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Preanalytical Processing

Purpose

This document defines the policies for specimen collection and handling requirements.

Scope

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

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

Continued on next page

Preanalytical Processing, Continued

Definitions

Term	Definition
Irreplaceable and/or Un-recollectable 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.

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 preanalytical portion of SCPMG Laboratory Care Delivery System testing.

Continued on next page

Preanalytical Processing, Continued

Policy

Test Orders/Requisitions

- 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:
  - *Receipt of Clinic Collected Specimens by the Clinical Laboratory without Documented Orders*
  - *Receipt of Clinic Collected Specimens by the Clinical Laboratory without Documented Orders – Pre-emptive Blood Draws*
  - *Receipt of Clinic Collected Specimens by the Clinical Laboratory without Documented Orders from Inpatient or Emergency Department*
- Specimens will have an adequate paper or electronic requisition and appropriate data elements are entered into the laboratory information system as applicable.

Patient Identification

- Patients are positively identified before specimens are collected using at least two identifiers.

Specimen Collection

- There are investigation processes and corrective action taken for all specimen collection errors.
- All employees involved in the specimen handling process are trained on collection techniques and the selection and use of equipment.
- There are verbal and/or written instructions for patients who collect their own specimens. Refer to LabNet for details.
- There are procedures to care for patients with adverse reactions from phlebotomy.

Continued on next page

Preanalytical Processing, Continued

Policy, continued

Labeling

- Primary specimen containers will have a pre-printed or handwritten label that contains at least two identifiers, date and time of collection and a method to identify the individual collecting the specimen. person who collected the specimen.
- Specimens are labeled at the time of specimen collection in the presence of the patient.
  - Specimen Labeling for Pretransfusion Testing
    - All specimens collected for pretransfusion testing (Blood Bank) are labelled at the time of specimen collection with:
      - Patient's first and last name
      - Unique identification number (Medical Record Number)
      - Date/time of collection (documented on the label or documented in the Cerner and/or MediCopia system)
      - Method to identify the individual collecting the specimen.
        - Refer to *Receipt of Blood Bank Specimens*
  - Label Correction
    - All mislabeled specimens (wrong patient identification) are subject to disposal and may be recollected unless the specimen is deemed irreplaceable.
    - A record of corrections for irreplaceable specimens will be maintained.
    - Specimens received with incorrect container labels (i.e., blue tube label on lavender tube) with correct patient identification may will be corrected by the person who has collected the specimen or a designee.
      - An investigation is performed, and corrective/preventive action may be issued including retraining as applicable.

Transport

- Specimens are packaged and shipped for transport according to applicable local, state, and federal guidelines as well as testing laboratory specifications.
  - 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 are held and documented every three years.

Continued on next page

Preanalytical Processing, Continued

Policy, continued

Specimen Tracking

- Specimens being transported to the Kaiser Permanente testing laboratories are tracked.
- Specimens are monitored for quality and corrective action will may be implemented for improperly submitted specimens.

Receipt of Specimens

- Specimens are reviewed for appropriateness and actions are taken if received in an unacceptable state.

Processing

- Specimens are positively identified.
- Containers and aliquots will have a unique label which can be audited back to the full patient identification.
- When aliquoting specimen prevention of cross-contamination is avoided by use a clean disposable pipettes and verification of patient identification on the aliquot container to ensure it matches the primary container.
  - Aliquoted specimens are never returned to the original specimen container
  - If previously aliquoted specimens are used for additional testing, the testing procedure must define when and how they can be used.
- All specimens which are interfaced to the Cerner system are logged into Cerner. The collection date, time and collection ID are required
- Specimen Centrifugation
  - Red top or serum separator tubes (SST), have the following considerations for adequate clot formation:
    - Minimum clotting time is 30 minutes but should not exceed 2 hours as serum/cell contact time exceeding 2 hours has been shown to affect test results significantly. 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.
  - All specimens requiring centrifugation are spun at 3000 rpm for 10 minutes or as otherwise defined in LABNET.

Continued on next page

Preanalytical Processing, Continued

Policy, continued

Equipment

- Refrigerator/freezer/incubator temperatures containing reagents or specimen storage are checked and recorded daily using a calibrated thermometer.
- Centrifuge operating speeds are checked annually.

Authorized requestor

- There are processes to ensure specimens are analyzed only at the request of an authorized person.
- If a verbal/phone request for a test is received, it is followed by written or electronic authorization within 48 hours for hospital inpatients/outpatients and outpatients and within 30 days for ambulatory patients.
  - Personnel receiving verbal/phone orders read back the entire order to verify accuracy of transcription.

Delivery to Test Area

- All specimens are delivered to the testing location within specified times of collection.

Feedback of Preanalytical Performance

- Timely feedback is given to the collector of the specimen on issues related to quality.

Controlled Documents

The following controlled documents support this 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 – Pre-emptive Blood Draws
Receipt of Clinic Collected Specimens by the Clinical Laboratory without Documented Orders from Inpatient or Emergency Department
Receipt of Blood Bank Specimens
Procedure for Venipuncture
Irreplaceable Specimens

Continued on next page

Preanalytical Processing, Continued

Non-Controlled Documents

The following non-controlled documents support this policy.

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

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Signature Manifest

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Preanalytic Regional documents

Initial Approval

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