**CLP 011**
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# Guidelines for the Rejection of Unlabelled Specimens

## 1. Background

The issue of the rejection of unlabelled specimens by private medical laboratories has been complicated in the past by the varied practices among the members of the industry. The present guideline seeks to establish industry-wide criteria for specimen rejection and to provide physicians with a clear understanding of the reasons for the policy.

Many of Ontario's private medical laboratories are accredited in other jurisdictions; such accreditation requires adherence to the most stringent standards of specimen handling. It is the view of the OAML that Ontario's physicians and their patients deserve no less.

As well, the College of Medical Laboratory Technologists of Ontario requires that its members adhere to strict standards respecting the identity and integrity of specimens.

It is for these reasons and to avoid the potential for error and legal liability that Ontario's private medical laboratories have adopted these criteria.

**Physicians who have questions about this guideline should contact the Director of the private medical laboratory from which they order services.**

## 2. Limitations

The present guideline is intended to provide a minimum standard and individual laboratory corporations may have policies that exceed these guidelines. While implementation of the recommendations contained in this guideline may be handled variously, it is expected that OAML member laboratories will meet these minimum requirements for specimen labelling.

For specimens submitted for HIV testing, the physician should refer to the Ministry of Health's *The Guide to the Collection and Submission of Specimens*.[2]

For other specimens, such as those for clinical trials, submitted with a unique alpha or numeric identifier assigned by the physician, the patient's birth date should also be included on the label.

For certain samples, which are irretrievable or difficult to collect, there may be exceptional practices; these will be detailed in the recommendations.

## 3. Recommendations

It is a principle of good laboratory practice that the sample must be "unequivocally associated" with the test requisition. This is interpreted as meaning that the specimen container and the requisition must both be uniquely identified, preferably with the patient's surname and first name, in full, or, at a minimum, with the patient's surname and first initial. In most cases the accession number assigned to the

requisition will also appear on the specimen label generated in collection centres operated by private medical laboratories.

The information which appears on the specimen and on the accompanying requisition must match in order for the specimen and the requisition to be "unequivocally associated."

**In a case where the specimen and the requisition cannot be "unequivocally associated," the laboratory, in the interests of patient safety and for reasons of legal liability, should reject the specimen.**

**Mismatched Specimens** are defined as specimens which are submitted with a requisition on which the identifying information does not **exactly** match that which appears on the specimen. There may be a mismatch of either the first name or surname. For instance, the requisition may bear the patient's nickname while the specimen label, generated from the health card bears the patient's full name. (As an example, "Margaret" may be known as "Peggy" to her physician.) Or a patient's health card may bear the patient's name in his native language while the physician orders tests for the patient using the patient's English name. (As an example, "Mei Li" may also be known as "Melissa".) Or, the patient may be identified by a married name or hyphenated name on the health card and may be known to the physician by her own family name.

In the instances noted above, the laboratory should contact the physician's office to verify that the requisition and specimen pertain to the same patient. The date, time and results of the conversation should be recorded and a note added to the requisition indicating that the change has been made, consistent with the physician's instructions. If no contact can be made with the physician, the laboratory should do the testing and add a disclaimer to the report to the physician, indicating that the specimen and requisition did not match and that the results of tests should be interpreted with care.

**Unlabelled Specimens/No Requisition**
Unlabelled specimens submitted without an accompanying laboratory requisition will be **rejected**. The laboratory may, if the physician can be identified, telephone the physician to inform him or her that unlabelled specimens have been received, without an accompanying requisition. **No testing will be done and no report generated**.

**Unlabelled Specimens/Requisition**
Unlabelled specimens received with a test requisition will be **rejected**. The laboratory may contact the physician to inform him or her that unlabelled specimens have been received with a requisition. The laboratory will **not** seek confirmation that the specimens are associated with the requisition. The receipt of unlabelled specimens with a requisition will be documented and **the laboratory report will indicate that no testing was done for the specimens**.

**Labelled Specimens/No Requisition**
The laboratory will contact the physician, if the physician can be identified, to inform him or her that labelled specimens have been received but without an accompanying test requisition. The laboratory may, in consultation with the physician, develop a requisition and proceed with testing. Reports will be issued and the laboratory will forward the requisition to the physician for signature. **If the physician cannot be identified, the specimen will generally be rejected**.

**Difficult to Collect and Irretrievable Samples**
Procedures for difficult to collect or irretrievable samples are necessarily different from those for samples which may readily be recollected. The following listing is not inclusive but, indicates those

difficult to collect or irretrievable samples to which special attention should be paid by both the physician and the laboratory:

- histopathology/cytology specimens (other than PAP smears, urines and sputums)
- synovial fluid
- blood cultures in height of fever
- biopsies
- kidney stones
- IUD's for culture

For the above-noted specimens submitted unlabelled, the laboratory may consider testing. The laboratory will contact the physician's office, if the identity of the physician can be determined, to advise that unlabelled specimens have been received. **The laboratory should make no effort to verify the identity of the patient**. An oral report of the results of testing of the unlabelled specimen will be provided but, a note should be made on the written test report indicating that unlabelled specimens were received and test reports must be interpreted with caution. The written report may be released upon the request of the physician.

**PAP Smears**
**PAP smears MUST have the patient's name clearly printed IN PENCIL on the glass slide.**

**Under no circumstances may laboratory staff transcribe the patient's name onto the slide.**

An unlabelled or improperly labelled slide and any associated material will be returned to the physician's office with a notation indicating that testing has not been done as the laboratory was unable to identify the patient from whom the specimen was obtained.

## 4. References

1. *General Checklist* and *Commentary,* College of American Pathologists, 1995.0 Edition, 1995.

2. *Practice Guidelines: Standards of Practice for Medical Laboratory Technologists,* College of Medical Laboratory Technologists of Ontario, 1995.

3. *The Guide to the Collection and Submission of Specimens*, Laboratory Services Branch, Ontario Ministry of Health, April, 1992.

## 5. Acknowledgments

The OAML gratefully acknowledges the contributions of the members of the Guideline Panel and others who have contributed their expertise, advice and technical support to the development and review of this guideline.

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This guideline has been reviewed by the members of the Professional Advisory Group to the Quality Assurance of Clinical Laboratory Practice Program, by the members of the Quality Assurance of Clinical Laboratory Practice Committee, by the Laboratory Proficiency Testing Program of OMA and by representatives of the Geriatrics, General & Family Practice, Laboratory Medicine and Obstetrics & Gynaecology sections of OMA.

## The Ontario Association of Medical Laboratories

The Ontario Association of Medical Laboratories (OAML) represents the community-based laboratory sector in Ontario.

Its mission is to promote excellence in the provision of laboratory services and, as an essential component of the health care system, to contribute to shaping the future of health care in Ontario.

The OAML encourages the highest level of professional and ethical integrity and technical excellence among laboratory owners, operators and staff in the provision of laboratory services for the benefit of the people of Ontario.

**Guidelines for Clinical Laboratory Practice**

The OAML, through its Quality Assurance and Clinical Laboratory Practice Committee, co-ordinates the development and dissemination, implementation and evaluation of Guidelines for Clinical Laboratory Practice.

**A proposed Guideline** is developed by a working group of the Committee with the participation of outside experts. The proposed guideline is then submitted to the Committee as a whole and to a Professional Advisory Group who provide an overall review of the document. The comments of the Committee and the Professional Advisory Group are incorporated into a revision of the guideline and this draft is submitted to laboratory Medical Directors, professional associations and other representatives of end users for additional comment. The document is revised in light of these comments and

There may be additional educational materials produced, if it is thought that they might be useful, and these are distributed with the guideline.

**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:

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| submitted to the OAML Board of Directors for approval.<br><br>**Approved guidelines** are distributed to Community-based Laboratories and by them to their client physicians. | Fax: (416) 250-8464<br>E-mail: oaml@oaml.com<br>Internet: http://www.oaml.com |


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