

IX. Laboratories:

| S. No. | Laboratory type | Basic Composite | Medium | Advanced |
|----------|---------------------------|---|---|--|
| (1) | (2) | (3) | (4) | (5) |
| I | Scope of Services | These tests (as mentioned below) can be performed in mobile laboratory at field locations also. | In addition to the tests performed in basic Composite laboratory, including tests mentioned as under. | In addition to tests performed in medium laboratory, additional tests mentioned as under. |
| | (a) Biochemistry | Routine Biochemistry tests like Blood Sugar, Renal Function Tests, Liver Function Tests, Amylase, Lipase, Lipid profile, Cerebro-Spinal Fluid (CSF) and other biological fluids (glucose and protein), Oral Glucose Tolerance Test, Electrolytes, Calcium or Phosphate, HbA1c, any biochemistry based rapid test. | Hormone Bioassay, Tumor markers, plasma protein electrophoresis | (a) Coagulation profile, Drug monitoring and toxicology assay, (b) Molecular genetics, tests for detection of inborn errors of metabolism |
| | (b) Haematology | Haemogram, Bleeding Time, Clotting Time, Prothrombin Time, Activated Partial Thromboplastin Time, Blood grouping and matching. | Coagulation Assay | All other Haematology tests also. |
| | (c) Histopathology | Nil | May do, subject to availability of equipment and specialist | Histopathology Examination |
| | (d) Molecular Genetics | Nil | May do, subject to availability of equipment and specialist | Molecular genetics |
| | (e) Cytopathology | Nil | PAPsmear, Fine Needle Aspiration Cytology (FNAC), sputum and CSF cytology | Immuno Cytochemistry. Other biological fluid cytology; Ultrasound or CT guided FNAC. |
| | (f) Immuno-histopathology | Nil | Nil | Immunohisto-chemistry: |

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| | (g) Medical Microbiology & Immunology | Basic tests like Rapid Test (Point of Care tests) for infection, urine routine examination and microscopy, Hanging drop for Vibrio cholerae, Stool for ova/ cyst. All HIV positive rapid Assays need to be confirmed from the next level diagnostic laboratory. | (a) Serological tests for viruses, bacteria, fungi, parasites (b) Cultural Sensitivity tests: Bacterial or fungal (c) Other special stains besides Gram's stain. | (a) Culture sensitivity tests for Bacteria. (b) Real Time Polymerase Chain Reaction (RTPCR) tests. (c) Tissue diagnosis test for infectious diseases. |
| II INFRASTRUCTURE | | | | |
| | | Basic Composite | Medium | Advanced |
| 1. Signage | | | | |
| | (a) Basic signage-A signage within or outside the facility should be made available containing the following information. | Essential | Essential | Essential |
| | (b) Name of the person-in-charge with Qualification and registration number | Essential | Essential | Essential |
| | (c) Broad services Provided i.e. Haematology, Biochemistry Clinical Pathology, Histology, Cytology, Molecular Genetics- whichever is applicable | Essential | Essential | Essential |
| | (d) Timings of the different consultants | Desirable | Essential | Essential |
| | (e) Internet facility or Telephone and mobile number for appointment | Desirable | Desirable | Desirable |
| | (f) Fee structure: To be displayed separately including type of investigation and charges i.e. Special and routine tests | Essential | Essential | Essential |

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| 2. Safety Signage (Wherever applicable) | | | | |
| | (a) Safety hazard and caution signs- Biomedical waste segregated in coloured bins and bags as per Biomedical Waste Management Rules, 2016 including radioactive materials, toxic chemicals, microbial agents, infected biological material. | Essential | Essential | Essential |
| | (b) Appropriate Fire exit signages - Minimum one fire extinguisher | Desirable | Desirable | Essential |
| 3. Space requirement | | | | |
| | (a) Registration and waiting room, public utilities, safe drinking water etc. | Desirable | Essential | Essential |
| | (b) Sample collection area | Essential | Essential | Essential |
| | (c) Laboratory with adequate diffuse and spot lighting | Essential | Essential | Essential |
| | (d) Toilet | Essential | Essential | Essential |
| | (e) Reporting and billing area | Essential | Essential | Essential |
| | (f) Staff room and doctor's duty room - Male and female different where 24 hours services available | Desirable | Desirable | Essential |
| | (g) Washing room | Essential | Essential | Essential |
| | (h) Preservation of the specimens and slides | Essential | Essential | Essential |
| | (i) Electrical facilities | Essential | Essential | Essential |
| | (j) Temperature control for specialized equipment like flow cytometry and chemiluminescence equipment, ELISA test equipment etc. | Essential | Essential | Essential |

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| | (k) Counselling room for HIV | Essential, if HIV test is done | Essential, if HIV test is done | Essential, if HIV test is done |
| | (l) FNAC room for all patients for sample collection | Desirable | Desirable | Desirable |
| | (m) Darkroom for Immunofluorescence | Not required | Not required | Essential |
| | (n) Frozen Section facilities | Not applicable | Essential | Essential |
| | 4. Furniture and fixtures | Essential | Essential as per scope of services | Essential as per scope of services |
| | 5. Communication system - Telephone and mobile number for appointment | Desirable | Desirable | Desirable |
| | 6. Wash Basins | Essential | Essential | Essential |
| III. HUMAN RESOURCE | | | | |
| | <p>a) Minimum Qualification of Technical Head of Laboratory or Specialist or* Authorised Signatories.</p> <p>NOTE:</p> <p>1. *The authorised signatory will be liable for authenticity of the laboratory report only.</p> <p>2. Medical tests should normally be undertaken on the advice of a registered medical practitioner.</p> | <p>Essential –</p> <p>1. MBBS registered with MCI or State Medical Council with at least one year training or work experience in a Medical Diagnostic Laboratory of same or higher level in a Government or Recognised medical college or hospital or institution or organisation.</p> <p>Those working in Government sector shall be exempted from the aforesaid training or experience</p> <p>Or</p> <p>2. M.Sc in Pathology or Medical Microbiology or Medical Biochemistry from a recognised university or institution with at least three years training or work experience in a Medical</p> | <p>Essential –</p> <p>1. Doctor of Medicine (MD) or Diplomate of National Board (DNB) in Pathology or Biochemistry or Medical Microbiology or Laboratory Medicine or Diploma in Clinical Pathology (DCP), registered with MCI or State Medical Council.</p> <p>Or</p> <p>2. MBBS with Ph.D qualification in the field of Pathology or Microbiology or Biochemistry or Genetics or Biotechnology or Immunology or Molecular Biology or Applied Biology from a recognised university or institution and having experience of at least three years post Ph.D in a Laboratory of same or higher level in a Government or Recognised medical college or hospital or institution or organisation shall be entitled to conduct the tests, generate, sign and issue test reports in respect of tests of their</p> | <p>Essential –</p> <p>1. Doctor of Medicine (MD) or Diplomate of National Board (DNB) in Pathology or Biochemistry or Medical Microbiology or Laboratory Medicine or Diploma in Clinical Pathology (DCP), registered with MCI or State Medical Council.</p> <p>Or</p> <p>2. MBBS with Ph.D qualification in the field of Pathology or Microbiology or Biochemistry or Genetics or Biotechnology or Immunology or Molecular Biology or Applied Biology from a recognised university or institution and having experience of at least three years post Ph.D in a Laboratory of same or higher level in a Government or Recognised medical college or hospital or institution or organisation shall be entitled to conduct the tests, generate, sign and issue test reports in respect of tests of their</p> |

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| | | <p>Diagnostic Laboratory of same or higher level in a Government or Recognised medical college or hospital or institution or organisation shall be entitled to conduct the tests, generate and sign test reports in respect of tests of their respective specialty, without recording any opinion or interpretation of laboratory results.</p> <p>All such test reports generated must necessarily bear a disclaimer to the effect that the reports are strictly for the use of medical practitioners and are not medical diagnosis as such.</p> <p>Note: Laboratory technician with qualification as mentioned in Part III (b) of this table working in a Medical Diagnostic Laboratory registered under a Central or State Clinical Establishments Registration Act, as applicable, and a Health care worker in a Government National Health program trained for conducting identified specific tests, may conduct the tests and generate test results which shall be submitted to the signatory authority at Sl. Nos. 1 or 2 as applicable</p> | <p>respective specialty.</p> <p>Or M.Sc. with Ph.D qualification in the field of Pathology or Medical Microbiology or Medical Biochemistry or Medical Genetics or Biotechnology or Immunology or Molecular Biology or Applied Biology from a recognised university or institution and having experience of at least three years post Ph.D in a Laboratory of same or higher level in a Government or Recognised medical college or hospital or institution or organisation shall be entitled to conduct the tests, generate and sign test reports in respect of tests of their respective specialty, without recording any opinion or interpretation of lab results.</p> <p>All such test reports generated must necessarily bear a disclaimer to the effect that the reports are strictly for the use of medical practitioners and are not medical diagnosis as such.</p> <p>Note: Interpretation of lab results or opinion there on, wherever required by the signatory authority at Sl. No.3, such test reports may be co-signed by the signatory authority at Sl. Nos. 1 or 2, after recording opinion or interpretation. Co-signee medical doctor shall be responsible only for the opinion or interpretation given.</p> | <p>respective specialty.</p> <p>Or M.Sc. with Ph.D qualification in the field of Pathology or Medical Microbiology or Medical Biochemistry or Medical Genetics or Biotechnology or Immunology or Molecular Biology or Applied Biology from a recognised university or institution and having experience of at least three years post Ph.D in a Laboratory of same or higher level in a Government or Recognised medical college or hospital or institution or organisation shall be entitled to conduct the tests, generate and sign test reports in respect of tests of their respective specialty, without recording any opinion or interpretation of lab results.</p> <p>All such test reports generated must necessarily bear a disclaimer to the effect that the reports are strictly for the use of medical practitioners and are not medical diagnosis as such.</p> <p>Note: Interpretation of lab results or opinion there on, wherever required by the signatory authority at Sl. No.3, such test reports may be co-signed by the signatory authority at Sl. Nos.1 or 2, after recording opinion or interpretation. Co-signee medical doctor shall be responsible only for the opinion or interpretation given.</p> |

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| | | | <p>Desirable:</p> <p>If any special test of other speciality is done, it is desirable that specialist of that subject needs be there on full time or part time or outsourced basis.</p> <p>*Special test means any other apart from routine basic biochemistry, hematology, or medical microbiology tests as listed in basic composite laboratory.</p> <p>Illustration:</p> <p>(i) Special Tests pertaining to Bio-Chemistry and Microbiology shall be reported by Doctor of Medicine (MD) or Diplomate of National Board (DNB) or Ph.D in Bio-Chemistry and Doctor of Medicine (MD) or Diplomate of National Board (DNB) or Ph.D in Micro-biology respectively.</p> <p>(ii) Biopsies or Cytology specimens has to be reported by a person possessing Doctor of Medicine (MD) or Diplomate of National Board (DNB) or Ph.D in Pathology.</p> | <p>Desirable:</p> <p>If any special test* of other speciality is done, it is desirable that specialist of that subject needs be there on full time or part time or outsourced basis.</p> <p>*Special test means any other apart from routine basic biochemistry, hematology, or medical microbiology tests as listed in basic composite laboratory.</p> <p>Illustration:</p> <p>Special Tests pertaining to Bio-Chemistry and Microbiology shall be reported by Doctor of Medicine (MD) or Diplomate of National Board (DNB) or Ph.D in Bio-Chemistry and Doctor of Medicine (MD) or Diplomate of National Board (DNB) or Ph.D in Micro-biology respectively.</p> <p>(ii) Biopsies or Cytology specimens has to be reported by a person possessing Doctor of Medicine (MD) or Diplomate of National Board (DNB) or Ph.D in Pathology.</p> |
| | (b) Number of laboratory technicians with Diploma in Medical Laboratory Technology (DMLT) or Bachelor of Science (B.Sc.) Medical Laboratory Technology (MLT) or Master of Science (M.Sc) Bio-chemistry or Microbiology qualification from a recognised university or institution. | Essential: 1 | Essential: 2 | Essential: 4 |
| | (c) Support staff (Laboratory Assistant or Laboratory Attendant) Roster of salary of staff. Periodic health check-ups and vaccination of staff. | Essential: 1 | Essential: 1 | Essential: 2”. |