

	<b>SPECIFIC CRITERIA FOR THE LABORATORY ACCREDITATION OF CLINICAL CHEMISTRY SECTION</b>	G-23/02 Issue Date: 28.04.06 Rev No: 00
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## 1. INTRODUCTION

- 1.1 a) This document describes the specific requirements for clinical chemistry laboratory before they can be accredited.
- b) This document shall be studied in conjunction with ISO15189 Medical laboratories – Particular requirements for quality and competence, other MEDICAL Series Technical Notes published by PNAC-MLAS (such as G-23/01) and other Guidance Notes such as “ISO 15190 Medical Laboratories–Requirements for Safety”.

## 2. GENERAL TECHNICAL NOTE: MEDICAL G-23/01

2.1 Please refer **General Technical Note: Medical – G-23/01** for the following:

- PERSONNEL
- COLLECTION AND HANDLING OF SPECIMENS
- PHYSICAL FACILITIES
- REAGENTS
- REFERENCE MATERIALS
- REQUISITIONS TEST METHODS AND METHOD VALIDATION
- MAINTENANCE OF EQUIPMENT
- CALIBRATION OF EQUIPMENT
- QUALITY CONTROL AND PROFICIENCY TESTING
- LABORATORY SAFETY
- RETAINED SAMPLES
- WASTE DISPOSAL
- REPORTING OF RESULTS

## 3. QUALITY CONTROL AND PROFICIENCY TESTING

- 3.1 Refer to Quality control and proficiency testing in **General Technical Note: Medical G-23/01**.
- 3.2 The laboratory shall have system of internal quality control and participate in proficiency testing.
- 3.3 Criteria against which analytical processes (measurement and also observation) are judged should preferably be based on biological variance.
- 3.4 Internal quality control results should be checked and kept at the bench according to the working procedures.



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**3.5** Internal quality control results also from point of care equipment, and proficiency testing results should be regularly evaluated. Staff meetings and actions taken should be documented.

**3.6** 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.

**4. COLLECTION AND HANDLING OF SPECIMENS**

**4.1** Refer to Collection and handling of specimens in **General Technical Note: Medical – G-23/01**.

**4.2** In addition to the above, 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 type of specimen types, The consultation function shall be part of any medical audit.

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

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

**4.5** There shall be a documented list of the laboratory tests available on a STAT and a 24-hours request.

**4.6** The request form shall be designed to obtain the necessary information for identification of the patient, the requesting physicians, requested tests and clinical information.

**4.7** The laboratory shall have procedures to ensure the confidentiality of patients is maintained.

**5. GENERAL CLINICAL CHEMISTRY**

**5.1** There shall be sufficient and appropriate space, equipment, facilities and supplies for the performance of the required volume of work with accuracy, precision, efficiency, and safety.

**5.2** The laboratory shall participate in recognized proficiency testing programmes and show acceptable performance. The proficiency testing programmes recognised by PNAC-MLAS shall be documented and with evidence of appropriate review, evaluation, and corrective action.



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- 5.3** Each laboratory shall have documented policies and procedures to address regulatory requirements regarding biological safety of patients and staff. There shall be documented safety plan procedures for biological, chemical and radiation safety and a system for monitoring training and compliance.
- 5.4** There shall be adequate and competent staff with 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.
- 5.5** Appropriate criteria must 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.
- 5.6** 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.
- 5.7** 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.
- 5.8** For Multiple Analysis Automated Instruments and Systems, written standard procedures shall be available for calibration set up, operation and control of the systems.
- 5.9** 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.
- 5.10** 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.
- 5.11** 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.
- 5.12** 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

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**General Technical Note: Medical - G-23/01** for the recommended calibration interval.

## **6. THERAPEUTIC DRUG MONITORING**

- 6.1** The same general requirements in Clinical Chemistry must be met in therapeutic drug monitoring as in clinical chemistry. Emphasis should be placed on examining the frequency of assay standardization.
- 6.2** The test report shall include expected therapeutic ranges for the drug and the range where toxicity is expected.

## **7. POINT OF CARE TESTING**

- 7.1** The same general requirements in Clinical Chemistry must 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 coordination 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.

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

## **8. EXPERIMENTAL TESTING**

- 8.1** There should be procedures for experimental testing, including regulation for informed consent and involvement of the medical ethical committee.
- 8.2** Testing should be performed strictly according to protocols.
- 8.3** If different conditions with respect to routine laboratory procedures exist, they should be made explicit.