

Guidelines for the Rejection of Specimens

CLP 011-001
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1. Rationale

Studies show that up to 56% of laboratory errors occur during the pre-analytical phase of testing¹. This phase begins in clinicians' offices with the initiation of the testing requisition and includes the steps for identification and preparation of patients' specimens. Strict adherence to proper pre-analytical procedures in the clinicians' offices and in the specimen collection centres and laboratories are essential to maintaining analytical quality and patient safety. Community laboratories strive for improvements in patient safety through the development of Practice Guidelines and through participation in Ministry of Health and Long Term Care laboratory accreditation programs (managed by the Quality Management Program-Laboratory Services (QMP-LS)). QMP-LS have recently mandated stringent standards for specimen processing in the Ontario Laboratory Accreditation (OLA) requirements.

This Guideline reflects specimen identification and acceptance criteria that comply with OLA requirements and good clinical practice. Community laboratories have adopted this Guideline so that patients and clinicians can be assured that the potential for pre-analytical error is minimized. Individual laboratory organizations may have policies and procedures that exceed the criteria and processes in this Guideline.

Clinicians who have questions about this Guideline are encouraged to contact the Director of the laboratory from which they order services.

2. Minimum Requirements for Determining Acceptance of Specimens

- a) At the time of collection, all specimens must be labelled with the patient's surname and first name, and one other unique identifier e.g. date of birth or Health Card Number (see Exception below).
- b) The name on the requisition* must appear exactly as on the Health Card.
- c) The identifiers which appear on the specimen container must match exactly the information provided on the accompanying requisition.
- d) The requisition must contain the signature of a clinician who is legally entitled to order laboratory tests, and include the date the requisition was signed (See Ontario Regulation 682).
- e) If the test request has been delegated, and a clinician's signature stamp is used, it must be authenticated with the delegated person's initials and include the date the requisition was initialled.
- f) Test(s) must be requested on the appropriate requisition i.e. OHIP*, Public Health Laboratory, cytology, histology or genetics requisitions.
- g) Test(s) requested must be clearly indicated and/or written legibly and unambiguously, using current nomenclature.
- h) The requisition must contain the full name of the clinician and the clinician's practice address, to which the laboratory report will be sent.

Exception: For specimen containers, slides etc. that have very little space for labelling, initials for first name are acceptable, provided that the second identifier on both the requisition and the specimen container exactly match.

*Note: OHIP requisitions must not be modified in any way. Only exact OHIP replicas without modification are acceptable.

3. Special Consideration

Irreplaceable specimens

Irreplaceable specimens are those specimens for which outright rejection poses a potentially unacceptable risk to the patient, when compared to the risk of proceeding with analysis. In these circumstances, to fully understand the potential risks, the clinicians are encouraged to contact the Laboratory Director from which they order services, before making clinical decisions.

The following list is not exhaustive, but indicates those specimens to which both the clinician and the laboratory should pay special attention:

- Histopathology/cytology specimens other than screening gynecological cytology
- Tissue aspirates for microbiology or cytology
- Kidney stones
- CSF

When an unlabelled, irreplaceable specimen has been received, **the laboratory will not label the specimen.** If the identity of the clinician can be determined, the laboratory will contact the clinician's office to advise that an unlabelled irreplaceable specimen has been received. The specimen may be returned to the clinician's office for investigation and potential resolution. In situations where specimen integrity could be compromised by a delay in processing, the specimen will be tested.

Reports, if issued, will be generated in compliance with each laboratory's strict protocol and contain an appropriate disclaimer, noting that the specimen arrived in the laboratory unlabelled and was identified by the clinician's office. Reports will only be issued after consultation by the clinician with the Laboratory Director.

Coded HIV Specimens

Coded specimens for HIV testing will be accepted if submitted with a unique alpha or numeric identifier assigned by the clinician, as well as a second unique identifier, such as the patient's birth date.

4. Guidelines for Rejection of Specimens

Note: For treatment of irreplaceable and coded specimens see the "Special Consideration" section above.

The specimen and/or requisition deficiencies described below may result in delayed or incomplete testing, or in most cases rejection of the specimen. Specimens which are rejected because they do not meet acceptable criteria, cannot be returned to clinician's office, and will be destroyed.

Deficiencies

- Unlabelled specimens
- Inadequately labelled specimens
- Improperly labelled specimens
- Requisition but no specimen
- Specimen arriving without a requisition
- Unique identifiers on the specimen and requisition do not match
- Inadequate number of tubes
- Inadequate volume of specimen submitted
- Specimens whose special handling requirements are not met, i.e. frozen
- Leaking or broken containers
- Specimen arriving in an incorrect container
- Specimen arriving in an incorrect condition of preservation
- Substances which are known to interfere with analysis e.g. haemolysis, lipemia, icterus

5. References

- OLA: Ontario Laboratory Accreditation (Quality Management Program-Laboratory Services) Version 3
- Laboratory General Checklist College of American Pathologists, 10/06/2005
- Specimens Collection Guide, Public Health Laboratories , Ontario Ministry of Health and Long Term Care, August, 2006
- Ontario Regulation 682 of the Laboratory and Specimen Collection Centre Licensing Act

6. Source

1. Ernst, D., Balance, L. Quality collection: the phlebotomist's role in pre-analytical errors. *MLO*, Vol 38, No.9 (September, 2006), pp. 32-38.

7. Supporting Documents

- Pre-Analytical Laboratory Procedures for Medical Office Staff CLP 011a-001 revised March, 2007
- Patient Safety Reference Sheet CO22 March 2007

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Laboratory Guidelines in Support of Clinical Practice

<p>The OAML, through its Quality Assurance Committee, co-ordinates the development, dissemination, implementation and review of Guidelines for Clinical Laboratory Practice.</p> <p>Guidelines are reviewed every 5 years. When consensus on the Guideline is achieved by the Committee, the Guideline is submitted to the OAML Board of Directors for approval before distribution to clinicians.</p> <p>The comments of end users are essential to the development of guidelines and will encourage adherence. You are strongly encouraged to submit your comments on this or any other OAML Guideline to:</p> <p>Chair Quality Assurance Committee Ontario Association of Medical Laboratories 5160 Yonge Street, Suite 710 North York, Ontario M2N 6L9</p> <p>Tel: (416) 250-8555 Fax: (416) 250-8464 E-mail: oaml@oaml.com Internet: www.oaml.com</p>	<p>Quality Assurance Committee Members</p> <p>Frank Thompson MD, FRCPC Medical Director, MDS Laboratories, Ontario</p> <p>Philip Stuart PhD, MD, FRCPC Medical Director, CML Laboratory</p> <p>Joel Goodman PhD VP, Strategies and Innovations Gamma-Dynacare Medical Laboratories</p> <p>Janice Nolan MLT CQA (ASQ) Director, Quality & Regulatory Affairs MDS Laboratories</p> <p>Chair Judy Ash MLT, ART, CQMgr, CQA (ASQ) Director, Programs & Member Services Ontario Association of Medical Laboratories</p> <p>No conflict of interest declared</p>
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Warning & Disclaimer for Laboratory Resources

This Guideline was prepared to assist clinicians who order tests from community laboratories. Users must ensure that their own practices comply with all specific legislative, government policies or accreditation requirements that apply to their organizations. The Guideline is not meant to be construed as legal advice or be all inclusive on this topic. Given the complexity of legal requirements, users are reminded that whenever there is uncertainty regarding whether some aspect of a Guideline is appropriate for their practice or organization, further direction should be obtained from the Laboratory Director, their own professional association, college and/ or legal counsel or appropriate government ministry.