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Irreplaceable Specimens

Purpose

This document defines the policy for the management of irreplaceable specimens in the SCPMG Medical Center (MC) clinical laboratory or other collection sites (Medical Office Buildings (MOB) /Urgent Care)

Scope

This policy is intended for all staff in the clinical laboratory who evaluate specimens submitted for acceptability, including managers/directors, and CLIA Directors in the SCPMG Laboratory Care Delivery System.

Definitions

Irreplaceable Specimen/ Un-recollectable Specimen	A specimen obtained by an invasive procedure, such as but not limited to spinal fluid, body fluids, crystals, biopsies, or other pathology specimens. **OR** Specimens submitted where a medication has been administered or a medical treatment has been performed which may affect the laboratory result • Culture (including blood culture) when an antibiotic has subsequently been administered after specimen collection • Drug level when the drug has subsequently been administered after specimen collection Ultimately the CLIA Director or designee at the Medical Center will determine if the specimen is Irreplaceable/Un-recollectable.
Unlabeled specimen	No label or patient identification on primary container
Mismatched specimen	Specimen identification information does not exactly match the information of the transmittal form/order submitted
Mislabeled specimen	Specimen and requisition form identification information match, but the specimen belongs to another patient.

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Irreplaceable Specimens , Continued

Policy

- Each site may choose the use either the *Specimen Labeling/Re-Labeling Waiver* form or the *Specimen Label Correction Log* depending on local protocol. Use of both forms is not recommended.
    - All waivers completed or specimens logged will have an Unusual Occurrence Report (UOR) submitted to assist with investigation and development of corrective action as appropriate.
- In cases where the irreplaceability is in question the CLIA Director or designee will make the final determination.
- The test result (report) must indicate information regarding the mis-labeled specimen and the ordering provider or designee who completed the waiver/log.

Process

When an irreplaceable and unacceptable specimen is identified	
Step	**Action**
1	

If sample accessioning and testing occurs	**Then**
Only in Clinical Laboratory (includes testing performed at RRL or outside laboratories)	Notify appropriate Manager or designee (Go to step 2)
Only Cytology	Notify appropriate Manager or designee (Go to step 2)
Only Anatomical Pathology (AP)	Follow normal process to forward sample to AP laboratory for accessioning/testing
Shared across clinical laboratory, anatomical pathology, and/or cytology laboratories	Notify managers/designees for respective areas

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Irreplaceable Specimens , Continued

Process con't

When an irreplaceable and unacceptable specimen is identified

Step	Action
2	For specimens received in the clinical laboratory the manager or designee will confirm specimen is **irreplaceable:** • If specimen is determined NOT to be irreplaceable, or the provider/designee declines to complete the waiver or complete the log, then the manager/designee will direct laboratory staff to follow current process for cancellation and notification. • Refer to step 12 for details. • The manager or designee may consult with the CLIA Director or designee to determine if the specimen submitted qualifies as an Irreplaceable Specimen

If medical center uses…	Then
Specimen Labeling/Re-Labeling Waiver form	**Go to Steps 3 and 4**
Specimen Label Correction Log (local or regional version)	**Go to Step 5**

3	The laboratory manager or designee will complete the following items on the *Specimen Labeling/Re-Labeling Waiver* form. • Patient identifiers (top of form) • Specimen source, test(s) ordered, accession number, collection date/time and error description (In the "To be completed by Laboratory Staff" section) The form is then submitted/presented to the provider/designee.
4	The provider or designee will complete the following items on the form in the "To be completed by Provider/Designee" section. • The provider/designee name (printed) and signature fields. • Check a reason that specimen cannot be replaced/recollected. o For the reason of "Other" a reason can be completed The form and corrected specimen are then resubmitted to the laboratory. Go to Step 6
5	Alternatively, the use of the *Specimen Label Correction Log* can be used • Ensure the Date, Time, MRN, Patient Name, Reason for Label Correction, and Correction Made by columns are correctly completed prior to proceeding to next step.

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Irreplaceable Specimens , Continued

Process con't

When an irreplaceable and unacceptable specimen is identified

Step	Action
6	The corrected specimen will be electronically documented in the appropriate laboratory information system(s)

If	Then
Cerner: Accessioned by MC/MOB staff	The laboratory manager or designee will add the following **Order Comment** to Cerner: *"Unlabeled/mislabeled specimen submitted, corrected by _____ after submission to laboratory."*
Co-Path: accessioned by MC/MOB staff	The laboratory manager or designee will add a **deficiency entry** to Co-Path. The specimen will be transported to Cytology using current processes.
Co-Path: **NOT** accessioned by MC/MOB staff	The specimen will be transported to Cytology using current processes. with a copy of the completed form/log

7	The laboratory manager or designee will sign, date/time the waiver form or log. This signature signifies that the waiver form/log has been reviewed: • For completeness • That applicable order comment/deficiency has been placed in Cerner/Co-Path o If unable to enter deficiency comment into Co-Path a copy of the completed waiver form/log is forwarded with the specimen.
8	The laboratory manager or designee will release the specimen.
9	The laboratory Quality Manager/Designee will review the waiver form and sign, date/time. • This signature signifies that the waiver form has been reviewed for completeness, the order comment/deficiency entry has been placed in Cerner/CoPath, and an UOR was submitted.
10	The laboratory CLIA Director/Designee will review the waiver form and sign, date/time the waiver form.
11	Completed waivers/logs will be retained per current records retention requirements.

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Irreplaceable Specimens , Continued

Process con't

When an irreplaceable and unacceptable specimen is identified

Step	Action
12	If the specimen is determined **NOT to be irreplaceable** OR If the ordering provider or designee **declines** the option to correct the error and sign the waiver/form, the test will be cancelled in the applicable systems (Cerner or CoPath).

IF	AND	Then
Sample is accessioned in Cerner	Not a GYN sample	Cancel order and Add **Order Comment** to Cerner: "Provider xxx notified @ date/time"
Sample is accessioned in Cerner	Is a GYN sample	Cancel order and Add **Order Comment** to Cerner: "Provider xxx notified @ date/time" AND Forward sample to Cytology to cancel Pap test in CoPath
Sample is accessioned in Co-Path only (GYN Sample for Pap)	Co-Path accessioning is **not** performed by MC/MOB	Forward specimen to Cytology to accession/cancel Pap test in CoPath
Sample is accessioned in Co-Path only	Co-Path accessioning is performed by MC/MOB	Follow current process for order management.

Submit an UOR for mis-labeled specimen.

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Irreplaceable Specimens , Continued

Non-Controlled Documents

The following non-controlled documents support this policy.

- CAP Laboratory General Checklist, All Common current version

Controlled Documents

The following controlled documents support this policy.

Preanalytical Processing
Specimen Labeling/Re-Labeling Waiver form
Specimen Label Correction Log

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Signature Manifest

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New Preanalytic Regional

Initial Approval

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