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Preanalytical Processing

Purpose

This document defines the policy for the Preanalytical Processing requirements.

Scope

This policy is intended for the Southern California Permanente Medical Group (SCPMG) Laboratory Systems and all employees handling specimens prior to testing. The following items are covered in this policy:

- Confirmation of test orders
- Patient identification
- Feedback to collector on specimen issues related to quality
- Specimen collection
- Instructions to patients collecting their own specimens
- Labeling of specimens including compatibility testing
- Transport requirements and training
- Specimen tracking
- Receipt of specimens
- Requisitions
- Processing
- Authorized requestor
- Delivery to test area

Definitions

Unrecollectable and/or irreplaceable specimen	A specimen that cannot be replaced for one of several reasons:
	• The specimen was obtained by an invasive procedure. Examples include spinal fluid, body fluids, crystals, biopsies or other pathology specimens.
	• A medication has been administered or a medical treatment has been performed that affects the laboratory result. Examples include:
	  • Culture [including blood culture] when an antibiotic has been given after the specimen was obtained
	  • Drug level when the drug has been administered after the specimen was obtained.

Inpatient	A person formally admitted to the hospital with a doctor's order.
Hospital Outpatient	A person getting emergency department services, observation services, outpatient surgery, lab tests, x-rays, or other hospital services and the doctor has not written an order to admit the person to the hospital as an inpatient.
Ambulatory	A person who is seen at an outpatient services center.

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Preanalytical Processing, Continued

Background

According to literature research, between 32% and 75% of errors in the laboratory are associated with the preanalytical process of laboratory testing, most of which arise in problems in patient preparation, sample collection, transportation and preparation for analysis and storage. The agencies [College of American Pathologists (CAP), The Joint Commission (TJC), COLA] that accredit SCPMG laboratories all have requirements governing the preanalytical phase of testing. This document is intended to encapsulate those requirements as a foundation for the preanalytic portion of SCPMG Laboratory Systems testing.

Policy

All of the proceeding policies are in concert with SCPMG medical center laboratory based policies and procedures. Refer to your medical center laboratory specific policy for details.

- Test Ordering – In instances when the test order is unclear and the specimen has been drawn from the patient, the specimen will be held while the provider is contacted to place orders in the Kaiser Permanente HealthConnect® System or clarify the order. Refer to the following policies:
    - Receipt of Clinic Collected Specimens by the Clinical Laboratory without Documented Orders
    - Receipt of Clinic Collected Specimens by the Clinical Laboratory without Documented Orders – Preemptive Blood Draws
    - Receipt of Clinic Collected Specimens by the Clinical Laboratory without Documented Orders from Inpatient or Emergency Department
- Patient Identification – Patients will be positively identified before specimens are collected using at least two identifiers.
- Phlebotomy:
    - There will be timely feedback given to the collector of the specimen on issues related to quality.
    - There will be procedures to care for patients with adverse reactions from phlebotomy.
- Specimen Collection
    - There will be an investigation process and corrective action taken for all specimen collection errors.
    - All employees involved in the specimen handling process will be trained on collection techniques and the selection and use of equipment.

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Preanalytical Processing, Continued

Policy, continued

- There will be verbal and/or written instructions for patients who collect their own specimens. Refer to LabNet for details.
- Labeling
    - Primary specimen containers will have a pre-printed or handwritten label that contains at least two identifiers, date and time of collection and identification of person who collected the specimen.
    - Specimens will be labeled at the time of specimen collection in the presence of the patient.
- Label Correction
    - All mislabeled specimens [wrong patient identification] will be recollected unless the specimen is deemed unrecollectable. A record of corrections for unrecollectable specimens will be maintained.
    - Specimens received with incorrect container labels [i.e. blue tube label on lavender tube] with correct patient identification will be corrected by the person who has collected the specimen or a designee.
    - An investigation will be performed and corrective/preventive action will be issued including retraining as applicable.
- Compatibility Specimen Labeling – Identification and labeling of compatibility specimens will be performed before leaving the patient as described in the standardized transfusion procedure. Refer to the following policy:
    - Collection and Receipt of Blood Bank Specimens
- Transport – Specimens will be packaged and shipped for transport according to applicable local, state and federal guidelines.
- Transport Training – Infectious material transport training to include use of rigid containers [where appropriate], temperature control and notification procedures in case of accident or spills will be held and documented every three years.
- Specimen Tracking
    - Specimens being transported to the Kaiser Permanente testing laboratories will be tracked.
    - Specimens will be monitored for quality and corrective action will be implemented for improperly submitted specimens.
- Receipt of Specimens – Specimens will be reviewed for appropriateness and actions will be taken if received in an unacceptable state.
- Requisitions – Specimens will have an adequate paper or electronic requisition and appropriate data elements will be entered into the laboratory information system as applicable.

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Preanalytical Processing, Continued

Policy, continued

- Processing
  - Specimens will be positively identified.
  - Containers and aliquots will have a unique label which can be audited back to the full patient identification.
  - All specimens are logged into Cerner. The collection date, time and collection ID are required
  - Specimen Centrifugation
    - Red top or serum separator tubes [SST], have required clot formation. Clotting time is 30 minutes but may be increased by clotting factor deficiencies. NCCLS recommends separation of serum and cells as soon as possible after clot formation not to exceed 2 hours. Serum/cell contact time exceeding 2 hours has been shown to affect test results significantly. Tests impacted the most include blood glucose, potassium, inorganic phosphate, phosphorus and magnesium determinations.
    - Specimen tubes containing anticoagulants must be spun as soon as possible.
    - Spin most specimens at 3000 rpm for 10 minutes or as defined.
- Equipment
  - Refrigerator/freezer/incubator temperatures will be checked and recorded daily.
  - Centrifuge operating speeds will be checked annually.
- Authorized requestor
  - There will be a mechanism to ensure specimens are analyzed only at the request of an authorized person.
  - If a verbal request for a test is received, it will be followed by written or electronic authorization within 48 hours for hospital inpatients and outpatients and within 30 days for ambulatory patients.
- Delivery to Test Area – All specimens will be delivered to the testing location within specified times of collection.

Non-Controlled Documents

The following non-controlled documents support this policy.

- CAP Accreditation Program Laboratory General Checklist
- TJC Guidelines
- COLA Guidelines

Controlled Documents

The following controlled documents support this policy.

Policy
Receipt of Clinic Collected Specimens by the Clinical Laboratory without Documented Orders
Receipt of Clinic Collected Specimens by the Clinical Laboratory without Documented Orders – Presumptive Blood Draws
Receipt of Clinic Collected Specimens by the Clinical Laboratory without Documented Orders from Inpatient or Emergency Department
Collection and Receipt of Blood Bank Specimens

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Signature Manifest

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Preanalytical Processing

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