HealthPartners®

Subject	Attachments
Management of Mislabeled/Unlabeled Specimen Procedure	☒ Yes ☐ No
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Review Responsibility Laboratory Administration	**Contact** Laboratory Administration

Management of Mislabeled or Unlabeled Specimen Procedure

PURPOSE

This procedure provides direction managing situations where patients have not been properly identified and/or specimens have been mislabeled or is unlabeled.

Improper patient identification and/or specimen mislabeling are a leading causes to pre-analytical errors that may result in inaccurate laboratory results leading to inappropriate delays with patient care, adverse patient outcomes and significant impacts on patient safety, waste of staff time, resources, and erode our patients' trust in us.

POLICY

- All patients will be properly identified at all touch points through the visit. Patient identification will

include, but is not limited to:
- Patient full name and spelling
- Patient Date of Birth

- All specimens will be properly labeled with at least two unique identifiers. Specimen labeling will include:
  - Patient full name with correct spelling
  - Patient DOB or MRN number
  - Date and time of collection

  Note: Blood bank and aliquot specimens require the tech code or initials of the person who collected or who made the aliquot.

- Patient-Collected Specimens – collected at the clinic or taken home for collection:
  - All specimen collection containers or test kit will be labeled with at least two unique identifiers.
  - A patient should never be handed a test kit or container that is not properly labeled.
  - This includes but is not limited to hemoccult cards, FIT kits, sterile cups, O&P containers, or 24-hour collection containers.

- An Accession number is not a unique identifier and is unacceptable for patient identification for primary specimen containers and may be used only as outlined in the Specimen Labeling and Specimen Disposal policy.

- Only a Laboratory Leader can direct laboratory staff to perform testing and report results on a retrievable (replaceable) specimen that is outside of the parameters of this policy.

- Only a Laboratory Leader can determine if a specimen is an irretrievable (irreplaceable) specimen that is outside of the established definition.

- Data from these mislabeled/unlabeled occurrences will be used for monitoring and measuring the number of specimens that do not meet patient identification and labeling requirements and used to develop and implement improvement strategies.

PROCEDURE

A. Retrievable and Irretrievable Specimens

1. Retrievable (Replaceable) Biological Specimen: Specimens that are able to be recollected. See definition for more information.

    - Retrievable (replaceable) specimens will be rejected if they are unlabeled or labeled with the wrong patient name.

2. Irretrievable (Irreplaceable) specimens that are not easily recollected, recollection may negatively impact care, or the recollected specimen is not medically equivalent to the original. See definition for more information.

    - Irretrievable (irreplaceable) specimens that do not have the correct patient identification will be handled on a case by case basis by consulting with the Provider and a Laboratory Leader.

- Partially labeled Capiject specimens – while technically a retrievable specimen, the delay in testing for baby bilirubin, and/or hematology tests warrant handling this type of labeling event as an irretrievable specimen.

B. Retrievable Specimens - Determining and Resolving Incorrect Patient Identification or Specimen Labeling

- **Unlabeled or mislabeled retrievable specimens**, Laboratory staff will do the following:
    1. Send a Telephone encounter to the Care Team using the dotphrase LABNOLABEL (edit as necessary)

    2. **Copy the CDS** of the clinic along with the Care Team for the Telephone encounter. For a list of the CDS by clinic, click here.

    3. Cancel the test in the Laboratory Computer System with the appropriate cancellation code
       Approved cancellation codes are:
       UNLAB: specimen received unlabeled
       MISLA: Specimen Mislabeled
       OIP-MISLA: Ordered on Incorrect patient; Specimen Mislabeled

    4. If the unlabeled or mislabeled specimen is communicated verbally to the Care Team, order and result a Tele8 with the following format:

       Example: Strep Swab received unlabeled. Informed provider on 06.12.2016 at 0914.
       Example: TSH mislabeled. Informed Jane Doe, RN at CO on 06.06.2016 at 1433.

    5. **Do NOT send** a Provider Responsibility form to the provider for retrievable unlabeled or mislabeled specimens.

    6. **Unlabeled/Mislabeled Specimen by Lab**: After the provider has provided the laboratory staff with direction on how soon a patient needs to return and have the test recollected, the laboratory staff will re-order the test in Epic and will contact the patient to return.

    7. **Unlabeled/Mislabeled Specimen by the Care Unit**: The Care team will re-order the test in Epic and contact the patient to return for recollection.

- **Partially Labeled Incomplete Patient Identity**- Specimens Collected in the Care Unit (i.e., wet preps):
    1. Specimens where the outer container is labeled but the specimen is unlabeled is considered unlabeled and will be rejected and testing cancelled.
    2. Specimens that contain only one patient identifier are considered unlabeled and will be rejected and testing will be cancelled.

- **Partially Labeled incomplete Patient Identity**- Specimens collected by the patient (i.e., stool specimens, 24-hr urine):
    1. When a patient delivers a specimen to the lab, ensure the specimen is properly labeled **before the patient leaves**. Label or re-label while in the presence of the patient.

    2. For specimens relabeled in the presence of the patient, a Provider Responsibility Form does not need to be sent to the Provider.

3. For specimens mailed in (hemoccult cards, FIT specimens), do your best to identify the patient if only 1-identifier is present (i.e., first and last name of patient, address return label).

    - This is for the purpose of notifying the Care Team/Provider that the specimen was unlabeled or mislabeled and will need to be recollected.

- **Partially Labeled Specimens – Miscellaneous:** Laboratory staff will initiate the Provider Responsibility Form and send to the Provider for the following so that testing can be performed:

    1. Outer tube labeled but capiject/microtainer is unlabeled

    2. Epic label is correct but Lab Computer label is for wrong patient and not due to a legal name change (Lab relabel error).

    3. Handwritten label has 2 identifiers but name has a minor misspelling (i.e., Peterson vs. Petersen, Cheri vs. Sherry vs. Shari).

- **Managing Legal Name Changes for Patients**
    1. For Care Unit Staff who pre-print Epic visit labels in anticipation of collecting a specimen, these should be reprinted with legal name change.

    2. For patients who come to a Clinic Lab Greet Station and inform the person of a name change, the patient should be directed to the Clinic Assistant and Check-in desk so that these changes can be made. Remind the patient to update their insurance with their name change.

    3. Patient-collected specimens should be reviewed and relabeled with the legal name change.

    4. Clinic Assistants are able to make legal name changes with appropriate ID and documentation.

- **Testing retrievable mislabeled or unlabeled specimens outside the parameters of this procedure**

    1. If the provider insists that a retrievable (replaceable) mislabeled/unlabeled specimen be tested, then:
        4. Only the ordering/treating provider can make this request (not the nurse or designee).
        5. Laboratory staff will consult with a Laboratory Leader regarding the provider's request.
        6. Only a Laboratory Leader can direct laboratory staff to perform testing and report results on a retrievable (replaceable) specimen.

    2. If testing is approved by a Laboratory Leader, then the Provider will be required to sign the Provider Responsibility form indicating they are taking responsibility for the unlabeled/mislabeled specimen and test results. This form **CANNOT** be signed by a nurse or designee.

    3. All required fields of the form will be completed or the form will be rejected and sent back to the Provider.

    4. The form should be returned to the Lab within 24 hours.

    5. Test results will not be released until the completed form is received.

6. All tests that are resulted will contain the ETC code – MSRR on every result field.

7. The copy of the Provider Responsibility form will be sent to the Laboratory Quality Consultant. The completed form will be retained in accordance with the Record Retention policy.

8. For specimens sent to another laboratory for testing, attach documentation to the test that will allow the testing staff to add MSRR to every result field. See section E. Handoff Communication for how to communicate improperly labeled specimens that are tested at a different laboratory.

C. Irretrievable Specimens: Determining and Resolving Incorrect Patient Identification or Specimen Labeling

- Only Irretrievable (irreplaceable) Specimens or the Partially Labeled Specimens Collected by a patient or Partially Labeled Specimens Miscellaneous as listed above will be considered for testing.

1. If specimen stability allows, hold the testing until the completed Mislabeled/Unlabeled Responsibility form is received.

2. If specimen stability does not allow the specimen to wait until the Mislabeled/Unlabeled Responsibility form is received, consult with a Laboratory Leader on whether testing should be performed.

3. All test results will be held and not released until the Mislabeled/Unlabeled Responsibility form is received.

4. All tests that are resulted will contain the ETC code – MSRR on every result field.

5. The copy of the Mislabeled/Unlabeled Responsibility form will be sent to the Laboratory Quality Coordinator. The completed form will be retained in accordance with the Record Retention policy.

6. For specimens sent to another laboratory for testing, attach documentation to the test that will allow the testing staff to add MSRR to every result field. See section in E. Handoff Communication for how to communicate improperly labeled specimens that are tested at a different laboratory.

D. Provider Responsibility Forms:

- Provider will be required to sign the Provider Responsibility form indicating they are taking responsibility for the unlabeled/mislabeled specimen and test results. This form **CANNOT** be signed by a nurse or designee.

1. All required fields of the form will be completed or the form will be rejected and sent back to the Provider.
2. Laboratory staff will document sending the Mislabeled/Unlabeled Responsibility form to the provider as directed by a Laboratory Leader.
3. The form should be returned to the Lab within 24 hours.

E. Procedure for managing test results on specimens not identified as being mislabeled before testing:

- **Patient states they did not have a specimen collected:**
    1. There are times when a mislabeled specimen is not discovered until the patient receives results for testing they did not have performed.

    2. If the specimen is still available, the lab staff will examine the specimen for labeling discrepancies.

    3. The test results will be replaced with **DRWP-MISLA** and the test charges removed. (See the Test Cancellation Procedure and the Detecting Laboratory Errors Procedure)

    4. Do not send a Provider Responsibility Form to the Provider

    5. **Do not transfer** test results to the "correct patient". The test will need to be re-ordered and recollected on the correct patient if clinically indicated.

- **Patient results are inconsistent with patient history or diagnosis:**
    7. There are times when a mislabeled specimen is not discovered until the specimen has been tested and the results do not match previous history or with the diagnosis.

    8. If the specimen is still available, the lab staff will examine the specimen for labeling discrepancies.

    - For tests that outline how to troubleshoot delta failures, staff should follow that process. This will include examining the specimen for possible labeling errors.
    - If the provider questions the results, contact a Lab Leader for direction. Replace with DRWP-MISLA if directed by a Lab Leader and remove the test charges. (See the Test Cancellation Procedure).

    - Do not send a Mislabeled/Unlabeled Responsibility Form to the Provider

    - **Do not transfer** test results to the "correct patient". The test will need to be re-ordered and recollected for the correct patient if clinically indicated.

F. Extra Labeling Requirements for Specific Specimens and Tests

- Blood Bank Specimens or Aliquot Samples:
    - Initials or tech code are required for Blood Bank and aliquot samples or specimens will be rejected

- Cytology or Pathology Specimens:
    - Source(s) is required both in the order and on the specimen label from the Care Unit. Refer to the specific procedure for how to resolve specimen questions for Cytology and Pathology specimens.

    - Source is written on specimen but is a mismatch to test order will have the mismatch clarified through the completion of the Mislabeled/Unlabeled Responsibility form.

G. Handoff Communication Process for Improperly Labeled Specimens that are Tested at a Different Laboratory

In the rare instance that an improperly labeled specimen has been approved for testing and that testing occurs at a different laboratory within HealthPartners family of care, the following communication process should occur:

1. Put the specimen in a separate bag with a copy of the Provider Responsibility Form

2. If the Provider Responsibility form is not completed and specimen stability will not allow you to hold the specimen, write up a brief record indicating ordering provider, patient and specimen information, Lab Leader who approved testing, brief description of labeling issue and put in the bag with the specimen.

3. Order and complete a TELE 8 with the following information:

   - Labeling issue, testing approved by, Lab sent to, date and time.

   Example: Unlabeled body fluid approved for testing by Doug Olson sent to Regions 07072016 at 1437.

DEFINITIONS

1. Retrievable (Replaceable) Biological Specimen: Specimens that are able to be recollected
   - Blood – includes serum and/or plasma
   - Urine & Stool
   - PAP/cytology specimens from cervix or other sources
   - STD probe specimens
   - Swabs
   - Sputums

2. Irretrievable (Irreplaceable) specimens that are not easily recollected, recollection may negatively impact care, or the recollected specimen is not medically equivalent to the original.
   - Anatomic Pathology or surgical specimens
   - Specimens from invasive procedures (spinal tap, fine needle aspiration, joint or other body fluids, bronchoscopy, etc.)
   - Autopsy/Medical Examiner cases
   - Stat specimens from trauma, cardiac arrest, NICU, baby/infant bilirubin specimens, or operating room specimens
   - Blood gas specimens
   - Blood or urine where the patients was given special medication for special timed tests or other studies and procedures where the re-administration of the medication would be a risk to the patient or where the procedure cannot not be replicated within an appropriate time frame to facilitate diagnosis or critical treatment decisions.

3. Biological Specimen: A discrete portion of bodily fluid or tissue that has been removed from a patient's body with the intention of transporting it to the laboratory for purpose of clinical testing.

4. Properly labeled specimen: A specimen that contains two unique identifiers and all the required information needed for patient identification and specimen processing/testing.

5. Unlabeled Specimen: A specimen that has no identification attached to the specimen or transport container or only one identifier is on the specimen.

6. Mislabeled Specimen: A specimen that has been labeled with the wrong patient information.

7. Partially Labeled Specimen: A specimen that has the proper patient identification information but is lacking some or all of the required information.
    - A specimen where the transport container is labeled with the patient identification but the actual specimen is unlabeled is considered a partially labeled specimen.
    - A specimen where the source or other required information is missing or is discrepant with the test order

8. Provider: Any person with a license to practice medicine in the State of Minnesota that is an authorized, billable provider.

9. Laboratory Leader: Regional Clinic Laboratory Supervisor, Central Laboratory Technical Specialist Lead, Laboratory Managers, Regions Technical Specialists, Clinic Laboratory Operations and Business Manager, Administrative Laboratory Director, Laboratory Medical Director, Clinical Laboratory Director, and Laboratory Operations and Quality Consultant.

COMPLIANCE

Failure to comply with this policy or the procedures may result in disciplinary action, up to and including termination.

ATTACHMENTS

1-2-3 Identify Me
1-2-3 Identify Me – KOH
1-2-3 Identify Me – Non Bloods (Cytology, Pathology, Microbiology)

OTHER RESOURCES

Patient Identification Policy
Specimen Labeling and Specimen Disposal Policy
Specimen Aliquot Policy
Specimen Acceptability Process
Safety and Chemical Hygiene Plan

APPROVAL(S)

Manager, Clinic Laboratory Operations & Business
Manager, Central Laboratory

ENDORSEMENT Laboratory Administration