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Document History:

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

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Approved by: *(approval on file)*	Dr. A. Kabani	**Date:**	02-AUG-2023
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Details of Recent Revision

Added hyperlinked Table of Contents
Added "Rejection" to document title for clarity
Corrected reference in 2.1.2
Updated Exception in 6.4.6 to state "**Exception:** MRN may be used as an alternate patient identifier for cytology samples. When accepted as an alternate unique identifier for gyne specimens a PHIN formula must be entered in CoPath."
Added to 6.1.2 "Refer to F100-10-20A for details on proper labelling of tubes."
Removed strike-through on 2.1.5
Added a Note under 6.4 "**Note:** a photo (ie on a phone) of a client's MHSC will be acceptable (so long as all information is clearly visible from the front and back of the card), if a physical copy is not available"
Added bullet 5.9 - Add a REQC to the registered lab number. Answer &LABUA Specimen Received Unlabeled. Authorization to release results without confirmation of patient identification given by ordering profession: "enter doctor name"
Added bullets 7.6 JA40-10-0315 REJS Help and 7.7 JA100-10-79D REQC comments
Changed 2.0 from "Policy" to "General Requirements"
Added link to LIM on bullet after 2.1.15
Added Note 1, Note 2 and Note 3 to section 2.1
Added to 4.6.6 and 4.7Pathology/cytology sections revised throughout
Added Cytogenetics to Section 4; Updated reference documents to include Cytogenetics acceptance document

Table of Contents

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 medio-legal purposes such as employment, immigration or child custody is not performed by Shared Health laboratories

2.0 General Requirements (for all specimen types):

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
2.1.3 Date of birth
2.1.4 Gender (sex)
2.1.5 Patient phone number
2.1.6 Physician 24/7 critical results contact number
2.1.7 Location of patient (ie. Nursing unit, collection site)
2.1.8 Phlebotomist / collector identifier (initials)
2.1.9 Name of authorized ordering professional (see 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

NOTE 1: *for test(s) requiring additional information refer to the relevant Laboratory Requisition or Laboratory Information Manual (LIM) https://apps.sbgh.mb.ca/labmanual/test/findTestPrepare

NOTE 2: if a rare, unusual or newly emerging infectious disease is suspected, this should be indicated on the requisition (ie prion diseases [Jakob-Creutzfeldt or other], Ebola, etc)

NOTE 3: Specimen container(s) and requisition must be submitted together

2.2 Specimen Labeling

2.2.1 The specimen container must be clearly and legibly labeled with the first and last name of the patient and the patient's PHIN or equivalent identifier; the information on the specimen container must exactly match the information on the requisition

3.0 Rejection Criteria

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

3.1 Specimen Labeling Errors

3.1.1 Unique patient identifier(s) on the specimen label and test requisition do not match
3.1.2 Patient first and last name and/or PHIN (or other unique identifier) are not on both the test requisition and the specimen label
3.1.3 For Surgical Pathology and Cytology cases – specimen type on container does not match exactly with specimen type on requisition

3.2 Requisition Errors

3.2.1 For out of hospital/outpatient clinics the name of the ordering professional is not on the test requisition and cannot be confirmed
3.2.2 The location of the patient is not on the test requisition and cannot be confirmed
3.2.3 Phlebotomist identification is missing and cannot be confirmed
3.2.4 Date and time of collection is not identified and cannot be confirmed
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 # field is listed as required information with an "*"
3.2.5.1 This requirement is for outpatient requisitions only as there is no 24/7 service available
3.2.5.2 For inpatients the ward is available 24/7 for critical results

3.2.6 "Physician Signature" field is blank when it is listed as required information with an "*"
3.2.7 Clinician ordering the test is not authorized to order a specialty test, as indicated on the requested or requested on the wrong requisition by an unauthorized clinician
3.2.7.1 **Note 1:** Missing patient phone number *does not* necessitate rejection of the sample
3.2.7.2 **Note 2**: missing signatures on Non-Gynecological Cytology requisitions *does not* necessitate rejection for urine specimens

3.3 **Unacceptable Specimen Quality** – if specimens do not meet analytical requirements, results may be inaccurate, therefore these specimens cannot be processed. This includes but is not limited to:
3.3.1 Inappropriate transport
3.3.2 Inappropriate storage
3.3.3 Inappropriate container or specimen tube(s)
3.3.4 Inappropriate preservative and/or volume of preservative
3.3.5 Hemolysis
3.3.6 Lipemia
3.3.7 Insufficient quantity of sample for analysis (NSQ)
3.3.8 Age of specimen
3.3.9 Specimen(s) listed on the LIM that are not accepted for routine testing

4.0 Discipline Specific Requirements

4.1 Transfusion Medicine
2.2.2 Refer to 160-MP-02*, Specimen Acceptance, Rejection and Suitability*, for all requirements for transfusion medicine

4.2 Transplant Immunology
4.2.1 All general requirements must be met
4.2.2 Date of collection is required on specimen
4.2.3 Time of collection is not required on the requisition

4.3 Clinical Biochemistry
4.3.1 All general requirements must be met
4.3.2 For tests with multiple time points (ie. Fasting, 2hr, etc) all time points must be labeled on the specimen
4.3.3 Clinical indicator must be provided if required to order a test

4.4 Rural – Clinical Biochemistry / Hematology
4.4.1 All general requirements must be met
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
4.4.3 Clinical indicator must be provided if required to order a test

4.5 Clinical Microbiology
4.5.1 All general requirements must be met
4.5.2 Specimen source must be identified on the requisition and container
4.5.3 Time of collection is not required on the requisition; date of collection is required

4.6 Pathology
4.6.1 All general requirements must be met
4.6.2 **Specimen Containers**
4.6.2.1 Must be labeled with specific anatomical site/source of specimen, including right/left if applicable
4.6.2.2 Specimen anatomic site/source must exactly match that stated on the requisition
4.6.2.3 Multiple specimen containers must be sequentially lettered (A, B, C etc)
4.6.3 **Requisitions**
4.6.3.1 Must be labeled with specific anatomical site/source of specimen, including right/left if applicable
4.6.3.2 Multiple specimens must be sequentially lettered (A, B, C etc)
4.6.3.3 Specimen anatomic site/source must exactly match that stated on the specimen container
4.6.3.4 Time the specimen removed from the patient, and collection date and time placed into formalin must be stated for all surgical specimens

4.6.3.5 Time specimen removed from patient must be stated for specimens submitted fresh (without formalin)

4.6.4 **Breast specimens**

4.6.4.1 Both the time removed from the patient and the time it is placed into formalin must be stated on the requisition for all breast excision specimens (does not apply to core biopsies). This allows determination of the specimen ischemic time.

4.6.5 **Clinical Information** – must be provided, and is the responsibility of the submitting physician

4.6.6 **Physician Signature** –is required; this confirms for the laboratory that the physician has taken responsibility that all information provided with the specimen submission is correct. Electronic signature is acceptable.

4.6.7 **IMPORTANT NOTE**: pathology specimens are considered irreplaceable; correction protocols must be followed for any deficiency.

4.7 Cytology

4.7.1 All general requirements must be met

4.7.2 Cytology does NOT process stool, blood or semen; these specimen types will be rejected

4.7.3 **Specimen Containers**

4.7.3.1 Must be labeled with specific anatomical site/source of specimen, including right/left if applicable. NOTE: A LIS label alone is not acceptable.

4.7.3.2 Specimen anatomic site/source must exactly match that stated on the requisition

4.7.3.3 Each separate cytology specimen must be accompanied by a separate requisition

4.7.3.4 For Cytology urine specimens must be labeled “urine” on the specimen container

4.7.4 **Slides**

4.7.4.1 If slides are submitted (smears) the slide must be labeled with the patient’s first and last name and PHIN or equivalent identifier

4.7.5 **Requisition**

4.7.5.1 Must be labeled with specific anatomical site/source of specimen, including right/left if applicable

4.7.5.2 Specimen source must be indicated on specimen container and must match the requisition. This applies to ALL specimens being submitted i.e. “Urine” stated on requisition AND on specimen container.

4.7.5.3 Procurement method (ie FNA, brushing, etc) must be stated

4.7.5.4 Collection time is required for all specimens except gyne cytology (pap test) and urines

4.7.6 **Clinical Information** – must be provided, and is the responsibility of the submitting physician

4.7.7 **Physician Signature** – is required for all specimens EXCEPT gyne cytology (pap test) and urine. Electronic signature is acceptable.

4.7.8 **IMPORTANT NOTE**: With the exception of urine, cervical cytology, and sputum specimens (which can relatively easily be recollected), cytology specimens are considered irreplaceable; correction protocols must be followed for any deficiency.

4.8 Semen Analysis

4.8.1 All general requirements must be met

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

4.9 Molecular Diagnostics

4.9.1 All general requirements must be met

4.9.2 Time of collection is NOT required on the requisition

4.9.3 For molecular hematopathology test requests, refer to 140-130-85 *Test Cancellation and Sample Rejection*.

4.10 Hematology

4.10.1 All general requirements must be met

4.11 Cytogenetics

4.11.1 Refer to 200-10-04 *Cytogenetic Sample Retrieving and Acceptance*

5.0 Correction protocols for submission deficiencies (requirements not met – specimen not rejected)

5.1 When required information is missing or incorrect on the requisition and/or specimen label that is not subject to rejection as noted in Rejection Criteria (above), the lab will contact the collection site to obtain the necessary information

5.1.1 Appropriate steps should be taken to ensure stability of the specimen (ie specimen is centrifuged and serum/plasma removed from cells); specimen will be processed and results released once all applicable requirements have been met

5.1.2 For labile samples, testing will be performed but no results will be released until all applicable requirements have been met. Examples:

5.1.2.1 Incorrect sample type/location

5.1.2.2 Difficult to obtain sample

5.1.2.3 Test request does not make sense

5.1.3 F10-50-03A (Specimen Error Report and Waiver) will be completed and LIS updated (where applicable) or other type of error tracking will be completed or updated to document all errors, rejections and subsequent dispositions; completed forms will be retained by the site as per retention policy requirements

5.1.4 For Pathology/Cytology specimens

The F10-50-03B will be used to track and document the correction of submission deficiencies. The sending site will be called to request the ordering provider (or designate authorized by the ordering provider) to come to the laboratory to document correction of the specimen deficiency. This means they must complete and sign the F10-50-03B form documenting that the specimen identity (correct patient, correct body site) is confirmed. If specimen identity cannot be confirmed, a pathologist will contact the submitting physician.

5.1.5 A non-conformance report may be created and submitted

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

5.2.1 The sending site is to be notified as soon as possible. Appropriate steps should be taken to ensure stability of specimens (ie specimen is centrifuged and serum/plasma removed from cells); specimen will be processed and results released once all applicable requirements have been met

5.2.2 For labile samples, testing will be performed but no results will be released until all applicable requirements have been met

5.2.3 A non-conformance report may be created and submitted

6.0 Rejected Specimens

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

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

6.2.1 All other rejections will have a comment code entered into LIS (where applicable) or the requisition will be updated with the rationale for rejection

6.2.2 The information will be sent to the collection site informing that the sample has been rejected

6.3 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 the procedure outlined for Irreplaceable or Time Sensitive Specimens

7.0 Irreplaceable or Time Sensitive Specimens

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

7.1.1 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

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

7.2.1 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

7.3 Lab staff will use the following list as an aid to determine which specimens are *potentially* irreplaceable or time sensitive (NOTE: this list may not be all inclusive):
- 7.3.1 STAT or EMERGENT requests from Emergency or ICU
- 7.3.2 Sterile body site fluids (ie. CSF, blood cultures)
- 7.3.3 Bone marrow aspirates
- 7.3.4 Bronchial alveolar lavage
- 7.3.5 Neonatal blood
- 7.3.6 Selected sites/specimens that require special attention as determined by site specific patient population/needs
- 7.3.7 Timed specimens (ie drug levels)
- 7.3.8 All fluids for chemistry
- 7.3.9 Cultured cells
- 7.3.10 Specimens submitted to Microbiology requiring culture where requisition indicates that it was taken prior to starting antibiotics
- 7.3.11 Cytology non-Gyne specimens, including fine needle aspirates (FNAs), surgical specimens (tissues)
- 7.3.12 Autopsy cases
- 7.3.13 Pathology specimens
- 7.3.14 – considered irreplaceable or critical (although in some cases re-biopsy may be possible, it requires discussion between site medical manager or designated pathologist and submitting physician) Note: Surgical specimens with errors will be held in formalin until the issue is properly addressed. Cytology specimens procured by an invasive procedure – considered critical; includes (although some could be re-collected):
  - 7.3.14.1 FNA
  - 7.3.14.2 CSF
  - 7.3.14.3 Bronchoscopic
  - 7.3.14.4 Endoscopic
  - 7.3.14.5 Cystoscopic
  - 7.3.14.6 Body fluids by aspiration
- 7.3.15 Cytology specimens not collected by an invasive procedure that can be recollected are NOT considered critical and should be recollected whenever patient identity is in question (major submission discrepancy):
  - 7.3.15.1 Voided urine
  - 7.3.15.2 Sputum
  - 7.3.15.3 Cervical cytology

7.4 f 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

7.5 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 F10-50-03A
- 7.5.1 If signed by a designate, 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

7.6 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

7.7 Testing will not proceed until written authorization on either F10-50-03A or F10-50-03B (as appropriate) is received by the lab
- 7.7.1 The only exception is when the sample is precious and not stable, in which case testing will proceed but not results will be release until written authorization is received

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

7.9 Add a REQC to the registered lab number. Answer &LABUA Specimen Received Unlabeled. Authorization to release results without confirmation of patient identification give by ordering profession: “enter doctor name”

8.0 Miscellaneous Issues

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

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

8.1.2 Attach the label directly to the tube; refer to F100-10-20A for details on proper labeling of tubes

8.1.3 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

8.2 Multiple Tubes from One Collection/One Requisition

8.2.1 Lab will process all specimens that meet acceptance criteria

8.2.2 Remaining specimens will be rejected

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

8.3 ID of Phlebotomist/Collector

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

8.3.2 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

8.4 PHIN or Other Unique Patient Identifier

NOTE: a photo (ie on a cell phone) of a client's MHSC will be acceptable so long as all information is clearly visible from the front and back of the card, if a physical copy is not available

8.4.1 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

8.4.2 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

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

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

8.4.4.1 RCMP
8.4.4.2 Military
8.4.4.3 First Nations and Inuit Health Card
8.4.4.4 Passport
8.4.4.5 Health Card from another province
8.4.4.6 Health number (10-digit number)

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

8.4.6 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 may be used as an alternate patient identifier for cytology samples. When accepted as an alternate unique identifier for gyne specimens a PHIN formula must be entered in CoPath

8.4.7 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.

8.4.8 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

8.5 Long Names

8.5.1 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

8.5.2 Pap Test – a minimum of 8 letters (first name and last name) can be used for significantly long names

8.6 PHIN Discrepancies Between MB Health Database and LIS

8.6.1 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 the patient identify. Enter a 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

8.6.2 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

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

9.0 Associated Documents

9.1 F10-50-03A, Specimen Error Report and Waiver
9.2 F10-50-03B, Pathology Specimen Error Report and Waiver
9.3 F10-50-03C, Specimen Error Tracking Log
9.4 Show Your ID Card Poster
9.5 Inter-Provincial Health Card Poster
9.6 JA40-10-0315, REJS Help
9.7 JA100-10-79D, REQC Comments
9.8 200-10-04, Cytogenetic Sample Retrieving and Acceptance

10.0 Process Flowchart