

## **Terms of Reference**

### **About Kalam Institute of Health Technology (KIHT)**

A WHO Collaborating Centre for Health Innovation & A Regional Resource Centre (RRC) of Health Technology Assessment in India (HTAI) under the Department of Health Research (DHR), Ministry of Health & Family Welfare, Government of India

#### **Company Website:**

<https://www.amtz.in/>

<https://kiht.in/>

<http://biovalley-amtz.in/>

<https://medivalley-aic.in/>

### **Job Title – Scientist - KIHT, IVD Lab**

#### **Key Responsibilities**

1. Perform molecular and immunological testing in accordance with approved Standard Operating Procedures (SOPs).
2. Conduct nucleic acid extraction, RT-PCR, ELISA, Rapid Diagnostic Kit (RDK), and other laboratory assays as assigned.
3. Participate in method verification, method validation, lot-to-lot verification, and performance evaluation studies.
4. Maintain laboratory documentation, including worksheets, raw data, equipment logs, quality control records, and test reports.
5. Support implementation and maintenance of the Quality Management System (QMS) in compliance with ISO 15189:2022 and ISO/IEC 17025:2017.
6. Perform routine Internal Quality Control (IQC), proficiency testing (PT), and Inter-Laboratory Comparison (ILC) activities.
7. Operate, maintain, calibrate, and perform routine performance verification of laboratory instruments and equipment.
8. Monitor environmental conditions and ensure compliance with laboratory quality and biosafety requirements.
9. Assist in preparation for internal audits, external audits, and accreditation assessments.
10. Support preparation and revision of SOPs, validation protocols, quality manuals, and other controlled documents.
11. Ensure compliance with Good Laboratory Practices (GLP), biosafety guidelines, and laboratory safety procedures.

12. Assist in troubleshooting laboratory assays and implementing corrective and preventive actions (CAPA).

### **Qualifications & Experience**

1. Bachelor's degree in Biotechnology, Microbiology, Molecular Biology, Biochemistry, Medical Laboratory Technology, Life Sciences, or related disciplines with a minimum of 5–8 years of relevant laboratory experience; OR Master's degree in Biotechnology, Molecular Biology, Microbiology, Biochemistry, Medical Laboratory Technology, or related disciplines with a minimum of 1–2 years of relevant laboratory experience.
2. Hands-on experience in molecular diagnostics, including nucleic acid extraction, RT-PCR, qPCR, and immunodiagnostic techniques.
3. Working knowledge of ISO 15189:2022 and/or ISO/IEC 17025:2017 Quality Management Systems.
4. Experience in method validation, equipment qualification, calibration, and quality control practices.
5. Familiarity with NABL accreditation requirements, internal audits, proficiency testing, and laboratory documentation.
6. Experience in handling clinical samples and maintaining laboratory records in accordance with regulatory and quality requirements.
7. Strong analytical, documentation, troubleshooting, and communication skills.
8. Experience in diagnostic laboratory operations, IVD kit validation, or accredited testing laboratories will be considered an added advantage.
9. Age up to **40** years