



<div><div>University Health Network Toronto General Toronto Western Princess Margaret St. Michael's Toronto St. Paul's</div><div>Mount Sinai Hospital Sinai Health System Hospital of St. Michael's Hospital of St. Paul's Hospital of St. George's</div></div> <div>Department of Microbiology</div>	Policy # MI_SM_RJCT	Page 1 of 15
	Quality Manual	
Section: Specimen Processing Procedures	Subject Title: Specimen Rejection Criteria	
Prepared by QA Committee		
Issued by: Laboratory Manager	Revision Date:6/30/2025	
Approved by Laboratory Director: Microbiologist-in-Chief	Next Review Date: 4/30/2027	

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Purpose:

To provide Microbiology specimen rejection criteria and the procedure to follow when rejecting specimens for process.

Procedure:

When it is determined that a specimen is not suitable for processing, following the specimen rejection criteria listed below,

1. Document the receipt of the specimen in LIS (as specimen "received")
2. Enter the appropriate LIS QA code (listed below) into the QA field in LIS order/entry screen result the report in LIS with the appropriate resulting message (listed below)

For irretrievable or sterile samples or any STAT sample requests rejected:

- Tissues
- Sterile fluids (CSF, Blood culture, body fluids)
- STAT requests
- Donor samples

Note: If you are unsure about a sample, please contact the charge or microbiologist for advice.



3. Notify the ward/sender by telephone immediately
4. Document the telephone message in the LIS with the name of the person accepting the call
After 3 attempts, forward the problem to the senior or charge technologist. Save the specimen in the problem basket or senior basket until the sender can be reached.

Specimen Rejection Criteria

Leaking Specimens

Leaking specimens pose a problem in microbiological specimens:

- 1) they may be an infectious hazard to those handling the specimen
- 2) they may provide misleading result if they are contaminated and the contaminants are interpreted as pathogens

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- Leaking specimens are not routinely processed in Microbiology
- The ward is notified immediately by telephone; reason for rejection and the name of the person accepting the telephone notification is documented in the computer.
- LIS QA Code: LEAK
- LIS Report Comment: Specimen leaked in transit. Informed on ... floor. Culture not done.
DO NOT remove the specimen from the biohazard bag when accessioning.
- Irreplaceable specimen may be processed but a comment is added to the report indicating possible contamination.
In a biological safety cabinet, open the biohazard bag and place the specimen onto paper towels and spray the specimen with VIRALEX. Leave for 5 minutes. Plant the specimen and then place the specimen into a new clean biohazard bag. Change gloves.

Unlabeled / Mislabeled Specimens

Unlabeled and mislabeled specimens are not routinely processed in the Microbiology Laboratory.

- 1) The ward is notified immediately by telephone; reason for rejection and the name of person accepting the telephone notification is documented electronically.
- 2) send a final report the reason for rejection and attempts made to notify the ward and file an incident report internally. See tables below for details regarding comments to append.
- 3) keep the specimen in the problem basket for a week,



If the specimen is deemed “irretrievable” and physician and/or nurse requests lab to proceed with testing:

- 1) **Microbiologist-on-Call Review and Verification:**
 - The microbiologist-on-call must speak directly with the physician and/or nurse who collected the specimen or was present during the collection.
 - It is essential to obtain an accurate matching description of the specimen and container, along with an explanation of how the physician and/or nurse is able to verify the specimen’s identity
- 2) **Physician/Nurse Responsibility**
 - The physician/nurse must accept full responsibility for the specimen’s identity and request to proceed with testing.
- 3) **Documentation and Labeling**
 - the individual performing the relabeling must complete the [Unlabeled/Mislabeled Form for Irretrievable Samples Only](#)
 - A large LIS Order label must be affixed to the upper corner of the completed form
 - The completed form must be scanned into SOFTMEDIA

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4) Incident Reporting:

- A SAFER report must be completed online.
- Upload the completed Unlabeled/Mislabeled Form for Irretrievable Samples Only as supporting document with the report
 - o If testing is approved by microbiologist, see [Appendix A](#)

Labelled specimens without requisition

Labelled specimens received without a requisition will be accepted provided the health care provider can be identified and the laboratory, in consultation with a member of the health care team, can develop a requisition. If the provider cannot be identified, the specimen shall be rejected.

Wrong Transport Media

Specimens collected in the wrong transport media will be rejected. Bacteria, viruses and other microorganisms require specific transport media to be viable for certain tests. If an incorrect media is used, the test will be cancelled, specifying which transport media is to be used.



CRITERIA	REPORT COMMENT	LIS QA Code
Unlabelled specimen with requisition or HIS order (for specimen that can be replaced)	"No specimen with this patient's name was received. Please repeat if necessary. Informed..... onward."	UNLB
Unlabelled specimen with requisition or HIS order (for specimen that cannot be replaced)	"No specimen with this patient's name was received. Test was performed on the unlabelled specimen. Informed..... onward. Results should be interpreted accordingly."	UNLB
Unlabelled specimen without requisition or HIS order	If there is an incomplete name or initial on the specimen, enter into the LIS and result as "Specimen not labeled" and keep the specimen in the problem for 48hrs.	UNLB
Mislabeled specimen (for specimen that can be replaced)	"The specimen received with this order/requisition is labeled with another patient's name and has therefore not been processed. Informed onward."	MSLB
Mislabeled specimen (for specimen that cannot be replaced)	"The specimen received with this order/requisition is labeled with another patient's name. Test was performed on the mislabeled specimen. Informed onward, results should be interpreted accordingly."	MSLB

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Other Specimen Rejection Criteria by Tests


SPECIMEN TYPE	TEST	REJECTION CRITERIA	REPORT COMMENT (LIS Result Code)	LIS QA Code
STOOL	C&S	<ul style="list-style-type: none"> Not submitted in enteric pathogen transport media. 	<ul style="list-style-type: none"> Specimen not received in enteric transport medium. 	WTPM
		<ul style="list-style-type: none"> Patient admitted for 72 hours or more. 	<ul style="list-style-type: none"> "This specimen was not cultured for community acquired enteric pathogens because the patient has been hospitalized for 3 or more days. Discuss with the Medical Microbiologist if necessary." 	>72H
		<ul style="list-style-type: none"> Multiple specimens collected from the same in-patient the same day (only one specimen per patient per test per day is to be processed). 	<ul style="list-style-type: none"> "This specimen has not been processed as a specimen submitted from the same day has already been processed." 	RPTS
		<ul style="list-style-type: none"> Stools from outpatients often arrive in batches and are usually a series taken from separate days. Process the most recent sample and reject the others. 	<ul style="list-style-type: none"> "Multiple specimens received. Only the most recently collected specimen has been processed." 	RPTS
		<ul style="list-style-type: none"> All formed stools except when <i>S. typhi</i> requested. 	<ul style="list-style-type: none"> "Formed stool received. Test cancelled." 	UNST
		<ul style="list-style-type: none"> Stool sample in Cary-Blair transport medium with yellow indicator indicating failure of the buffering system to maintain a neutral pH. 	<ul style="list-style-type: none"> "This specimen was not processed as the transport medium failed to stabilize the specimen and maintain a neutral pH." 	UNST
STOOL	O&P	<ul style="list-style-type: none"> Not submitted in SAF container 	<ul style="list-style-type: none"> "Specimen not received in SAF (fixative for 	WTPM

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SPECIMEN TYPE	TEST	REJECTION CRITERIA	REPORT COMMENT (LIS Result Code)	LIS QA Code
		<ul style="list-style-type: none"> Patients who have been admitted more than 72 hours 	<ul style="list-style-type: none"> parasite)." "This specimen was not processed for community acquired enteric pathogens because the patient has been hospitalized for 3 or more days. Discuss with the Medical Microbiologist if necessary." 	>72H

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SPECIMEN TYPE	TEST	REJECTION CRITERIA	REPORT COMMENT (LIS Result Code)	LIS QA Code
STOOL	<i>C. difficile</i> toxin	Submitted in enteric pathogen transport medium or SAF container.	Not processed. Specimen received in enteric pathogen transport medium. Unsuitable for <i>C. difficile</i> testing. If testing is still required, please submit a stool specimen in a sterile container	WTPM
	<i>C. difficile</i> toxin (cont'd)		<p style="text-align: center;">OR</p> Not processed. Specimen received in SAF (fixative for parasite). Unsuitable for <i>C. difficile</i> toxin testing. If testing is still required, please submit a stool specimen in a sterile container	WTPM
		Formed Stool	Not processed. Formed stool received. Test cancelled.	
		Rectal Swab	Not processed. Rectal swab received; unsuitable for testing. If testing is still required, please submit a stool specimen in a sterile container	
		Negative within 7 days	“This patient has tested negative for C.difficile toxin B gene within the past week. A single negative test is sufficient to rule out C.difficile. If you believe your patient has developed diarrhea	

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SPECIMEN TYPE	TEST	REJECTION CRITERIA	REPORT COMMENT (LIS Result Code)	LIS QA Code
	<i>C. difficile</i> toxin (cont'd)	Positive within 15 days	<p>due to <i>C.difficile</i> since the previous negative result and would like repeat testing, please contact the Microbiologist-on-call.”</p> <p>“This patient has tested positive for <i>C.difficile</i> toxin B gene within the past 15 days. Do not repeat <i>C.difficile</i> toxin testing unless the patient has received a full course treatment (14 days) and has developed recurrent symptoms of <i>C.difficile</i>. Repeat <i>C.difficile</i> toxin testing is not indicated in patients who have clinically responded to treatment.”</p>	
		Indeterminate within 7 days	<p>This patient has tested indeterminate for <i>C.difficile</i> toxin B gene within the past week. Indeterminate results indicate either detection of low levels of <i>C.difficile</i> toxin B gene or a false positive result. If your patient has signs/symptoms consistent with <i>C.difficile</i> infection, an indeterminate result most likely reflects a low level positive result and</p>	

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		Interfering substance	the test does not need to be repeated. If you would like repeat testing for another reason, please contact the Microbiologist-on-call. Not Processed. Due to the presence of interfering substance(s) in the specimen, the presence or absence of C. difficile target DNA could not be determined. If testing is still required, please submit a new stool specimen in a sterile container	
		Children<12 months of age	Sample not processed. C.difficile testing is not routinely recommended for children under 12 months of age.	
Foley catheter tips and ETT tips (adult)	C&S	Unsuitable specimen	"Specimen unsuitable for culture.... because of....add qualifier."	UNST
SPUTUM	C&S	> 25 squamous epithelial cells/lower power field except from PMH patients.	"Greater than 25 squamous epithelial cells per low power field."	

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SPECIMEN TYPE	TEST	REJECTION CRITERIA	REPORT COMMENT (LIS Result Code)	LIS QA Code
Urine	C&S	<ul style="list-style-type: none"> • Condom catheter • Foley catheter tips and bags • Leaking specimens • Inappropriate/swab/non-sterile container • >24 hr delay before specimen received (in Sterile Specimen Container) • >48 hr delay before specimen received (in Urine C&S Preservative tube. • Duplicate specimens (more than one processed urine within 24 hrs) • Insufficient quantity received in the Urine C&S Preservative tube. • Specimen received in the 	<ul style="list-style-type: none"> • "Specimen unsuitable for culture because the specimen appears to be a condom catheter urine. }COND • "Specimen unsuitable for culture because the specimen appears to be a Foley catheter tip or bag." }CATH • "Specimen unsuitable for culture because the specimen is leaking." }LEAK • "Specimen unsuitable for culture because the specimen was received in a non sterile container. }NOST • "Specimen was received in the lab >24 hours after it has been collected; unsuitable for culture." }>24H • "Specimen was received in the lab >48 hours after it has been collected; unsuitable for culture." }>48hr • "This is a duplicate order. This test has been cancelled. Please refer to test results on identical sample type collected on same date." }DUPL • "Insufficient quantity of 	<ul style="list-style-type: none"> • UNST • UNST • LEAK • UNST • DLAY • DLAY • RPTS • UNST • UNST

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SPECIMEN TYPE	TEST	REJECTION CRITERIA	REPORT COMMENT (LIS Result Code)	LIS QA Code
		wrong tube.	urine received. Please fill grey top tube with urine to the indicated line. Suggest repeat specimen if clinically indicated.” }INSG • “Specimen received in wrong tube for C&S testing. Please submit urine in grey top tube that specifies "Urine C&S Preservative" and fill to the indicated line.” }WRNG	
Dry Swabs	C&S	If received in the lab >1 hour after collection.	"Specimen not received in transport medium and was in transit for > 1 hour.” Spec}DRY	WTPM
Blood cultures, tissues, sterile body fluids	C&S	If received in the lab >48 hours after collection. If received in expired blood culture bottle	Process specimen. Enter Report Comment: “Specimen was received in the lab >48 hours after it has been collected; results should be interpreted accordingly.” }>48H Process specimen. Enter comment: Specimen received in expired container; results should be interpreted accordingly.	DLAY
All specimens other than urine, blood cultures, tissues	C&S	If received in the lab >48 hours after collection.	"Specimen was received in the lab >48 hours after it has been collected; unsuitable for	DLAY

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SPECIMEN TYPE	TEST	REJECTION CRITERIA	REPORT COMMENT (LIS Result Code)	LIS QA Code
sterile body fluids			culture." }>48hr	
All specimen types except : <ul style="list-style-type: none"> • Tissue • Sterile body fluid • Brain and liver abscess • Aspirated pus • Bone and soft tissue biopsies with diagnosis of gas gangrene, narcotizing fasciitis or narcotizing cellulitis 	Anaerobic culture	Not submitted in special anaerobic transport media.	"No anaerobic swab received; anaerobic culture not done."	WTPM
BLOOD	CMV antigenemia Assay	<ul style="list-style-type: none"> -Not submitted in EDTA (purple top) -Clotted blood (inadequate mixing of anticoagulant after collection or red top tube) - Extremely low leukocyte counts or insufficient volume (generally <2 mL) - More than 3 samples from the same person in the same week, unless authorized 	"CMV Antigenemia cannot be processed on red top tubes. Please collect blood in an EDTA (lavender top) tube." "Insufficient white blood cells to perform test." "This specimen was taken too soon after the previous one, therefore not processed for virology. Please refer to previous specimens."	WTBE WNST RPTS

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All specimen types (unless otherwise authorized)	Virology: PCR assay	-Specimens collected in SAF, Enteric, charcoal, Amies/eswab or other non-viral transport media.	“Specimen received in unsuitable transport media therefore not processed for Virology.”	WTPM
Serum/Plasma	Architect Serology	-Grossly hemolyzed samples	@8GRH “Specimen was grossly hemolysed, unsuitable for testing”	8QCOM

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Appendix A – Processing irreplaceable specimens that have been unlabeled/mislabeled.

Ensure request to reassign has been approved by medical microbiologist.

- 1) Document name of physician/delegate requesting
- 2) Document name of approving medical microbiologist
- 3) Create correct accession number
- 4) Relabel aliquots including freezer vials
- 5) If no results have been released yet, proceed with testing and reporting
 - a. Cancel the error accession number
 - b. Proceed with testing and reporting on correct accession number
- 6) If result has been released and the lab receives a request to reassign the result to correct patient,
 - a. Correct the report on the error accession number with comment
Please disregard the previous result of “ _____ ” as this result does not belong to this patient.
 - b. Move result to the correct accession number
 - c. Document on the back of workcard with comment
The specimen received was labeled with another patient’s identifiers, but was collected from [correct patient name and MRN] by [healthcare worker name] as verified by [healthcare worker name]. Results initially reported under accession ____ have been transferred to accession _____. Approved by medical microbiologist
 - d. Inform wards/MOH/IPAC as appropriate and document
 - e. Inform LIS team to ensure all results transferred to OLIS
- 7) File incident report

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Record of Edited Revisions

Manual Section Name: Specimen Rejection Criteria

Page Number / Item	Date of Revision	Signature of Approval
Page 1 procedure added	November 19, 2004	Dr. T. Mazzulli
Page 3 Unlabelled/mislabeled specimen categories added	November 19, 2004	Dr. T. Mazzulli
Page 4 Blood and sterile sites new	November 19, 2004	Dr. T. Mazzulli
Stool C&S modified (transfer from Enterics Manual)	March 27, 2004	Dr. T. Mazzulli
Virology acceptable times changed	January 27, 2005	Dr. T. Mazzulli
Annual Review	July 23, 2006	Dr. T. Mazzulli
Expand C. difficile toxin criteria	May 15, 2007	Dr. T. Mazzulli
Annual Review	August 13, 2007	Dr. T. Mazzulli
Annual Review	May 31, 2008	Dr. T. Mazzulli
Annual Review	May 31, 2009	Dr. T. Mazzulli
Annual Review	May 31, 2010	Dr. T. Mazzulli
Annual Review	May 31, 2011	Dr. T. Mazzulli
Annual Review	May 31, 2012	Dr. T. Mazzulli
Added insufficient specimen in urine preservative tube	November 9, 2012	Dr. T. Mazzulli
Added Urine tubes other than urine preservative tube	November 9, 2012	Dr. T. Mazzulli
Annual Review	May 31, 2013	Dr. T. Mazzulli
Annual Review	May 09, 2014	Dr. T. Mazzulli
Added: C.diff indeterminate within 7 days & Interfering substance Removed: WNV IgM and IgG serology (no longer done)	March 26, 2015	Dr. T. Mazzulli
Annual Review		
Annual Review	March 26, 2016	Dr. T. Mazzulli
Addition of architect grossly hemolyzed rejection for serum/plasma samples	August 10, 2016	Dr. T. Mazzulli
Added note in procedure for steps if unable to reach ward/sender after 3 attempts. Updated MSH logo in header	December 5, 2016	Dr. T. Mazzulli
Annual Review	March 26, 2017	Dr. T. Mazzulli
Annual Review	March 30, 2018	Dr. T. Mazzulli


Page Number / Item	Date of Revision	Edited by:
Updated Cdiff rejection comments	Nov 25, 2020	Jessica Bourke
Updated BC received in expired culture bottle	Jan 27, 2021	Dorna Zareianjahromi
Added note regarding labeled specimens without requisition	Feb 12, 2021	Dorna Zareianjahromi
Added note for irreplaceable specimens "results should be interpreted accordingly."	Mar 30, 2021	Wayne Chiu
Minor formatting changes made	April 11, 2021	Jessica Bourke
Added appendix A – reassigning results from mislabeled specimen	May 19, 2021	Wayne Chiu

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Added note regarding relabeling aliquots and notifying LIS when processing mislabeled irretrievable samples	May 20, 2022	Wayne Chiu
Update condom catheter urine unsuitable specimen LIS code from UNST to COND correct code. Updated DUPL comment code.	August 19, 2022	Jessica Bourke
Added age based rejection criteria for C difficile (<12 months)	July 07, 2024	Qin Liu
Updated handling procedures for Unlabeled/Mislabeled Form for Irretrievable Samples only- pg2	June 20,2025	Qin Liu

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