

Pre-Analytical Laboratory Procedures for Medical Office Staff CLP 011a-001

Revised March, 2007

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 has been developed in collaboration with Ontario Medical Secretaries Association. It is intended to provide assistance to those medical office staff who initiate laboratory testing requisitions and/or collect specimens. Medical office staff can help to ensure the quality of the laboratory testing process and timely reporting of patients' laboratory results to clinicians, by following the procedures in this Guideline.

Following this Guideline will help to ensure:

- a) OHIP*, cytology or histology requisitions that are submitted to community laboratories, are completed legibly and accurately.
- b) The correct requisition is used and is fully and legibly completed for specimens that will be analyzed in other laboratories e.g. Public Health Laboratory, Genetic Testing Centres.
- c) The name on the requisition and the specimen containers appears exactly as on the Health Card.
- d) Specimens are labelled in a manner that unequivocally associates the requisition(s) with the specimen and the patient e.g. the patient's surname and first name, and one other unique identifier e.g. date of birth or Health Card Number.
- e) The requisition contains the signature of a clinician who is legally entitled to order laboratory tests, and includes the date the requisition was signed (See Ontario Regulation 682).
- f) 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.
- g) Specimens are safely packaged.
- h) Appropriate specimens and numbers of tubes are submitted to the laboratory.
- i) Delivery of laboratory reports to copied clinicians.
- j) Delivery of urgent and critical results to clinicians.
- k) Patients are made aware of any uninsured tests that have been ordered for which they will be required to pay.

For the reasons stated above and to avoid the potential for error and legal liability, Ontario's community laboratories have adopted strict criteria for the rejection of incorrectly processed or labelled specimens, as outlined in OAML's *Guidelines for the Rejection of Specimens*.

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

2. Limitations

Medical office staff should refer to *Specimens Collection Guide, Public Health Laboratories, MOHLTC*, for anonymous specimen labelling instructions e.g. for HIV testing.

3. Procedures for Ensuring the Accuracy & Completeness of Requisitions

A. Requisition Requirements:

- Name on the requisition should appear exactly as on the Health Card
- The identifiers which appear on the specimen container must match exactly the identifiers on the accompanying requisition
- The requisition must contain the signature of a clinician, who is legally entitled to order laboratory tests, and include the date on which it was signed (See Ontario Regulation 682)
- If delegated, and a clinician's signature stamp is used, it must be authenticated with the delegated person's initials and date on which it was initialled
- Test(s) requested must be clearly indicated or written legibly and unambiguously, using current nomenclature
- The full name of clinician and the clinician's practice address to which the laboratory reports are to be sent must be complete and legible
- Clinician's billing number is mandatory
- Clinical information related to the tests ordered that would be helpful to the on-call clinician should be noted e.g. patient is a known diabetic or have chronic renal failure
- Clinical information related to the cytology or histology specimens

Additional Requisition Content for Specimens Collected in Clinicians' Offices

- Type of specimen must be clearly identified
- Date & time of specimen collection is mandatory
- For therapeutic drugs, the time of last dose must be noted

B. Facilitating the delivery of laboratory reports to copied clinicians

To avoid privacy issues, copies of reports will be issued to other clinicians only if the following information is clearly provided on the originating requisition:

- Full name of clinician and either the complete practice address or the clinician's billing number, for each clinician to whom a copy is to be sent

If this information is not supplied to the laboratory, the ordering clinician will be notified. A comment will be added to the report, which indicates that the laboratory was unable to send additional copies due to incomplete information.

C. Delivery of urgent and critical results to clinicians

Urgent Test Requests

In keeping with the urgent nature of the request, it is the clinician's responsibility to provide contact information to the laboratory so that the laboratory can report urgent results to the clinician in a timely manner.

Critical Results

Clinicians must have on file with the laboratory a 24 hour contact number, to allow transmission of critical results in keeping with the critical nature of test result.

D. Uninsured Tests

Certain laboratory tests are not OHIP insured. At the time the uninsured test is ordered, patients must be advised of the reason why the test(s) is being ordered and that they will be required to pay for the test(s). If possible, they should be advised of the approximate amount that they will be required to pay.

E. Instructions to Patients

To minimize the potential for error, medical office staff are requested to instruct patients to review their requisition to ensure that:

- Their name on the requisition matches exactly their name on their Health Card.
- Their name on the requisition is in the same order as it is on their Health Card; last name, then first name.
- Their demographic information is correct i.e. birth date, gender, address and home phone number or 24 hour contact number, where the patient can be reached in the event of unexpected results.
- When therapeutic drug monitoring is requested, that the time of last dose and the time of specimen collection is written on the requisition (when the specimen is collected in the clinician's office).

Staff should instruct patients to identify to the staff any required corrections, so that staff can make the corrections. Patients must not make any changes to the requisitions themselves.

4. Procedure for Ensuring Specimens Meet Acceptance Requirements:

A. Specimen Identification

Medical office staff ensures that:

- At the time of collection, all specimens are labelled with the patient's surname and complete first name, and one other identifier unique to the patient e.g. date of birth or Health Card Number (see Exception below).
- The identifiers which appear on the specimen container match exactly the identifiers on the accompanying requisition.
- Identification is placed on the body of the specimen container, not on the lid.
- Containers for tissues, aspirated fluids, or swabs are labelled with the anatomical site of origin or source.
- Conventional PAP smears have the patient's surname, first name, and initial clearly printed in pencil on the glass slide. *Under no circumstances* may laboratory staff transcribe the patient's name onto the slide.
- Specimens are packaged as specified in the Transportation of Dangerous Goods Act.

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

B. Appropriate Specimens and Number of Tubes

Laboratories must receive the appropriate number of tubes, as indicated in the specimen collection guide provided to the clinician's office by the testing laboratory. If an inadequate volume of specimen is received, tests may not be performed; if tests are performed they may not correspond to those of greatest clinical interest for a given

patient. If there is any doubt regarding the appropriate number of tubes required, it is important that office staff and clinicians consult the laboratory's specimen collection guide or the laboratory.

C. Specimens which Require Freezing

Certain tests require the specimen to be frozen to maintain its integrity. Failure to do this may cause the specimen to be rejected, and if tested could lead to erroneous results that may have serious consequences to patients. Patients requiring such tests are best referred to a specimen collection centre for appropriate specimen collection. Where this is impractical, please contact the laboratory for specific specimen collection and transportation requirements.

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

7. Supporting Documents

- Patient Safety Reference Sheet CO22 March 2007
- Guidelines for the Rejection of Specimens CLP 011-001 Revised March, 2007

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Darlene Henrickson
Director, Quality Management Programs
Gamma-Dynacare Medical Laboratories

Dee Selvaggio
Director Client Services, Ontario
MDS Laboratory Services

Mary Zadel
Operations Manager, SW and N Ontario
CML Healthcare - Laboratory and Imaging Services

Marianne Musters-Pawley
Past President
Ontario Medical Secretaries Association

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 on 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 could be obtained from the Laboratory Director, their own professional association, college and/ or legal counsel or appropriate government ministry.