEROLOGY | | | | | |
| 1. | SERUM | HBsAg | Immunochromatographic one step rapid visual test for Hepatitis B surface antigen – Devise | Positive / Negative | NA |
| 2. | SERUM | HCV | Flow through anti – HCV spot / immunodot test kit | Positive / Negative | NA |
| 3. | SERUM | Rapid test for Syphilis | Immunochromatographic by Syphicheck-WB (modified TPHA) | Positive / Negative | NA |
| 4. | SERUM | HIV 1 & 2 | Lateral flow chromatographic immunoassay - HIV 1/2 Ab rapid test Cassette Immobilized on a porous immunofiltration membrane – HIV TRI-DOT Test Device Western-Blot assay – HIV 1 & 2 Western Blot Test Strips | Positive / Negative | NA |

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