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# MAURITAS
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## Guidance for operating Collection Points attached to Medical Laboratories

**Mauritius Accreditation Service**

# CONTENTS

FOREWORD ..... 2

1. PURPOSE ..... 3

2. SCOPE AND RESPONSIBILITIES ..... 3

3. REFERENCES ..... 3

4. DEFINITION ..... 3

5. GENERAL ..... 4

6. ENVIRONMENTAL CONDITIONS ..... 4

7. PERSONNEL ..... 4

8. SAMPLE COLLECTION PROCEDURES ..... 5

9. SAMPLE PRESERVATION/STORAGE ..... 5

10. LABORATORY EQUIPMENT, REAGENTS AND CONSUMABLES ..... 5

11. SAMPLE TRANSPORTATION ..... 5

12. DISPOSAL OF WASTE ..... 6

13. MAURITAS ASSESSMENT OF COLLECTION POINTS ATTACHED TO MEDICAL LABORATORIES ..... 6

APPENDIX A: AMENDMENT TABLE ..... 6

 

# 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 and are entitled to use the MAURITAS Accreditation symbol.

# About MAURITAS publications

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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# Guidance for operating Collection Points attached to Medical Laboratories

## 1. Purpose

This document has been prepared to provide guidance to medical testing laboratories operating Collection Points to comply with the requirements set in ISO 15189 with respect to collection, handling, storage and transportation of samples.

Application of this document will ensure quality at Collection Points attached to Medical Laboratories as it has a vital role in allowing the proper diagnosis and treatment of the patient.

## 2. Scope and Responsibilities

Medical laboratories operating Collection Points are encouraged to make use of this document.

## 3. References

**3.1.** Fremont Rideout Health Group Laboratory Services, FRHG (2011). Blood Collection and transportation by non-laboratory medical staff.

**3.2.** International Laboratory Accreditation Cooperation. Guidance for the implementation of a medical laboratory accreditation system.

**3.3.** National Pathology Accreditation Advisory Council (2013). Guidelines for approved pathology collection centres. 3rd Edition.

**3.4.** Requirements for the Packaging and Transport of pathology specimens and associated materials. (2013). National Pathology Accreditation Advisory Council.

**3.5.** World Health Organisation . Guidance on regulations for transport of infectious substances (2021-2022).

**3.6.** ISO/TS 20658: Medical Laboratories – Requirements for collection, transport, receipt and handling of samples

**3.7.** ISO 15189: Medical Laboratories: Requirements for quality and competence.

## 4. Definition

**4.1.** A Collection Point is an outlet associated to a licensed Medical Laboratory where samples are collected/prepared/stored/transported.

**4.2.** Pathogens are defined as micro-organisms (including bacteria, viruses, parasites, fungi) and other agents such as prions, which have the potential to cause disease in humans and/or animals.

 

# 5. General

**5.1.** Collection Points should be legally recognised and should not be considered as stand-alone medical laboratories.

**5.2.** The Quality Management System of the medical laboratory should address all issues related to quality in Collection Points. Instructions on patient preparation, sample collection and preparation, handling, storage and transport should be documented and should be made available to all personnel involved.

**5.3.** The internal audit plan of the medical laboratory should include the Collection Points. The medical laboratory should also ensure that the internal audit of all its Collection Points are completed as per their audit plan/programme. The internal audit report should be presented and discussed during the management review of the medical laboratory.

**5.4.** All samples and other materials or products that are known to contain, or are reasonably expected to contain pathogens should be considered as potentially infective substances and hence should be handled and/or transported with all the necessary precaution as per established procedures or regulations.

# 6. Environmental Conditions

**6.1.** The medical laboratory should document policies and procedures for proper hygiene, lighting, environmental conditions and privacy so as to ensure that its Collection Points maintain an adequate level of accommodation and environmental conditions.

**6.2.** Collection Points attached to medical laboratories should have adequate space and appropriate design to avoid any cross contamination and measures should be taken to ensure confidentiality of patients. The waiting room should be separate from the collection area.

**6.3.** The medical laboratory should also ensure that the safety (for example first aid kits and other safety materials), comfort and privacy of the patients are maintained in its Collection Points.

**6.4.** The premises should be equipped with easily cleanable surfaces and non-porous floor coverings.

**6.5.** Collection Points attached to medical laboratories should provide toilet facilities with doors lockable from the inside and unlockable from the outside in case of emergency.

**6.6.** Collection areas should have adequate space for furniture to enable patients to be seated or to be recumbent according to medical requirements.

**6.7.** Drinking water facilities should be provided in the waiting area.

**6.8.** The medical laboratory should ensure that records of environmental conditions are maintained.

# 7. Personnel

**7.1.** Staff employed at the Collection Points should be properly trained for the work they perform and in basic first aid measures.

**7.2.** The medical laboratory should ensure proper evaluation of the training and competence of its staff working at the Collection Points.

7.3. Staff employed at collection point should be trained on the relevant part of the management system implemented in the medical laboratory.

 

**7.3.** Staff should also be provided with proper emergency response training so as to minimise the risk of exposure and subsequent transmission of infection or diseases.

**7.4.** Records of training, evaluation and competence should be maintained and readily available.

# 8. Sample Collection Procedures

**8.1.** Relevant information should be given to the patient prior to the sample collection procedure.

**8.2.** The staff of the collection point should ensure that the sample collection procedure is done under sterile condition, where relevant, and should wear appropriate personal protective equipment.

# 9. Sample Preservation/Storage

**9.1.** The medical laboratory should document procedures for the proper sample preparation prior to transportation of the sample.

**9.2.** Procedures should also be documented for storage of samples in cases when the latter are retained pending transportation. Safety, specimen stability and security requirements should be addressed and documented as per the relevant requirements of ISO 15189.

**9.3.** Procedures should be made readily available to the personnel involved in sample preservation/storage.

**9.4.** Records of storage and preservation of all samples should be maintained.

# 10. Laboratory Equipment, Reagents and Consumables

**10.1.** The medical laboratory should maintain a list of equipment located in each Collection Point and should be available in the respective Collection Point.

**10.2.** Procedures relative for both handling of equipment and instructions for use of equipment at the Collection Points should be in line with those observed by the medical laboratory.

**10.3.** Procedures for maintenance and calibration of equipment located at the Collection Points should be documented.

**10.4.** The maintenance and calibration schedules of the medical laboratory should also include the equipment of the Collection Points. The medical laboratory should ensure that same are being followed and records made available upon request.

**10.5.** The medical laboratory should document procedures for reception and storage, acceptance criteria for testing, inventory management and handling of reagents and consumables at the Collection Points. Records thereof should be maintained.

# 11. Sample Transportation

**11.1.** Appropriate conditions to avoid deterioration of samples should be maintained during their transportation to the medical laboratory. These should be in conformity with local/national regulations as well as with those of the World Health Organisation for transportation of infectious substances.

 

**11.2.** Samples that have been prepared for transportation should clearly be labelled with biohazard signs.

**11.3.** Procedure for transportation of samples should be made available to the personnel of Collection Points as well as those transporting the samples.

**11.4.** The infectious substances to be transported should be initially categorized prior to opt for the appropriate packaging to be used based on for example the UN Model or other modal agreements.

**11.5.** All infectious substances should be basically contained in a triple-layered packaging system which consists of:

a) a primary receptacle which is watertight, leakproof, properly labelled and wrapped in absorbent material
b) a second watertight and leakproof container must be used to contain the primary receptacle and its content
c) a third outer layer of packaging/container must be used to contain both above and should provide overall protection.

**11.6.** Different categories of infectious substances should be packaged as appropriately as recommended by national/international regulations.

**11.7.** Emergency response information should be available for relevant personnel in the event a breach of packaging takes place.

**11.8.** Temperature and conditions of sample upon receipt by the medical laboratory from Collection Points should also be recorded.

**11.9.** The medical laboratory should establish sample acceptance/rejection criteria which should be made available at the Collection Points.

**11.10.** Records of transportation of sample should be maintained.

# 12. Disposal of Waste

**12.1.** Procedures for appropriate disposal of waste should be made according to prevailing national and other regulations.

**12.2.** Record of disposal of waste should be maintained.

## 13. MAURITAS Assessment of Collection Points attached to Medical Laboratories

**13.1.** MAURITAS will assess all Collection Points of a particular medical laboratory at least once in an accreditation cycle.

**13.2.** During the assessment of a Collection Point, the following aspects, but not limited to, will be checked by the assessment team:

a) The environmental conditions of the Collection Points;
b) Sample collection and competency of personnel collecting the sample;
c) Sample preservation/storage pending transportation;
d) Sample transportation conditions;
e) Records of sample conditions maintained by Collection Points, for transportation and upon receipt by the main laboratory;
f) Confidentiality and privacy of the patients/sample collection area.

 

# Appendix A: Amendment Table

| SN | Section | Amendment |
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