



**ACCREDITATION SCHEME FOR LABORATORIES**

## **Technical Notes MED 002**

### **Specific Criteria for Clinical Chemistry Section**

## 1. Introduction & Scope

- 1.1 a) This document describes the specific requirements for clinical chemistry laboratories to be accredited.
- b) The International Standard 'ISO 15189 Medical laboratories – Particular requirements for quality and competence', other MEDICAL Series Technical Notes published by SAC-SINGLAS shall be studied in conjunction with this document.

## 2. General Technical Note : Medical 001

2.1 Please refer **General Technical Note: Medical - 001** for the following:

- Personnel
- Accommodation & Environmental Conditions
  - Physical Facilities and Laboratory Safety
- Laboratory Equipment – Calibration & Maintenance
- Pre-examination Procedures
  - Requisitions, Collection and Handling of Specimens
- Examination Procedures
  - Test Methods and Method Validation
- Assuring Quality of Examination Procedures
  - Quality Control, Proficiency Testing, Reagents and Reference Materials
- Post-examination Procedures
  - Retained Samples and Waste Disposal
- Reporting of Results

## 3. Personnel

- 3.1 Refer to Personnel in **General Technical Note: Medical - 001**. In addition to that the following is applicable to the clinical chemistry laboratory.
- 3.2 There shall be adequate and competent staff with the required education, training and experience to perform the procedures and tests. A comprehensive competency assessment programme should be in place with provisions made for all personnel to further their knowledge and skills.

## 4. Accommodation and Environmental Conditions

- 4.1 Refer to Accommodation & Environmental Conditions - Physical Facilities and Laboratory Safety in **General Technical Note: Medical - 001**. In addition to that the following is applicable to the clinical chemistry laboratory
- 4.2 When using hazardous materials (toxic, mutagenic and radioactive), there shall be clear documented procedures describing the appropriate measures taken to protect the personnel and the environment.

## 5. Laboratory Equipment

5.1 Refer to Laboratory Equipment in **General Technical Note: Medical – 001**. In addition to that the following is applicable to the clinical chemistry laboratory.

### 5.2 General Clinical Chemistry

5.2.1 Written and documented policies and procedures shall be available for all equipment before they can be used for patient testing. Preventive maintenance and instrument function checks shall be put in place.

5.2.2 For Multiple Analysis Automated Instruments and Systems, written standard procedures shall be available for calibration set up, operation and control of the systems.

5.2.3 For items such as pipettes, glassware, instruments and equipment, thermometers, centrifuges, analytical balances, spectrophotometers, and other basic analytic systems for primary analytical techniques appropriate calibration maintenance and servicing is mandatory. Refer to TABLE 1 of **General Technical Note: Medical - 001** for the recommended calibration interval.

## 6. Pre-examination Procedures

6.1 Refer to Pre-examination Procedures – Requisitions, Collection and Handling of Specimens in **General Technical Note: Medical – 001**. In addition to that the following is applicable to the clinical chemistry laboratory.

### 6.2 Collection and Handling Of Specimens

6.2.2 The laboratory shall have regular consultations with clinical staff on the use of the laboratory and laboratory tests, including the efficacy of tests, repeat frequency and required specimen types. This shall be part of any medical audit.

6.2.3 There shall be a documented list of the requested tests, including specimen type, specimen volume, special precautions, expected turn-around time and reference ranges.

6.2.4 There shall be documented procedures for both urgent (STAT) and routine requests.

6.2.5 There shall be a documented list of the laboratory tests available on a STAT and 24 hour basis.

## 7. Examination Procedures

7.1 Refer to Examination Procedures in **General Technical Note: Medical - 001**. In addition to that the following is applicable to the clinical chemistry laboratory.

## 7.2 General Clinical Chemistry

7.2.1 Each laboratory shall have documented policies and procedures to address regulatory requirements regarding biological safety of patients and staff. There shall be the documented safety plan procedures for biological, chemical and radiation safety and a system for monitoring training and compliance.

7.2.2 Appropriate criteria shall have been developed and should be available for test selection, specimen collection and procession. Procedures should be in place to ensure accurate and reliable tests reporting systems. There shall be appropriate record storage and retrieval systems.

## 7.3 Therapeutic Drug Monitoring

7.3.1 The same general requirements in Clinical Chemistry shall be met in Therapeutic Drug Monitoring as in clinical chemistry. Emphasis should be placed on examining the frequency of assay standardization.

## 7.4 Point of Care Testing

7.4.1 The same general requirements in Clinical Chemistry shall be met in Point of Care testing as in clinical chemistry. Point of care testing (POCT) is defined as laboratory analytical testing of services within an institution that are performed outside the physical facilities of the clinical laboratory, in a non-dedicated space.

Examples include bedside and/or ward testing and they will be handled as additional laboratory sections when they are under the direction and authority of the laboratory director of the main clinical laboratory. It is recommended that there be centralized co-ordination of the point of care testing program with designated laboratory personnel responsible for monitoring testing procedures and quality control, and conducting training of the individuals who perform the tests.

7.4.2 There shall be a defined role for the laboratory in the validation, assessment and quality control of point of care testing.

## 7.5 Experimental Testing

7.5.1 There shall be procedures for experimental testing, including regulation for informed consent and involvement of the medical ethical committee.

7.5.2 Testing shall be performed strictly according to protocols.

7.5.3 If different conditions with respect to routine laboratory procedures exist, they should be made explicit.

## **8. Assuring Quality of Examination Procedures – Quality Control and Proficiency Testing**

## 8.1 General Chemistry

- 8.1.1 Refer to Assuring Quality of Examination Procedures - Quality Control, Proficiency Testing, Reagents and Reference Materials in **General Technical Note: Medical - 001**. In addition to that the following is applicable to the clinical chemistry laboratory.
- 8.1.2 The laboratory shall have a system/programme of internal quality control and participate in proficiency testing.
- 8.1.3 Criteria against which analytical processes (measurement and also observation) are judged should preferably be based on biological variance.
- 8.1.4 Internal quality control results should be checked and kept at the bench according to the working procedures.
- 8.1.5 Internal quality control results, including results from point of care equipment, and proficiency testing results shall be regularly evaluated. Staff meetings and actions taken shall be documented.
- 8.1.6 Records of internal quality control results should be archived for at least three years. External quality assessment results should be archived for at least five years.
- 8.1.7 There shall be appropriate internal quality control procedures for each testing process, selected on the basis of the analytical quality required. Control specimens (type and frequency) for the various analytical systems shall be carried out to demonstrated on-going system stability.
- 8.1.8 Where available, appropriate multi-level control specimens shall be used at least daily whenever patient specimens are run. These results shall be documented. Positive and negative controls for qualitative tests shall be run at least once on each day of analysis, based on the manufacturer's instructions. For quantitative tests, control samples at more than one level shall be run at least once each day of analysis.

## 8.2 Diagnostic Immunology and Serology

- 8.2.1 Positive and negative controls for qualitative tests shall be run at least once on each day of analysis, based on the manufacturer's recommendations.
- 8.2.2 For quantitative tests control samples at more than one level shall be run at least once each day of analysis.
- 8.2.3 New kits and reagents shall be checked against old reagents to ensure comparable reactivity and the results shall be documented.

## 9. **Post-examination Procedures**

- 9.1 Refer to Post-examination Procedures in **General Technical Note: Medical - 001**.

## **10. Reporting of Results**

- 10.1 Refer to Reporting of Results in **General Technical Note: Medical - 001**. In addition to that the following is applicable to the clinical chemistry laboratory.
- 10.2 There should be timely reporting of test results based on testing priorities and a system should be in place to document problems in communication of laboratory results.
- 10.3 Therapeutic Drug Monitoring
- 10.3.1 The test report shall include expected therapeutic ranges for the drug and the range where toxicity is expected.