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Nonrecollectable Specimens

Purpose

This document defines the process to manage nonrecollectable specimens in the SCPMG Laboratory Care Delivery System when specimens are not acceptable at time of receipt.

Scope

This policy is intended for laboratory personnel in the clinical laboratory who evaluate specimens submitted for acceptability.

Definitions

Nonrecollectable Specimen (also known as Irreplaceable)	Specimens that cannot be recollected or when recollecting or reobtaining them would place the patient at significant risk. Examples are: • Anatomic pathology and surgical specimens • Specimens other than blood collected through invasive procedures such as: – Cerebrospinal aspiration – Fine-needle aspiration – Arthrocentesis – Bronchoscopy – Bone marrow aspiration – Biopsy – Specimens collected during autopsy or by medical examiner – Suprapubic urine aspiration • Specimens changed by intercurrent therapy, for which time or treatment affects results – 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 – Drug level where drug has been administered prior to specimen collection for which a timed result is necessary – Specimens to monitor anticoagulant therapy • Tests from newborns with limited blood volumes that preclude recollection

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Nonrecollectable Specimens, Continued

Policy

- The laboratory must ensure specimens submitted are acceptable for testing.
- The laboratory must document when specimens are not acceptable for testing and subsequently accepted for testing.
  - Any exceptions are to be documented on 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.
- The CLIA Director will make the final determination for cases in which nonrecollectability is in question or for exceptions to allow unacceptable recollectable specimens.
- The test result (report) must indicate information regarding the mislabeled specimen and the ordering provider or designee who completed the waiver/log.

Process

The following process is defined for handling unacceptable nonrecollectable specimens.

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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Nonrecollectable Specimens, Continued

Process, Continued

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>2</td><td>For specimens received in the clinical laboratory the manager or designee will confirm specimen is nonrecollectable.
• If specimen is determined NOT to be nonrecollectable, 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 a Non recollectable Specimen
<table>
<tr><th>If medical center uses…</th><th>Then</th></tr>
<tr><td>Specimen Labeling/Re-Labeling Waiver form</td><td>Go to Steps 3 and 4</td></tr>
<tr><td>Specimen Label Correction Log (local or regional version)</td><td>Go to Step 5</td></tr>
</table>
</td></tr>
<tr><td>3</td><td>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.</td></tr>
<tr><td>4</td><td>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.
– 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</td></tr>
<tr><td>5</td><td>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.</td></tr>
</table>

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Nonrecollectable Specimens, Continued

Process, Continued

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>6</td><td>The corrected specimen will be electronically documented in the appropriate laboratory information system(s)
<table>
<tr><th>If</th><th>Then</th></tr>
<tr><td>Cerner:
Accessioned by MC/MOB staff</td><td>The laboratory manager or designee will add the following Order Comment to Cerner:
“Unlabeled/mislabeled specimen submitted, corrected by _____ after submission to laboratory.”</td></tr>
<tr><td>Co-Path:
accessioned by MC/MOB staff</td><td>The laboratory manager or designee will add a deficiency entry to Co-Path.
The specimen will be transported to Cytology using current processes.</td></tr>
<tr><td>Co-Path: NOT accessioned by MC/MOB staff</td><td>The specimen will be transported to Cytology using current processes.
with a copy of the completed form/log</td></tr>
</table></td></tr>
<tr><td>7</td><td>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
– If unable to enter deficiency comment into Co-Path a copy of the completed waiver form/log is forwarded with the specimen.</td></tr>
<tr><td>8</td><td>The laboratory manager or designee will release the specimen.</td></tr>
<tr><td>9</td><td>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.</td></tr>
<tr><td>10</td><td>The laboratory CLIA Director/Designee will review the waiver form and sign, date/time the waiver form.</td></tr>
<tr><td>11</td><td>Completed waivers/logs will be retained per current records retention requirements.</td></tr>
</table>

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Nonrecollectable Specimens, Continued

Process, Continued

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>12</td><td>If the specimen is determined NOT to be nonrecollectable
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).
<table>
<tr><th>IF</th><th>AND</th><th>THEN</th></tr>
<tr><td>Sample is accessioned in Cerner</td><td>Not a GYN sample</td><td>Cancel order and Add Order Comment to Cerner:
“Provider xxx notified @ date/time”</td></tr>
<tr><td>Sample is accessioned in Cerner</td><td>Is a GYN sample</td><td>Cancel order and Add Order Comment to Cerner:
“Provider xxx notified @ date/time”
AND
Forward sample to Cytology to cancel Pap test in CoPath</td></tr>
<tr><td>Sample is accessioned in Co-Path only (GYN Sample for Pap)</td><td>Co-Path accessioning is not performed by MC/MOB</td><td>Forward specimen to Cytology to accession/cancel Pap test in CoPath</td></tr>
<tr><td>Sample is accessioned in Co-Path only</td><td>Co-Path accessioning is performed by MC/MOB</td><td>Follow current process for order management.</td></tr>
</table>
Submit an UOR for mislabeled specimen.</td></tr>
</table>

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Nonrecollectable Specimens, Continued

Non-Controlled Documents	The following non-controlled document supports this policy. • CAP Laboratory General Checklist, All Common
Controlled Documents	The following controlled documents support this policy. • Specimen Acceptance and Rejection • Specimen Labeling/Re-Labeling Waiver form • Specimen Label Correction Log
Authors	PreAnalytic Processing Working Group

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Signature Manifest

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Nonrecollectable Specimens

Operations Director Approval

Name/Signature	Title	Date	Meaning/Reason
Carlo Punu (F316195)	DIR OPER AREA LAB	14 Apr 2025, 01:05:02 PM	Approved

Medical Director Approval

Name/Signature	Title	Date	Meaning/Reason
Christopher Hale (K706810)	CLIA Director	14 Apr 2025, 01:29:05 PM	Approved