LABORATORY POLICY AND PROCEDURE

<table>
<thead>
<tr>
<th>TITLE/SUBJECT:</th>
<th>Specimen Submission, Acceptance, and Rejection Policy</th>
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<tbody>
<tr>
<td>FILE NUMBER:</td>
<td>QA 10.05</td>
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<tr>
<td>ORIGINATION DATE:</td>
<td>December 2, 2008</td>
</tr>
<tr>
<td>EFFECTIVE DATE:</td>
<td>January 7, 2015</td>
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<tr>
<td>DISTRIBUTION:</td>
<td>All Saint Michael's Hospital Network Laboratories</td>
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**PRINCIPLE/PURPOSE:**

It is the policy of the Saint Michael's Hospital Laboratory that all Clinical Laboratory and Anatomic Pathology specimens are labeled adequately to ensure correct patient identification and allow appropriate result reporting and billing.

This policy describes specimen labeling requirements, provides a protocol for dealing with common specimen labeling issues and further defines labeling errors that require the judgment of the Laboratory Manager, Administrative Director and/or Medical Director to balance risks and benefits in an individual circumstance.

It is mutually understood that all members of the patient care delivery team ensure that all specimens are labeled completely and accurately, and that everyone willingly participates in efforts to evaluate and correct recurring specimen labeling errors.

**STANDARDS:**

1.0 Specimen integrity, which includes specimen and requisition identification, is an integral part of delivering a high quality laboratory test result.

2.0 The College of American Pathologists (CAP) further dictates that if any potential error in patient or specimen identification is found, that best practice is to recollect the patient sample.

3.0 CAP, The Joint Commission (TJC) and CLIA specifically define the necessary elements of an appropriately labeled requisition and specimen:

3.1 Requisition must include the following:

3.1.1 Adequate patient identification (full name, medical record number, and facility)
3.1.2 Patient sex
3.1.3 Patient date of birth
3.1.4 Provider/physician name and address (if non-Ministry provider)
3.1.5 Tests requested (avoiding abbreviations for uncommon tests)
3.1.6 Time and date of specimen collection when appropriate
3.1.7 Source of specimen, when appropriate
3.1.8 Diagnosis - numeric is preferred

3.2 Specimens and Specimen Containers must include the following:

3.2.1 Patient FULL (formal – first and last) name
3.2.2 Examples of inappropriate names:
   
   3.2.2.1 Bill, instead of William
   3.2.2.2 A. Smith, instead of Angie Smith
   3.2.2.3 Use of Mr, Mrs, Ms
   3.2.2.4 Johnson, instead of Johnsen
   
   3.2.3 Patient date of birth and/or Ministry Medical Record number
3.2.4 Time of collection
3.2.5 Date of collection
3.2.6 Collector’s initials
3.2.7 Non-Blood specimens require a Source when appropriate
3.2.8 Specimens received in aliquot tubes must indicate whether serum or plasma
   
   3.2.8.1 Indicate tube type sample collected in: Citrate, Red Top, SST, EDTA, etc)

PROCEDURE:

1.0 Patient’s identity must be checked using at least two (2) identifiers before collection.

1.1 Inpatient’s wrist band may be checked for name and unique hospital number
1.2 Outpatient’s full name and birth date
1.3 Patient’s room number is not acceptable
1.4 The patient’s identity should be verified by asking the patient to identify him or herself.
   
   1.4.1 If the patient is unable to identify themselves (child, non-English speaking, mentally disabled), it is acceptable to:
   1.4.1.1 Consult a family member or caregiver for identification verification, using two types of identification.
   1.4.1.2 Consult a nurse for identification verification, using two types of identification.
1.4.1.3 If the patient is a resident of a nursing facility, a staff member can provide two types of identification.

1.5 Special attention must be made when handling newborns and multiple births. Consulting Nurse for verification is common practice.

1.5.1 Newborns may be “Baby Boy Doe”, but patient ankle band must be verified.

1.6 Laboratory tests may only be ordered by an authorized person – Physicians, Dentists and Chiropractors, Mid-level providers such as Physician Assistants and Nurse Practitioners.

2.0 All specimens must be accompanied by an adequate requisition.

2.1 Requisitions must be retrievable and retained for 2 + current years.
2.2 See Standards 3.1, details the requisition requirements.
2.3 Patient charts can be used as requisition or documentation of order, however the charts are subject to periodic audits to ensure record retention and appropriate documentation is maintained.

3.0 Changes or additions to the original laboratory test requisition.

3.1 Must be documented in patient’s chart.
3.2 Add-ons to the original requisitions will be documented either on the original requisition or an additional requisition will be requested from the providers office.

4.0 Specimen Rejection - Specimens that fail to meet labeling standards are subject to rejection by the laboratory department. See Rejection Protocol Table for handling of rejected specimens. Examples of reasons specimens that may be rejected:

4.1 Samples received unlabelled.
4.2 Patient name mismatch between requisition and sample.
4.3 Specimen received is incorrectly labeled or unreadable.
4.4 Specimen does not include the patient’s full name (ie: last name only).
4.5 Specimens collected improperly.

4.5.1 Wrong anticoagulant.
4.5.2 Failing to follow proper storage requirements.
4.5.3 Failing to follow proper collection procedures.
4.5.4 Grossly hemolyzed samples.
4.5.5 Specimen is of insufficient quantity.
4.5.6 Specimen is from unacceptable source or is wrong sample type.
4.5.7 Specimen was not received by the laboratory in a timely manner (ie: semen analysis, stool, or other cultures).
5.0 **Retrievable Specimens** – Specimens that are considered easily recollected, with minimal or no negative impact on the patient and can be characteristically representative of the original specimen.

5.1 Throat swabs – Nasopharyngeal swabs  
5.2 Urine samples, cathed and voided specimens  
5.3 Stool specimens  
5.4 Pap smear collection  
5.5 Sputum  
5.6 STD collections – excluding those involved in legal cases  
5.7 Blood specimens (non-arterial)  
5.8 Arterial Blood Gas (ABG) – \textit{drawn from an arterial line}

6.0 **Irretrievable Specimens** – specimens that can NOT be easily recollected, does have the potential to cause significant negative impact to the patient and any recollection will not absolutely represent the original sample.

6.1 Tissue biopsies  
6.2 Cerebrospinal fluid, serous fluid, synovial fluid  
6.3 Bone Marrow collections  
6.4 Trauma related collections  
6.5 Wound cultures  
6.6 Arterial Blood Gas (ABG) – \textit{drawn from wrist}

7.0 Specimens with special collection protocols (ie: Pertussis, Chlamydia cultures, etc) require collection kit insert guidelines be followed. Improperly collected specimens will be rejected by the appropriate laboratory.

**Specimen Protocol Table**

| Accept specimen, contingent upon verification | 1. Call to verify information  
| | 2. Accept specimen and report result  
| | 3. Add comment to test result describing discrepancy, including who verified information. If error is uncovered after results are reported, an EXTERNAL comment is entered. For all others, add an INTERNAL comment  
| | 4. Complete Incident Report  
| ▪ Minor spelling mismatch with matching additional identifiers  
| ▪ Common nickname with matching additional identifiers (example: Bill versus William)  
| ▪ Missing collection date and/or time or initials (if collected by laboratory staff)  

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### Reject specimen, based on unacceptable sample

<table>
<thead>
<tr>
<th>RETRIEVABLE:</th>
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<tbody>
<tr>
<td>1. Reject specimen. Testing cannot be performed.</td>
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<tr>
<td>2. Notify originating site, department, or provider of error and the need for recollection</td>
</tr>
<tr>
<td>3. Complete Incident Report</td>
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**IRRETRIEVABLE**

1. Notify originating site, department, or provider of error

2. Consult with Laboratory Coordinator or Pathologist and perform as much testing as is advisable.

3. If the test results are compromised by quality of sample, an external comment must go out with the results (example: CSF ___ hours old when cell count performed).

4. Complete Incident Report

### Reject specimen, based on unacceptable labeling

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- Missing or inaccurate first or last name
- Missing or inaccurate date of birth
3. Complete Incident Report

**IRRETRIEVABLE**

1. Hold specimen and minimize sample degradation (i.e., centrifuge if appropriate).

2. Notify originating site, department, or provider of error.

3. Fax Specimen Identification Discrepancy Form to the provider. This form can only be signed by provider. Signature by a nurse or MA is not acceptable.

4. Upon receipt of completed Specimen Identification Discrepancy Form, accept specimen and report results.

5. Add comment to test result describing discrepancy, including the name of the provider who signed the form. If error is uncovered after results are reported, an EXTERNAL comment is entered. For all others, add an INTERNAL comment.

5. Complete Incident Report

6. Return completed Identification Discrepancy Form to Laboratory Manager

**REPORTING:**

1.0 Document specimen error as defined in Specimen Protocol Table

2.0 Immediately notify provider or provider’s office that the sample was received and did not follow expected specimen labeling or collection requirements.

3.0 It is the responsibility of the department in which the error occurred to contact the patient for recollection.
CRITERIA FOR IMMEDIATE NOTIFICATION:

All specimen labeling and collection errors must be immediately communicated to the provider or provider’s office.

PROCEDURE NOTES:

1.0 All specimen collection and labeling discrepancies must be documented using the standard Ministry Incident Report

2.0 Unlabeled, mislabeled and improper collections are monitored and reported to the respective department Manager. Increased frequency of High Risk errors are reported by the Laboratory Quality Improvement Coordinator to the Medical and Administrative Laboratory Directors

3.0 Legal Alcohol collections are considered out of scope of this policy given the process in which the samples are collected and handled. Any identification errors will be identified at the testing facility at a time delay that voids any possibility of a recollection that will be fully representative of the original specimen.

SAFETY PRECAUTIONS

Follow procedures and precautions described in the Saint Michael's Hospital Infection Control and Hazard Communication manuals, as well as the Saint Michael's Hospital Chemical Hygiene Plan. Refer to the MSDS for reagent-specific handling guidelines.

ATTACHMENTS:

Specimen Identification Discrepancy Form

REFERENCES:

Harty-Golder, Barbara MD JD, Legal dangers of testing unacceptable specimens. Medical Laboratory Observer, September 2004

Harty-Golder, Barbara MD JD, When irreplaceable specimens are inadequate. Medical Laboratory Observer, December 2004


Glassbrenner, Cheryl, Identifying the Patient, Marshfield Clinic Laboratories, March 30, 2005.

Stirewalt, Michael, Laboratory Specimen Labeling Policy. New Hanover Regional Medical Center Laboratory, October , 2002
O R I G I N A T I N G  D E P A R T M E N T / S E C T I O N :  
Laboratory Administration

A U T H O R  A N D  D A T E :  
Ron Purkapile MS, Director, November 2008

R E V I S E D  B Y  A N D  D A T E :  
Michelle O’Connell, Quality Improvement Coordinator  
July 3, 2009

Michelle O’Connell, Quality Improvement Coordinator  
October 21, 2009

Michelle O’Connell, MT (ASCP) - Quality Improvement Coordinator  
January 7, 2015

A P P R O V A L :  

__________________________________________________________  
Dawn Finch, MT (ASCP), Director of Laboratory Services

__________________________________________________________  
Jason Heese, MD – Medical Director of Laboratory Services

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Specimen Identification Discrepancy Form
IRRETRIEVABLE SAMPLES ONLY

<table>
<thead>
<tr>
<th>Sample Received</th>
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<tbody>
<tr>
<td>Date/Time:</td>
<td></td>
</tr>
<tr>
<td>Specimen Description:</td>
<td></td>
</tr>
<tr>
<td>Specimen labeled as:</td>
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<tr>
<td>Requisition labeled as:</td>
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<tr>
<td>Comments:</td>
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<tr>
<td>Patient Location:</td>
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<tr>
<td>Provider Name:</td>
<td></td>
</tr>
<tr>
<td>Notification Name/Date/Time:</td>
<td></td>
</tr>
<tr>
<td>Lab Staff Name</td>
<td></td>
</tr>
<tr>
<td>Name of Staff who re-labeled specimen</td>
<td></td>
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</tbody>
</table>

IRRETRIEVABLE SAMPLES ONLY

*** Use for Confirmation of Specimen Identification:

This form must be completed to verify the accuracy of information of irretreivable specimens. This form will only be used for the following limited purposes:

| CORRECT Patient Name |          |
| CORRECT Birth date/ MR Number |          |

Check reason to continue with testing:

- [ ] Test result is critical and delay for a new specimen could compromise care
- [ ] Second sample can not be collected without risk to the patient
- [ ] Recollection will absolutely not reflect the original specimen
- [ ] Other (specify details) Laboratory Supervisor, Director or Pathologist approval required.

Administration Initials for Approval: ____________________________

Physician/ Provider Statement

I affirm the accuracy of the corrected information provided and request that the specimen be analyzed. The process of obtaining a new specimen could have a negative impact on the condition of the patient.

**Print Physician/ Provider Name: ____________________________

**Signature, date and time: ____________________________

Route completed form to Laboratory Quality Coordinator