



MAURITAS G13

Quality Indicators – A Guide for Medical Laboratories

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Foreword

The MAURITIUS ACCREDITATION SERVICE (MAURITAS) is a governmental body established in 1998 to provide a national, unified service for the accreditation of Conformity Assessment Bodies (CABs) such as calibration/testing laboratories, certification bodies and inspection bodies. Organizations that comply with the MAURITAS requirements are granted accreditation by MAURITAS.

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MAURITAS publications are categorized as follows:

- R series Publications containing general policy and requirements related to MAURITAS accreditation.
- G series Publications providing guidance on MAURITAS requirements.
- A series Publications related to assessment procedures.
- P series MAURITAS quality system procedures
- F series MAURITAS Forms
- Directories Classified listing of accredited organizations.

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Quality Indicators – A Guide for Medical Laboratories

1. Purpose

This document should be used as a guidance for medical laboratories in order to develop their quality indicators.

2 Scope and Responsibilities

2.1 This guidance document provides an indication of quality indicators that may be relevant to a medical laboratory.

Medical laboratories are encouraged to refer to this guidance document.

3. References

The following documents contain provisions which, through reference in this text, constitute provisions of the MAURITAS accreditation system. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. For undated MAURITAS references, the latest edition of the document referred to, applies. MAURITAS maintains a register, of the current valid MAURITAS accreditation documents.

3.1 ISO 15189 : Medical Laboratories - Requirements for quality and competence.

3.2 MAURITAS A Series documents

3.3 MAURITAS G Series documents

3.4 MAURITAS R Series documents

3.5 International Federation of Clinical Chemistry and Laboratory Medicine - Working Group “Laboratory Errors and Patient Safety”

4 Definitions

4.1 Haemolysed samples

Hemolysis is conventionally defined as the release of hemoglobin and other intracellular components of erythrocytes into the extracellular space of blood.

4.2 Clotted samples

A mass of blood that forms when blood platelets, proteins, and cells stick together.

4.3 External Quality Assurance (EQA)

EQA is defined as a system for objectively checking a medical laboratory’s performance against pre-established criteria by means of interlaboratory comparisons (using an external agency or facility).

4.4 Internal Quality Control (IQC)

The internal QC involves the in-house procedures for continuous monitoring of operations and systematic day-to-day checking of the produced data to decide whether these are reliable enough to be released. The procedures primarily monitor the bias of data with the help of control samples and the precision by means of duplicate analyses of test samples and/or of control samples.

5 Examples of Quality Indicators

Process indicator	Quality indicators	Examples
Pre-analytical	<i>1. Misidentification errors</i>	<ol style="list-style-type: none"> 1. Total number of unlabeled samples 2. Total number of mislabeled samples (e.g. name on sample label is different from that on the accompanied request form)
	<i>2. Incorrect sample type</i>	<ol style="list-style-type: none"> 1. Number of samples collected in wrong container (e.g. inappropriate anticoagulant) 2. Number of samples of wrong type (e.g. urine sample collected instead of blood sample)
	<i>3. Incorrect fill level</i>	<ol style="list-style-type: none"> 1. Number of samples with insufficient sample volume
	<i>4. Improperly filled request forms.</i>	<ol style="list-style-type: none"> 1. Number of requests forms with no address of sender/missing or incomplete information 2. Number of requests form with illegible handwriting
	<i>5. Unsuitable samples transportation and storage problems</i>	<ol style="list-style-type: none"> 1. Number of samples not received (e.g. only request form received) 2. Number samples spilt over (e.g. improperly capped containers)
	<i>6. Haemolysed samples</i>	<ol style="list-style-type: none"> 1. Number of haemolysed samples received (level of haemolysis + or above)
	<i>7. Clotted samples</i>	<ol style="list-style-type: none"> 1. Number of clotted samples received that cannot be analysed (e.g. HbA1c)
	<i>8. Wrong data entry by computer operators</i>	<ol style="list-style-type: none"> 1. Number of patients' name/surname which have been wrongly entered into the system 2. Number of patients' age which have been wrongly entered into the system 3. Number of requestors' address which has been wrongly entered into the system 4. Number of requests which have been omitted 5. Number of visits with incorrect test requests
Analytical	<i>1. Unacceptable performances in EQA-PT /IQC schemes</i>	<ol style="list-style-type: none"> 1. Number of parameters with unacceptable performances (e.g. monthly)
	<i>2. Quality Control failures</i>	<ol style="list-style-type: none"> 1. Number of parameters which fail to be within +/- 3SD and their frequency of occurrence
	<i>3. Analyser faults</i>	<ol style="list-style-type: none"> 1. Number of major faults with instruments
	<i>4. Working environment</i>	<ol style="list-style-type: none"> 1. Number of accidents at work
	<i>5. Unmatched Test Repeats</i>	<ol style="list-style-type: none"> 1. Number of tests performed which upon repeat give a result which is totally different from that of the first assay.
Post-Analytical	<i>1. Inappropriate turnaround time</i>	<ol style="list-style-type: none"> 1. Number of test reports sent for dispatch more than 90 minutes after sample(s) receipt (Applicable to Fast Track Bench). 2. Number of test reports sent for dispatch more than 2 weeks after sample(s) receipt
	<i>2. Incorrect Laboratory reports</i>	<ol style="list-style-type: none"> 1. Number of incorrect laboratory reports issued which had to be recalled.
	<i>3. Notification of critical values</i>	<ol style="list-style-type: none"> 1. Number of critical results of patients which have been communicated to patients, medical practitioners or ward nursing officers
	<i>4. Results input errors</i>	<ol style="list-style-type: none"> 1. Number of results wrongly entered into the system and detected/corrected before result release
	<i>5. Results not reaching destination</i>	<ol style="list-style-type: none"> 1. Number of results which have to be re-issued (copy) or given by phone although originals have been already dispatched.

6. Related Forms

Appendix A: Amendment Table

SN	Section	Amendment