	The Johns Hopkins Hospital <u>INTERDISCIPLINARY CLINICAL PRACTICE MANUAL</u>	<i>Policy Number</i>	PAT027
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KEY WORDS: specimens, lab results

PATIENT CARE OBJECTIVES

The goal of this policy is to ensure that diagnostic information for clinical decision-making accurately reflects the patients for whom the test or procedure was ordered. The use of at least two patient identifiers to label specimen containers in the presence of the patient is required for accurate patient identification. Specimen misidentification is the most common cause of erroneous laboratory results.

RESPONSIBILITIES

CLINICAL STAFF
 PROCURING SAMPLES

- ◆ Ensure that the specimen has been obtained from the correct patient, and that specimen tubes or containers are labeled with 2 identifiers in the presence of the patient. For inpatients, assure that the name and history number are the same on the patient’s wristband and on specimen labels. For patients without wristbands, (outpatients) use any combination of name and DOB, or SSN or mother’s maiden name (in EPR) to ensure identity of the patient. All specimen containers must be labeled with the patient’s name and history number.
- ◆ Ensure that the request form is properly completed and labeled with the required patient name and history number.
- ◆ If collection labels have been generated from the electronic ordering system, verify patient name and medical record number are the same on the patient’s wristband and on the label. Labels are also to be placed on the specimen containers in the presence of the patient.
- ◆ Work with Pathology staff to try to determine the identity of patients from whom non-replaceable samples have been obtained.


PATHOLOGY AND
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- ◆ Notify the ordering clinician /designee if a mislabeled or unidentified sample has been received.
- ◆ Ensure that specimens that are mislabeled or unidentified are not registered and processed without being approved by an authorized Pathology supervisor, Laboratory manager, assistant administrator, resident or faculty member.
- ◆ Ensure documentation of the reason for determination of uniqueness if non-replaceable, and ensure that this information appears as part of the results returned to the medical record.

LABORATORY
 MANAGERS,
 ASSISTANT
 ADMINISTRATORS
 AND SUPERVISORS,
 AND PATHOLOGY
 RESIDENTS
 PATHOLOGY
 RESIDENTS AND
 FACULTY

- ◆ Communicate as appropriate with supervisory personnel or pathologists any concerns regarding labeling of or replaceability of a specimen.
- ◆ Ensure that problem labeling events are reported in Patient Safety Net (PSN)
- ◆ Review individual non-replaceable specimens to determine if they can be uniquely identified.
- ◆ Document the means of identification, and transmit the information to the personnel authorized to process the sample.

- ◆ Work with clinical staff to resolve individual non-replaceable specimen problems.

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DEFINITIONS

MISLABELED OR UNIDENTIFIED SPECIMENS:

Common types of specimen misidentification include failure to label the container in which the patient's sample is placed (even if the accompanying requisition has correct information) or use of another patients' identification plate in stamping requisitions and/or labels.

Specimens and any accompanying requisition not clearly labeled with patient name and history number are considered misidentified or unidentified. Examples of mislabeled or unidentified specimens are:

1. Specimen received unlabeled
2. Requisition received unlabeled
3. Specimen and requisition patient identification do not match
4. Specimen and requisition match, wrong patient

NOTE:

Providing information on patient location, and a legible ordering physician name and ID number are considered important for optimal patient care and are required by hospital regulations. However, inaccuracies in these do not constitute misidentification as defined in this policy.

REPLACEABLE SPECIMENS:

Specimens which can be re-obtained without significant risk to the patient, and whose results are not likely to be different from those obtained initially because of any therapeutic intervention.

NON-REPLACEABLE SPECIMENS:

Those that cannot be re-obtained (detailed below).

PROCEDURES


It is essential to check patient identification at the time of specimen procurement and label the specimen in the presence of the patient .

1.0 Replaceable Specimens: REPLACEABLE SPECIMENS WILL NOT BE PROCESSED IF THE SPECIMEN IS MISLABELED OR UNIDENTIFIED.

- 1.1 Among blood and urine specimens, all but a few types are considered replaceable.
- 1.2 Specimens from patients with difficult or inconvenient venous access are considered replaceable unless they meet one of the criteria listed in section 2.2 below.
- 1.3 The ordering clinician or designee will be notified by telephone when a test is to be cancelled because of a mislabeled or unidentified replaceable specimen.
- 1.4 All blood samples sent to the Blood Bank for purposes of obtaining material for transfusion are automatically viewed as replaceable; that is, if mislabeled or unidentified they MUST be redrawn even if they fall under one of the qualifiers listed in section 2.2 below.

2.0 Non-replaceable Specimens

- 2.1 Non-replaceable specimens may be processed provided certain specific procedures are followed to determine and document the unique identity of the specimen.
- 2.2 The following are considered non-replaceable specimens:

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- a. Specimens obtained by invasive procedures such as surgery, biopsies, fluid aspirates, and fetal/amniotic sampling.
- b. Specimens obtained prior to an intervention that might alter the result (e.g. a specimen sent for blood culture where antibiotic therapy was administered before a repeat sample could be obtained).
- c. Blood specimens from neonates, or from infants less than 6 months of age for whom total blood volume is problematic.
- d. Specimens from outpatients whose distances from Johns Hopkins Medical Institutions preclude the shipment of a repeat sample by an overnight express service.
- e. Specimens from children who have been identified as routinely requiring multiple venipunctures.

3.0 Processing a non-replaceable specimen found to be initially mislabeled or unidentified

- 3.1 All specimens considered non-replaceable shall be investigated for criteria that can establish uniqueness and thus secure linkage to the correct patient. Features defining uniqueness may include the nature of specimen, and the time and location of procurement (e.g. the only pleural tap done in a particular location at a given time). Documentation of the criteria used to establish uniqueness shall be recorded on the appropriate laboratory documents.
- 3.2 Communication regarding the specimen shall occur between a member of the Pathology Department and the person who procured the specimen. Validation shall be performed by a laboratory supervisor, manager, assistant administrator or pathologist. This shall occur before the specimen is registered and processed. The validation shall be documented, including the name of the person who procured the specimen. If necessary, the sample will be stabilized until validation can be accomplished.
- 3.3 In rare circumstances, appropriately validated forensic tests may be used by the laboratory to identify a patient sample.
- 3.4 For non-replaceable specimens that cannot be demonstrated to be unique based upon the rarity of the type of sample as outlined in 3.1 above (e.g. an unlabelled non-replaceable blood specimen from a timed draw), the Pathology resident, in consultation as necessary with a Pathology attending, shall discuss with the person procuring the specimen the circumstances under which the specimen was obtained. If the resident judges that the data ensure patient identification, the resident will document in the laboratory his or her assurance of identity of the patient. If a specimen cannot be identified as originating from a particular patient, it will not be processed.

4.0 Laboratory Documentation

- 4.1 If the specimen is considered replaceable and the specimen cannot be processed, the laboratory shall cancel the test, and document the reason for cancellation.
- 4.2 If the specimen is considered non-replaceable but identifiable, the laboratory shall document the time of procurement, the name of the clinical unit from which the specimen was sent and the

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name of the person who obtained it. Documentation will be maintained in such a manner that it will be possible to detect trends in the source of mislabeled specimens

4.3 The laboratory shall document the validation criteria used.

5.0 Final Report Documentation

The final report will include the following information:

- 5.1 The report will note that the specimen was initially received with incomplete or inaccurate patient identifying information.
- 5.2 The report will record that patient identification was verified according to Pathology procedures, and include the name of the individual validating the identity of the specimen.

REPORTABLE CONDITIONS

- Any time a patient specimen arrives in the laboratory mislabeled or unidentified, the event should be reported via Patient Safety Net (PSN) http://www.uhc/psn_gateway.html.

DEVELOPER

- Laboratory Advisory Committee

SPONSOR

- Medical Care Evaluation Committee

COMMUNICATION AND EDUCATION

This policy will be communicated to the appropriate JHHS personnel via the following channels:

- Departmental Physician Advisors will discuss the policy through the Clinical Performance Improvement Committee. They will be requested to communicate it to their respective PI Committees.
- A copy of the policy will be distributed to Directors of Residency Training Programs for discussion with house officers.
- The policy will be disseminated to Nursing Education, the Laboratory Advisory Committee, the Medical Care Evaluation Committee, and the Administrative Committee of the Medical Board.
- Pathology personnel will be educated through Pathology administrative and quality assurance meetings, and through education by supervisors and residency training leaders.
- Departments will identify additional target individuals to receive training by Pathology personnel in the implementation of this policy.
- This policy will be placed in the Interdisciplinary Clinical Practice Manual on the JHH Intranet site <http://www.insidehopkinsmedicine.org/icpm>. Paper distributions will be made to the Functional Unit Nursing offices in the event of web access difficulty.

REVIEW CYCLE	• Three years	MEDICAL BOARD	Approval Date: 10/26/05 Effective Date: 10/26/05
VICE PRESIDENT FOR MEDICAL AFFAIRS			

Date:			