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Quality and Accreditation Institute
Centre for Laboratory Accreditation

INFORMATION BROCHURE



**QAI RECOGNITION FOR MEDICAL
LABORATORIES (QRML)- BASIC/
MEDIUM/ADVANCE**

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OVERVIEW

This recognition programme has been developed to promote medical laboratories to adopt quality and safety practices, and also to comply with minimum standards for medical laboratories as prescribed in Clinical Establishment Act in Gazette notification G.S.R. 468 (E) dated 18th May, 2018 and related amendment dated 14 February 2020 by Ministry of Health & Family Welfare (MOHFW), Government of India.



INTERNATIONAL AFFILIATIONS

ASSOCIATE MEMBER

APAC

**ASIA PACIFIC
ACCREDITATION COOPERATION**

(www.apac-accreditation.org)

BENEFITS OF RECOGNITION

- **Benefits for Users/ Patients**

- Users/ patients are the biggest beneficiary among all the stakeholders. Test results are crucial for the management of a patient. Any error in the test results may lead to wrong diagnosis and thus wrong treatment. Recognition results in improving the quality of test results and patient safety.

- **Benefits for Laboratories**

- Recognition to a medical laboratory stimulates continuous improvement. It enables laboratories in demonstrating commitment to quality. It raises community confidence in the services provided by them.

- **Benefits for Staff**

- The staff in a recognised laboratory is satisfied as it provides for continuous learning, good working environment and leadership. It improves overall professional development of all the staff including medical and para medical staff.

- **Benefits for Regulators/ Payers/ Insurance Agencies**

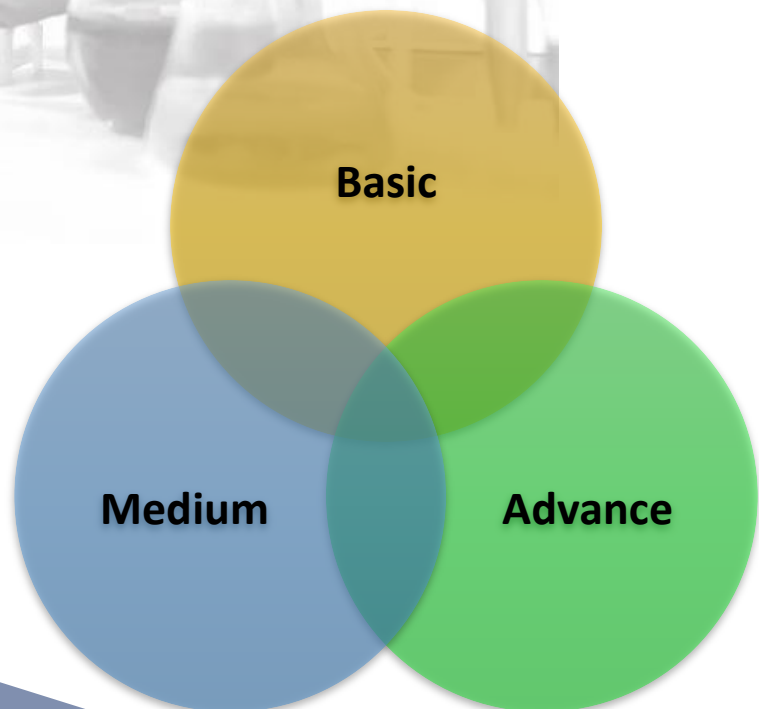
- Regulators can rely on QAI recognition as Deemed Compliance to minimum standards prescribed in Clinical Establishment Act. In other words, regulators may not require additional inspection.

**Wider publicity through listing on QAI Website
and allowing use of QAI Recognition Mark.**



QAI RECOGNITION FOR MEDICAL LABORATORIES FRAMEWORK

- Scope of Services
- Infrastructure
- Human Resource
- Instruments or Equipment or Drugs
- Legal or Statutory Requirements
- Record Maintenance and Reporting
- Standards on Basic Processes
- Continual Quality Improvement Practices



SALIENT FEATURES OF THE PROGRAMME

- Quick turnaround time
- Comprehensive standard tool and document review process
- Rigorous Assessor Management System
- Blend of clear strategy, experience and leadership
- Increased Reliability of Laboratory Results
- Earn a Recognition Mark
- Competitive Advantage and Public Recognition
- Government / Regulator and Insurance Companies Can Rely on Recognition
- Recognition is based on minimum requirements stipulated in Central Clinical Establishment Act and also follow the principle of All or None. Which means laboratory has to apply for all the scope of services available and can not choose specific test(s) for recognition.

ELIGIBILITY AND PREPARATION

A laboratory performing the tests covered (given in scope of services) under QAI Recognition for Medical Laboratory (Basic, Medium and Advance) in Gazette notification G.S.R. 468 (E) dated 18th May, 2018 and related amendment dated 14 February 2020 by MOHFW regarding Clinical Establishments (Central Government) Rules, 2012 is eligible to apply under this programme of QRML.

The laboratory seeking recognition shall understand the QAI assessment process. The laboratory shall ensure that all the requirements are implemented. The laboratory may get its personnel oriented/ trained in understanding and implementation of requirements of various sections. Such training programmes may be conducted by QAI from time to time.

SCOPE OF SERVICES

Scope of Services for QAI Recognition for Medical Laboratories- Basic

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 bio chemistry based rapid test.

Haematology: Haemogram (CBC, Hb, TLC, DLC, Platelet Count, RBC Count, HCT, MCV, MCH, MCHC, ESR), Bleeding Time, Clotting Time, Prothrombin Time, Activated Partial Thromboplastin Time, Blood grouping and matching.

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 using confirmatory tests.

SCOPE OF SERVICES

Scope of Services for QAI Recognition for Medical Laboratories- Medium

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 bio chemistry based rapid test, Hormone Bioassay, Tumor markers, plasma protein electrophoresis

Haematology: Haemogram (CBC, Hb, TLC, DLC, Platelet Count, RBC Count, HCT, MCV, MCH, MCHC, ESR), Bleeding Time, Clotting Time, Prothrombin Time, Activated Partial Thromboplastin Time, Blood grouping and matching, Coagulation Assay

Histopathology: May do, subject to availability of equipment and specialist

Molecular Genetics: May do, subject to availability of equipment and specialist

Cytopathology: PAP smear, Fine Needle Aspiration Cytology(FNAC), sputum and CSF cytology

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 using confirmatory tests. Serological tests for (viruses, bacteria, fungi, parasites) ,Cultural Sensitivity tests (Bacterial or fungal), Other special stains besides Gram's stain.

SCOPE OF SERVICES

Scope of Services for QAI Recognition for Medical Laboratories- Advance

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 bio chemistry based rapid test, Hormone Bioassay, Tumor markers, plasma protein electrophoresis , coagulation profile, Drug monitoring and toxicology assay, Molecular genetics, tests for detection of inborn errors of metabolism.

Haematology: Haemogram (CBC, Hb, TLC, DLC, Platelet Count, RBC Count, HCT, MCV, MCH, MCHC, ESR), Bleeding Time, Clotting Time, Prothrombin Time, Activated Partial Thromboplastin Time, Blood grouping and matching, Coagulation Assay, All other Haematology tests also.

Histopathology: Histopathology Examination

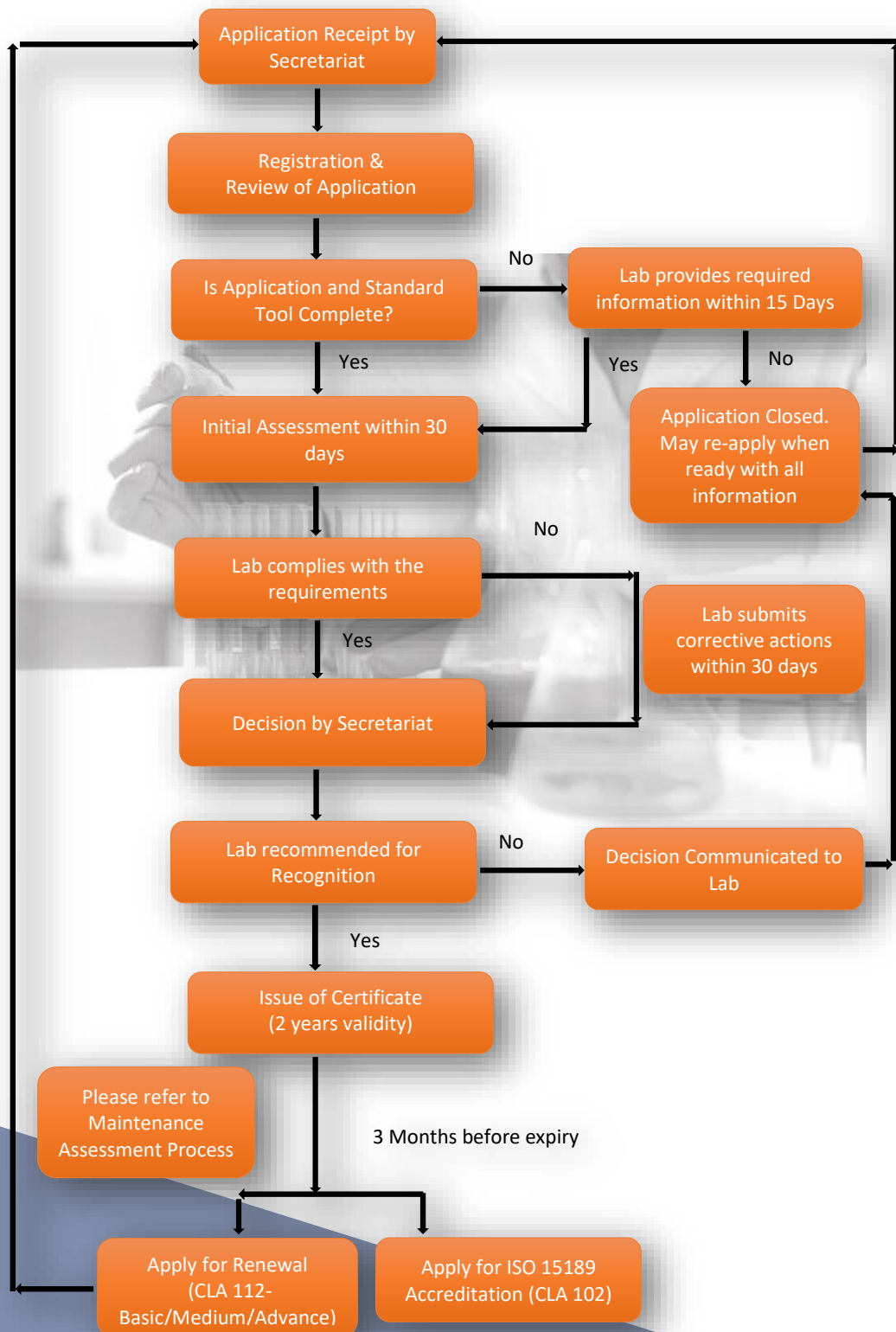
Molecular Genetics: Molecular genetics

Cytopathology: PAP smear, Fine Needle Aspiration Cytology(FNAC), sputum and CSF cytology , Immuno Cytochemistry , Other biological fluid cytology; Ultrasound or CT guided FNAC.

Immunohistopathology: Immunohisto-chemistry

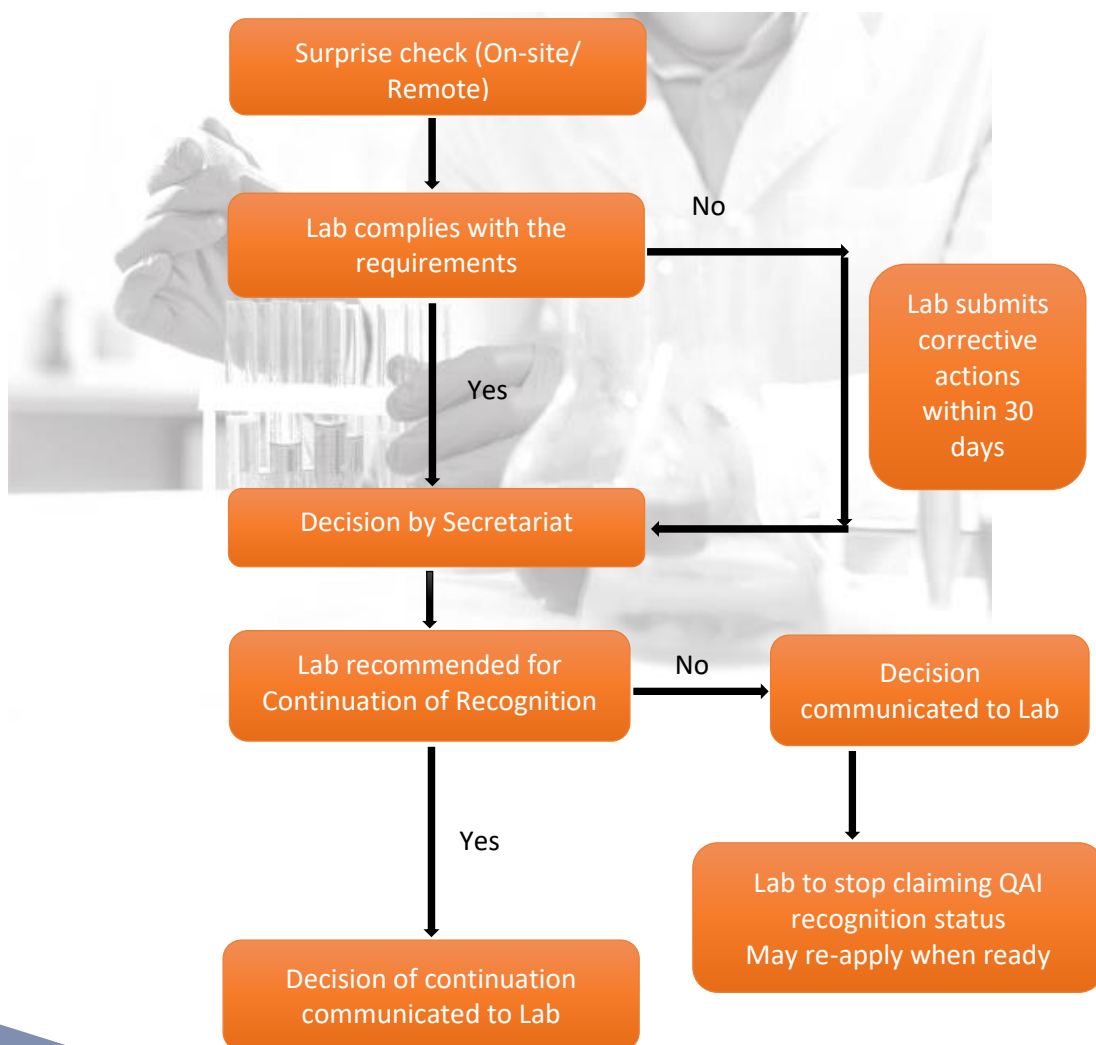
Medical Microbiology & Immunology: Basic tests like Rapid Test (Point of Care tests) for infection, urine routine examination and microscopy, Hanging drop for Vibrio cholerae, Stool for ova , cyst. All HIV positive rapid assays need to be confirmed from the next level diagnostic laboratory using confirmatory tests. Serological tests for (viruses, bacteria, fungi, parasites), Cultural Sensitivity tests (Bacterial, fungal, viruses), Other special stains besides Gram's stain, Real Time Polymerase Chain Reaction (RT-PCR) tests. Tissue diagnosis test for infectious diseases.

RECOGNITION PROCESS



SURPRISE CHECK (ON-SITE/REMOTE) PROCESS

QAI may conduct a surprise check (maintenance assessment) at any time during 2 years of the recognition cycle to ensure continued compliance of the standards.



FEE STRUCTURE

Type of Laboratory	Application fee and assessment charges (non-refundable, to be paid along with the application) (Rs. 12000)		Recognition Fee for two years
	Application Fee	Assessment Charges	Rs. 10000
Basic Medical Laboratory	Rs. 2000	Rs. 10000	

Type of Laboratory	Application fee and assessment charges (non-refundable, to be paid along with the application) (Rs. 18000)		Recognition Fee for two years
	Application Fee	Assessment Charges	Rs. 16000
Medium Medical Laboratory	Rs. 2000	Rs. 16000	

Type of Laboratory	Application fee and assessment charges (non-refundable, to be paid along with the application) (Rs. 20000)		Recognition Fee for two years
	Application Fee	Assessment Charges	Rs. 18000
Advance Medical Laboratory	Rs. 2000	Rs. 18000	

In addition to the above-mentioned fee, GST @18.0 % or as applicable from time to time to be paid.

ABOUT QAI

QAI was set up to create an ecosystem of education, training, quality improvement and accreditation/ certification. We aim to provide a platform to stakeholders including professionals and organisations, associated with quality in any way, to share their wisdom and knowledge. This further provides tremendous opportunities to all concerned to learn and contribute in improving quality and safety of healthcare organisations.

Vision

Nurturing the largest global pool of organisations and people through quality and accreditation framework.



Mission

To conceive and deliver education, training, accreditation and related programmes in partnership with stakeholders using an approach of co-design and co-creation.



Values

Listener: Seek continuous feedback from stakeholders to address their concerns

Competitive: Look for viable options to benefit users of our services

Transparency: Clearly defined policies made available in public domain

Innovation: Continuously evolve using co-design and co-creation



CONTACT US

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