Shared health
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Manitoba

Document History:

Title: Specimen Acceptance Policy **Site(s): Shared Health Diagnostic Services**

Document #:	**10-50-03**	**Version #:**	**07**
Section:	**Governance & Administration**	**Subsection:**	**Quality & Risk Management**

Approved by: **Signature:**	**Dr. A. Sokoro** **(signature on file)**	**Date:**	26-JAN-2021
		Effective Date:	04-MAR-2021

Details of Recent Revision

Changed references to DSM to Shared Health
Added 1.3, 2.3.2.5, 2.3.2.6 & 2.3.2.7
Changed Note in section 2.3.2; deleted "and/or physician 24/7 critical results contact number"
2.4.3 & 2.4.4 deleted "& Genetics"
Added 2.4.3.2, 2.4.4.2
Deleted 2.4.7.9
Added 2.4.8.4, 3.3 & 3.4
Revised all of section 4.0 (removed old section 5.0 as information was duplicated in section 4.0
Blended and renumbered old section 6.0 & 7.0 as section 5.0 as both sections covered the same information
Information in new 6.4.4 updated to match the list on the "Show your ID" poster
Updated section 2.2 with Pathology Specimen type
2.3.2.1- added requirement for after hours contact information for outpatient clinics, when Critical Results Phone # is listed as mandatory
2.3.2.7- do not require signatures for non-gyne cytology urine specimen
Major revisions to: 2.4.7, Pathology
2.4.8 Cytology
Section 5.3 and 5.5 related to pathology
Associated Documents updated

1.0 Purpose

1.1 To define the criteria and actions required for the acceptance or rejection of diagnostic specimens received by Shared Health Diagnostic Services to ensure patient safety.

1.2 To ensure that the rejections occur at the initial receiving site and that unsuitable specimens are not forwarded on to other Shared Health laboratories.

1.3 Shared Health Diagnostic Services provides medical laboratory testing for patient care that is covered by Manitoba Health for the purpose of providing medical care; testing for medico-legal purposes, such as employment, immigration or child custody, is not performed by Shared Health laboratories

2.0 Policy

2.1 Test Requisitions

The following information is required on the appropriate test requisition and must be clearly legible

2.1.1 First and last name of patient

2.1.2 PHIN or equivalent unique patient identifier. Refer to 8.4.4 for details on equivalent unique patient identifier.

2.1.3 Date of birth

2.1.4 Gender

~~2.1.5~~ Patient phone number

2.1.6 Physician 24/7 critical results contact number

2.1.7 Location of patient (i.e. Nursing unit, collection site, etc.)

2.1.8 Phlebotomist / collector identifier (initials)

2.1.9 Name of authorized ordering professional (refer to 10-50-04, *Authorization to Order Diagnostic Tests*)

2.1.10 Test(s) requested

2.1.11 Source of specimen, when appropriate*

2.1.12 Clinical information, when appropriate*

2.1.13 Procurement method, when appropriate*

2.1.14 Date & time of collection

2.1.15 Preservative/fixative (where applicable)

***** Refer to the relevant Laboratory Requisition or Laboratory Information Manual (LIM)

2.2 Specimen Labeling

The following information, at minimum, is required directly on the primary specimen container label and must be clearly legible and must match the accompanying test requisition. Additional discipline/laboratory specific requirements (if applicable) are noted in section 2.4

2.2.1 First and last name of patient

2.2.2 PHIN or equivalent unique patient identifier

2.2.3 Specimen Type (see Pathology 2.4.7)

2.3 **Rejection Criteria**

Shared Health laboratories will reject specimens for analysis for the following reasons

2.3.1 **Specimen labeling errors**

2.3.3.1 Unique patient identifier(s) on the specimen label and test requisition do not match

2.3.3.1 Patient first and last name and PHIN or other unique identifier are not on both the test requisition and the specimen label

2.3.3.2 Surgical Pathology and Cytology cases: specimen type on container does not exactly match specimen type on requisition.

2.3.2 **Requisition errors**

2.3.2.1 In out of hospital/ outpatient clinics the name of the ordering professional is not on the test requisition and cannot be confirmed

2.3.2.2 The location of the patient is not on the test requisition and cannot be confirmed

2.3.2.3 Phlebotomist identification is missing and cannot be confirmed

2.3.2.4 Date of collection is not identified and cannot be confirmed

2.3.2.5 Physician 24/7 critical results phone number is missing and not in Delphic in the “After Hours Phone #” field. This applies only to requisitions where the Critical Results Phone #” is listed as required information with an “*”

- This requirement is for outpatient requisitions only as there is no 24/7 service available
- For inpatients the ward is available 24/7 for critical results

2.3.2.6 “Physician Signature” field is blank when it is listed as required information with an “*”

2.3.2.7 Clinician ordering the test is not authorized to order a specialty test, as indicated on the requisition, or requested on the wrong requisition by an unauthorized clinician

NOTE:

- Missing patient phone number *does not* necessitate rejection of the sample
- Missing signatures on Non-Gynecological Cytology requisitions does not necessitate rejection for urine specimens

2.3.3 **Unacceptable specimen quality**

Specimens will not meet analytical requirements results will be inaccurate therefore these specimens cannot be processed. This includes, but is not limited to:

2.3.3.1 Inappropriate transport

2.3.3.2 Inappropriate storage

2.3.3.3 Inappropriate container or specimen tubes

2.3.3.4 Inappropriate preservative and/or volume of preservative

2.3.3.5 Hemolysis

2.3.3.6 Lipemia

2.3.3.7 Insufficient quantity of sample for analysis (NSQ)

2.3.3.8 Age of specimen

2.3.3.9 Specimens listed on LIM that are not accepted for routine testing

2.4 **Discipline Specific Requirements and Exceptions**

2.4.1 **Transfusion Medicine**

2.4.1.1 Refer to 160-MP-02, *Specimen Acceptance, Rejection and Suitability*, for all requirements for transfusion medicine.

2.4.2 **Transplant Immunology**

2.4.2.1 All requirements for requisitions and specimen labeling as noted above must be met

2.4.2.2 Date of collection is also required on specimen

2.4.2.3 Time of collection is not required on the requisition

2.4.3 **Clinical Biochemistry**

2.4.3.1 All requirements for requisitions and specimen labeling as noted above must be met.

2.4.3.2 For tests with multiple time points – all time points must be labeled on the specimen (i.e. fasting, 2hr, etc.)

2.4.3.3 Clinical indicator is missing where required to order a test

2.4.4 **Rural – Clinical Biochemistry, Hematology**

2.4.4.1 All requirements for requisitions and specimen labeling as noted above must be met.

2.4.4.2 Date and time of collection must also be present on all requisitions for specimens that may be referred to another lab for processing

2.4.3.3 Clinical indicator is missing where required to order a test

2.4.6 **Clinical Microbiology**

2.4.6.1 All requirements for requisitions and specimen labeling as noted above must be met.

2.4.6.2 **Exception 1** – Specimen source must be identified on the requisition and container

2.4.6.3 **Exception 2** – time of collection is not required on the requisition: date of collection ***is*** required

2.4.7 **Pathology: Histology (Surgical) and Cytology**

Note: Surgical specimens and many cytology specimens are irreplaceable. These specimens will not be processed until the correction is made. Extended wait times may adversely affect the specimens. Errors must be rectified as soon as collection site is contacted.

Surgical (Histology)

2.4.7.2 All requirements for requisitions and specimen labelling as noted above must be met.

2.4.2.1.27.2 **Containers:**

Specimen source must also be listed on the container including:

- Tissue type/source
- Specimen details (mass, tumor, bone, etc.)
- Anatomical site where it was obtained, including whether it is from a right or left anatomical site
- Procurement method (where applicable)

NOTE: IF collecting multiple surgical specimens, they are ***lettered*** sequentially (A, B, C, etc.)

2.4.7.3 **Requisitions:**

- Information on the requisition and specimen containers must be identical, including the number of containers
- Date & time of collection- Time specimen placed into formalin or other fixatives must be indicated in the space provided
- Time of collection is required for fresh specimens
- Clinical information must be provided on the requisition

2.4.7.7
- Ischemic time should be included for breast excisions

2.4.7.8
- Signature of physician is required

2.4.8 **Cytology**

2.4.8.1 All requirements for requisitions and specimen labelling as noted above must be met. **Exception -** Collection time is ***not*** required for Pap Test samples

2.4.8.2 Physician signature is required on Non- Gyne requisitions.

NOTE: missing signatures for urine samples on Non-gyne cytology requisitions will not result in specimen rejection

Physician signature is not required for Pap Test samples

2.4.8.3 Specimen source must be indicated on specimen container and must match the requisition (including urines)

2.4.8.4 MRN is not acceptable as a patient identifier for cytology specimens

Non-Gynecological Specimens

2.4.8.4 One Non-gynecological requisition is required for each specimen

collected

2.4.8.5 **Patient Collected Specimens (Self Collected)**

Requisition and specimen labeling must be completed by clinician's office prior to being given to the patient.

All necessary information is required on the requisition. Physician signature is preferred; if missing specimen will not be rejected

- Patient is to provide date of collection on both the requisition and the container

2.4.8.6 The following specimen types are not processed in Cytology and will be rejected if received:

- Stool
- Specimens where the patient is confirmed or suspicious for infection of CJD
- Bloods
- Semen

Gynecological Specimens

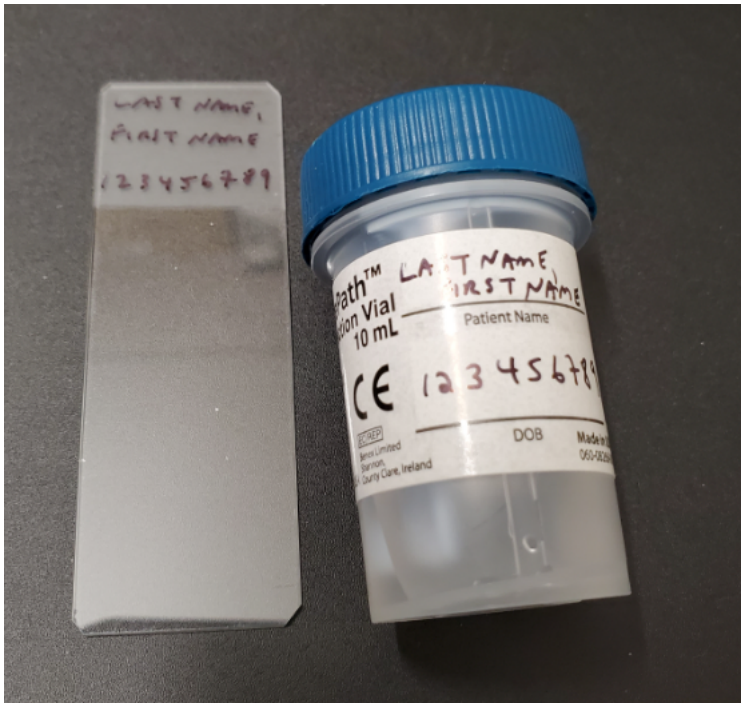
2.4.8.7 Use the MCCSP requisition for Pap Test

2.4.8.8 SurePath Vial/ Conventional Slide Labeling

All Pap Test samples must be labeled with the patient's last name, first name and PHIN.

- A minimum of 8 letters (first name & last name) can be used for significantly long names

- The conventional Pap slide example below designates LAST NAME, FIRST NAME, and numbers for PHIN on the frosted end of the slide



2.4.8.9 F10-50-03B, *Pathology Specimen Error Report & Waiver,* will be used to track all pathology errors.

2.4.9 **Semen Analysis**

2.4.8.1 All requirements for requisitions and specimen labeling as noted above must be met.

2.4.8.2 Date and time of collection must be included on the requisition and specimen

2.4.10 **Molecular Diagnostics**

2.4.9.1 All requirements for requisitions and specimen labeling as noted above must be met.

2.4.9.2 **Exception** – time of collection is not required on the requisition

2.4.11 **Hematology**

2.4.10.1 All requirements for requisitions and specimen labeling as noted above must be met.

3.0 Requirements Not Met – Specimen not rejected

3.1 When required information is missing or incorrect on the requisition and/or specimen label that is not subject to rejection under 2.3 the lab will contact (by phone, fax or issuing a report) the collection site to obtain the necessary information;

- Appropriate steps should be taken to ensure stability of specimen (i.e. specimen will be centrifuged, and serum/plasma separated from cells) and then the specimen will be processed and results released once all applicable requirements have been met.
- For labile samples, testing will be performed but no results will be released until all applicable requirements have been met. Examples: incorrect sample type/ location, difficult to obtain sample, test requested does not make sense

3.2 F10-50-03A & B (Pathology), *Specimen Error Report and Waiver*, will be completed and

LIS updated (where applicable) or other type of error tracking log will be completed or updated to document all errors, rejections and subsequent dispositions. F10-50-03A & B (if completed) will be kept by the site for tracking and trending purposes and retained as outlined in applicable retention policy.

3.3 Requisitions do not accompany samples (pre-registered and referred onto testing site) or samples do not accompany requisitions

The sending site is to be notified as soon as possible. Appropriate steps should be taken to ensure stability of specimens (i.e. specimen will be centrifuged, and serum/plasma separated from cells) and then the specimen will be processed, and results released once all applicable requirements have been met. For labile samples, testing will be performed but no results will be released until all applicable requirements have been met.

3.4 A non-conformance report is to be written and submitted related to points 3.1 and 3.3.

4.0 Rejected Specimens – General Policy

4.1 The specimen will be retained for the period consistent with acceptable storage for the testing requested

4.2 Ordering professional/collection site will be notified, at minimum, of all potentially irreplaceable or time sensitive sample rejections by phone

- All other rejections will have a comment code entered into LIS (where applicable) or the requisition will be updated with the rationale for rejection
- The information will be sent to the collection site informing that the sample has been rejected

4.3 When informed of a specimen rejection and the reason for rejection, the ordering professional may still consider the specimen to be irreplaceable or time sensitive and request testing be performed. Follow procedure outlined for Irreplaceable or Time Sensitive specimens.

5.0 Handling of Specimens That Are Potentially Irreplaceable or Time Sensitive

5.1 The ordering professional will be notified immediately by phone of all potentially irreplaceable or time sensitive sample rejections.

- The ordering professional is responsible for determining the next course of action, which may include recollection of the specimen or processing/testing of the specimen

5.2 The lab will retain these specimens for a period consistent with acceptable storage for the testing requested.

- In cases where the stability of the specimen is an issue, testing may be performed but results held pending resolution of the specimen ID issues.

5.3 Lab staff will use the following list as an aide to determine which specimens are *potentially* irreplaceable or time sensitive (note: this list may not be all inclusive):

- STAT or EMERGENT requests from Emergency or ICU
- Sterile body site fluids (i.e. CSF, Blood Cultures)
- Bone marrow aspirates
- Bronchial alveolar lavage
- Neonatal blood
- Selected sites/specimens that require special attention as determined by site specific patient population/needs
- Timed specimens (i.e. drug levels)
- All fluids for chemistry
- Cultured cells
- Specimens submitted to Microbiology requiring culture where requisition indicates that it was taken prior to starting antibiotics
- Pathology:
- Cytology Non-Gyne specimens, including fine needle aspirates (FNAs), Surgical specimens (tissues)
- Autopsy cases
- Pathology specimens – considered irreplaceable or critical (although in some cases re-biopsy may be possible, requires discussion between site medical manager or designated pathologist and submitting physician).
- Cytology specimens procured by an invasive procedure - considered critical (list = FNA, CSF, bronchoscopic, endoscopic, cystoscopic, body fluids by aspiration) although some could be re-collected.
- Cytology specimens not collected by an invasive procedure that can be recollected = voided urine, sputum, cervical cytology are NOT considered critical and should be recollected whenever patient identity is in question (major submission discrepancy).

5.4 If the ordering professional choses to process/test the specimen, they must acknowledge in writing that they are aware of the reasons for the rejection and accept full responsibility for any inherent risk associated with the use of the results by themselves or other healthcare providers

5.5 The ordering professional or authorized designate should come directly to the lab to authorize the testing in writing by completing the “Authorization to Proceed with Testing” section of either F10-50-03A or F10-50-03B

- If signed by a designated, indicate both the name of the ordering professional and the designate. Note Staff signing authorization to proceed with testing should be

reminded that they are responsible for ensuring all the collection processes and patient details are accurate.

5.6 In cases where it is not possible for the ordering professional or authorized designate to go to the lab, the authorization will be documented and submitted by FAX

5.7 Testing will not proceed until written authorization on either F10-50-03A or F10-50-03B is received by the lab

- The only exception is when the sample is precious and not stable, in which case testing will proceed but no results will be released until written authorization is received

5.8 F10-50-03A or F10-50-03B will be updated/completed by the lab and retained as outlined in applicable retention policy

6.0 Miscellaneous Issues

6.1 Labeling/Removal of Labels from Microtainer and All Other Applicable Tubes

6.1.1 1 For hand labeled tubes, rather than attempting to write directly on the tube, legibly write name and unique identifier on a label.

6.1.2 2 Attach the label directly to the tube. It is recommended to place the label horizontally around the tube joining the adhesive sides together creating a flap so that all information is still visible.

6.1.3 3 If required, the accessioning lab can remove the label and replace it with a LIS generated label; indicate on the requisition that the original label was separated from the tube and a new label was created.

6.2 Multiple Tubes from One Collection/One Requisition

6.2.1 Lab will process all specimens that meet acceptance criteria

6.2.2 Remaining specimens will be rejected

6.2.3 Final lab report will be amended stating that there were rejections related to the collection

6.3 ID of Phlebotomist / Collector

6.3.1 The person collecting must identify themselves on the requisition as part of the phlebotomy/collection process at the bedside/collection site

6.3.2 Although not preferable, in some cases this information is filled in by another person on the collector's behalf. Although the specimen will not be rejected on this basis, the person signing on behalf is accepting responsibility of the collector that the specimens were collected and documented properly and came from the correct patient.

6.4 PHIN or Other Unique Patient Identifier

6.4.1 The PHIN is the Personal Health Identification Number. All patients in Canadian provinces and territories have an assigned PHIN; with the exception of newborns, where the PHIN has not yet been assigned.

6.4.2 The intent of using the PHIN as part of primary patient identification is to utilize a number that is specific to the patient, regardless of where they reside.

6.4.3 With the exception of Manitoba PHIN, the province or territory must be included with the PHIN.

6.4.4 If a Manitoba PHIN is not available an alternative unique identification issued by another authority can be accepted. Types of identification include, but are not limited to:

- RCMP
- Military
- First Nations and Inuit health card
- Passport
- Health Card from another province
- Health number (10-digit number)

6.4.5 In special circumstances photo identification, such as driver's license, may be utilized.

6.4.6 In facilities where the hospital information system uses the MRN (Medical Record Number) as the unique patient identifier and this is the number printed on addressographs and transferred to LIS via the ADT systems, the MRN will be acceptable.

Exception: MRN is not accepted as a patient identifier for cytology

6.4.7 Referrals received from another province may be labeled with a unique laboratory identification number (such as an AP number or a DNA number). This unique identification number must appear on both the requisition and specimen to be accepted.

6.4.8 Once a specimen has received a unique lab identifier, transferring the specimen to another department within the lab does not require the identification process to be repeated.

6.5 **Long Names**

6.5.1 In cases where long names do not fit on electronically or mechanically generated specimen labels, these will be accepted as long as there are no other discrepancies between the requisition and what is visible on the specimen label.

6.5.2. Pap Smears: See labeling directives in section 2.4.8.8

6.6 **PHIN Discrepancies between MB Health Database and LIS**

6.6.1 If the specimen and requisition PHIN correspond but a discrepancy is noted between this number and that in the MB Health database the error should be investigated and may lead to rejection if there is significant doubt about patient identity. Enter an LIS comment to correct record or contact MB Health to address minor demographic discrepancies between requisition and MB Health Database. In these cases the MB Health database information should be used for registration and LIS comment should be used to identify difference and direct the ordering professional and/or patient to contact MB Health to correct if required.

6.6.2 If a discrepancy exists between the patient information provided and previous entries in the LIS this should not lead to a specimen rejection; once resolved the report should be amended to communicate to the ordering professional what the discrepancy was and how it was resolved.

6.6.3 For transfusion medicine specimens, Canadian Blood Services will reject and request recollection if the PHIN does not match the MB Health database.

7.0 Associated Documents

7.1 F10-50-03A, *Specimen Error Report and Waiver*

7.2 F10-50-03B, *Pathology Specimen Error Report and Waiver*

7.3 F10-50-03C, *Specimen Error Tracking Log*

7.4 Show Your ID Card poster

7.5 Inter-Provincial Health Card Poster

8.0 Process Flowchart