



Specimen Collection & Rejection Procedure

According to both the Clinical Laboratory Improvement Amendment (CLIA) regulations and the College of American Pathologist's (CAP) Accreditation Standards for Laboratory and Pathology Services, the laboratory must establish, and follow, written policies and procedures for specimen labeling and specimen acceptability and rejection. Included in these policies and procedures will be criteria for the disposition of rejected specimens.

The primary focus for a specimen rejection policy is to insure patient specimen identification and specimen integrity in order to maintain patient safety and accurate test results. Mislabelled specimens can lead to morbidity and even death. It is the responsibility of all departments involved with the collection of specimens that the system affords no opportunity for specimen misidentification or inadequate preservation. It is the responsibility of the laboratory to reject patient specimens which are compromised by incorrect or incomplete identification, inadequate sampling, improper storage, delayed transportation, or any other factor which impinges upon specimen integrity.

This policy will be reviewed and approved by the KRMC Medical-Executive Committee on an annual basis.

Specimen Collection and Labeling Requirements

- Collected in the appropriate container or test tube with preservative or anticoagulant as designated
- Properly labeled using legible handwriting in the **presence of the patient**.
- **Outpatient specimen(s)** accompanied by the appropriate **requisition or patient id document**, which include:
 - **Patient's legal first and last name**
 - **Address**
 - **Birth date**
 - **Date of collection**
 - **Specimen type & Specimen Source**
 - **Test(s) requested**
 - **The name and number on the requisition must match exactly the name and number on the specimen container.**
 - **Initials of the collector**
 - **Label on specimen container, not on the Biohazard bag or lid.**

The KRMC requisition has multiple identical ID numbers attached to the upper right corner, 1 of which should be attached to each specimen container to serve as a second form of patient ID.

For inpatient requests, a separate requisition is not needed since the orders are transmitted through the computer system.

Required specimen labeling includes the following:

Two (2) forms of patient identification, including:

1. The **patient's legal first and last name** (except for special "confidential cases")

AND

2. A **unique identification number** (preferably the **requisition number for outpatients**, but may be the patient's birth date, health record number, or Social Security number.

All Blood Bank specimens, the unique identification number must be the number shown on the patient's Blood Bank wrist band.

AND

3. **Date and time of collection.** These are critical to insure specimen integrity.

In addition, the initials of the collector are highly desirable in case a problem arises with the specimen, and the laboratory needs to contact the collector

- Pathology (Histology/Cytology) Specimens:

Labeling requirements are essentially identical to "All Other Specimens" as stated below; however, these specimens are generally considered irretrievable, and, the collector's initials and date and time of collection are **not** required on the specimen container.

All pathology specimens should be taken to the Histology or Cytology Department with information about the labeling problem. All corrective actions will be undertaken by members of the Pathology Department. Unlabeled or mislabeled inpatient specimens must be corrected utilizing the "Irretrievable Unlabeled/Mislabeled Specimen Form" (see "Requisitions" in "Special Instructions") as stated below. Outpatient specimens may be returned to the Healthcare Provider's office for corrections, and/or, at the discretion of the Pathology Department member, corrections may be completed via telephone and fax using the above form, when appropriate. Any questions regarding this procedure should be referred to a Pathologist or the Histology/ Cytology Charge.

- Blood Bank Specimens:

Labeling requirements are identical to "All Other Specimens" as stated below, except that the unique identification number must be the number on the patient's Blood Bank wristband.

- Confidential Cases:

On very rare occasions, such as sensitive hospital employee testing, the ordering health care provider may request that the patient's name not be provided on the specimen container or requisition. (They will be assigned a Statpac name and account number for identification, eg, STATPAC, John; V10265789)

Specimen Integrity Rejection

- Lavender-top tubes:
 - Clotted specimens will be rejected
 - Less than 1 mL of blood will be rejected
- Blue-top tubes:
 - Less than 80% full tube will be rejected
 - Less than 90% but >80% full tube will be accepted, but result will be reported with comment “Blue-top tube not full; results may be affected”.
- Hemolysis can compromise many specimens. These will be rejected based upon the CLS or CTS’s discretion and a redraw will be requested. Upon physician request, the results can be reported with a comment stating “Hemolysis present; validity of results should be determined by clinical judgment. Results reported at physician’s request.”
- All specimens that are **delayed too long before receipt** into the laboratory will be rejected if specimen integrity is compromised. See Alphabetical Test Listings for specific requirements.
- Specimens **not collected or stored appropriately**, according to the requirements outlined in the Alphabetical Test Listings will be rejected (inappropriate temperature, specimen type, transport medium, etc.)
- **Stool specimens for culture** >2 hours old will be rejected, unless a swab with Cary-Blair transport medium is used for culture collection. These swabs are stable for 24 hours. A *Clostridium difficile* stool toxin assay is acceptable up to 2 hours at ambient temperature or refrigerated for up to 24 hours. Any stool specimen contaminated with urine will be rejected.
- **Urine specimens for urinalysis or culture** must be refrigerated immediately and processed within 24 hours. The only exceptions are culture specimens collected in grey-top urine tubes containing lyophilized preservative. They may be held at ambient temperature or refrigerated, but must be processed within 48 hours.
- **Urostomy bag** - only specimens from a fresh bag will be accepted.
- Specimens for **anaerobic culture** must be in an anaerobic collection system or a sealed syringe.
- Unless otherwise specified, containers with insufficient sample will be rejected.
- Sputum specimens meeting Gram stain rejection criteria will be rejected.

Unlabeled/Mislabeled Specimens

Because of the potential for serious patient harm, unlabeled or mislabeled specimens must be re-collected, unless the patient’s ordering health care provider deems the specimen irretrievable on the “Irretrievable Unlabeled/Mislabeled Specimen Form”. This form will be completed by the laboratory personnel and sent to the ordering provider.

An **unlabeled/mislabeled specimen** is defined as a patient specimen (blood, urine, other body fluids, or tissues) that does not have 2 legible forms of identification (as described above) placed directly on the **specimen container**. Identification on the bag holding the specimen is not acceptable, since the specimen can get separated from the bag. Except for special “confidential cases” and unidentified Emergency Department patients, the **patient’s legible legal first and last name is an absolute requirement for 1 of the forms of identification**. The second form of identification consists of a unique number, preferably the laboratory requisition number for outpatients, with the patient’s birth date, health record number, or Social Security number also acceptable.

Thus, if a specimen is received with **only 1 form of identification**, it is considered to be **unlabeled** and will be **rejected** unless deemed irretrievable as described above. The reason for this strict policy stems from the fact that the laboratory frequently receives specimens from 2 patients with the same name on the same day. These may

even come from the same hospital floor, physician office, or the Emergency Department. Without the additional unique number identification, a specimen mix-up resulting in a serious or fatal outcome is a real possibility.

Examples of unlabeled/mislabeled specimens:

- Label not attached securely to specimen container.
- Label attached to bag holding the specimen container rather than the container.
- Label attached to the specimen container lid rather than the container (lids can be mistakenly placed on the wrong container).
- Label does not have both the correct first and last name and unique identifying number. One or more incorrect letter(s) or number(s) is unacceptable.
- Label shows only the patient's last name and unique number.
- Any portion of the name or number is illegible.

For outpatients, if the **name** and **number** on the specimen label does not exactly match the name and number on the test requisition, immediately contact the sender to determine which is correct. If the specimen label is correct, the specimen will be acceptable after the sender has sent and the laboratory received a corrected requisition. If the specimen label is incorrect, then it will be rejected as stated above.

For outpatients, it is not uncommon to receive specimens labeled with a patient's nickname or new married name, which may not match the name that the laboratory has in the current hospital records. The hospital record usually lists the patient by their legal name as shown on their insurance information, Medicare/Medicaid card or other official record. In such instances, the laboratory personnel will need to determine the true identity of the patient. If the patient's Social Security number is provided on the requisition, and it matches the Social Security number listed in the hospital computer, then the specimen can be accepted and results entered under the name shown in the computer. Otherwise, the laboratory will immediately contact the specimen sender to request the Social Security number, and will proceed as above. If the Social Security number is not available, the laboratory will collect the appropriate information from the sender needed to positively identify the patient and match him/her with the hospital computer information.

Irretrievable Unlabeled/Mislabeled Specimens

According to Laboratory and College of American Pathologist's (CAP) guidelines on specimen acceptability and rejection, it is the laboratory's responsibility to **promptly notify** the authorized person when a specimen meets its rejection criteria and is unsuitable for testing. Accordingly, if a specimen is received that is not labeled with the patient's legible legal first and last name and unique identification number, the laboratory will notify the sending location that, unless the patient's ordering health care provider deems the specimen irretrievable, it will be discarded; and a properly labeled, recollected specimen will be required.

If the specimen is deemed irretrievable, before the laboratory can proceed with processing the specimen, the individual who collected the specimen must perform the following 3 procedures:

- Complete the **"Irretrievable Unlabeled/Mislabeled Specimen Form"**. **The form will be completed by the laboratory staff and sent to the ordering provider.**
 - (This form can be tubed to inpatient areas or faxed to outpatient offices.)
- **The form must be signed by the individual who collected the specimen AND the health care provider who ordered the test.**
- Bring the completed form to the laboratory and properly label the specimen as specified above.

The specimen will be maintained under proper conditions for the type of specimen and test requested until the above is completed. Analysis will be performed on the specimen only if absolutely necessary, but

results WILL NOT be released **until the above has been completed, unless the patient's health care provider notifies the laboratory in writing that failure to release results would compromise patient safety more than the labeling problem.** If such notification is provided, it will be notated **with the provider's name** as a result comment on the patient report.

If the **name** and **number** on the specimen label **does not exactly match** the name and number on the test requisition, the laboratory will immediately contact the sender to determine which is correct. If the specimen label is correct, the specimen will be acceptable after the sender has sent and the laboratory has received a corrected requisition. If the specimen label is incorrect, refer above.

Otherwise Improperly Labeled Specimens:

Specimens that are not labeled with the legible date and time of collection and specimens with other labeling problems not addressed elsewhere in this policy will be placed in this category. Such specimens will be accepted after the collector or their designee properly completes a **"Specimen Discrepancy Form"** (see "Requisitions" in "Special Instructions"). For inpatient specimens, the form may be tubed to the collector or their designee, completed, and returned to the laboratory ASAP. For outpatient specimens, the form may be faxed to the originating office, completed, and returned to the laboratory ASAP.

The specimen will be maintained under proper conditions for the type of specimen and test requested until the above is completed. Analysis will be performed on the specimen only if absolutely necessary, but results will NOT be released **until the above has been completed, unless the patient's health care provider notifies the laboratory in writing that failure to release results would compromise patient safety more than the labeling problem.** If such notification is provided, it will be notated **with the provider's name** as a result comment on the patient report.

