



MAURITAS G11

Guidance for operating Collection Points
attached to Medical Laboratories

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Foreword

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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 (2012). 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 (2014). Guidance on regulations for the transport of infectious substances.

3.6 World Health Organisation (2016). Guidance on regulations for transport of infectious substances.

4. Definition

4.1 A Collection Point is an outlet associated to a licensed Medical Laboratory where samples are collected.

5. General

5.1. Collection Points are associated facilities of the main medical laboratory that collect/prepare/ store/transport samples. They should not be considered as stand-alone medical laboratories and should be legally recognised.

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.

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 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 phlebotomist should ensure that the procedure is done under sterile condition 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.** Procedure for transportation of samples should be made available to the personnel of Collection Points
- 11.3.** Temperature and conditions of sample upon receipt by the medical laboratory from Collection Points should also be recorded.
- 11.4.** The medical laboratory should establish sample acceptance/rejection criteria which should be made available at the Collection Points.
- 11.5.** 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 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) Internal audit records of the Collection Points.