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Kaiser Permanente	SCPMG Laboratory Systems
Medical Care Program	Quality Management
California Division – South	Policy

Storage and Handling of Reagents and Other Material Related to Laboratory Testing

Purpose

This document defines the policy for storage and handling of laboratory reagents, solutions, culture media, control materials, calibration materials, and other supplies per 42 CFR 493.1252 *Standard: Test Systems, equipment, instruments, reagents, materials, and supplies,* and related requirements by applicable laboratory accreditation agencies.

Scope

This policy is intended for all personnel within the SCPMG Laboratory Systems involved in storage and handling of reagents, solutions, culture media, control materials, calibration materials, and other supplies associated with laboratory testing.

Policy

- Reagents and materials related to laboratory testing (e.g., chemicals, stains, media) are stored and handled as defined by the laboratory/testing department and following the manufacturer's instructions, whichever is more restrictive.
- If there are multiple components of a reagent kit, the laboratory/testing department uses components of reagent kits only within the kit lot unless otherwise specified by the manufacturer.
- If the laboratory identifies a problem with a reagent that was used for patient testing (e.g., expired vial or reagent subjected to unacceptable storage conditions, etc.), the laboratory must evaluate the potential impact on patient test results and retain records of the evaluation and actions taken.
- The laboratory must manage notifications from vendors of defects or issues with reagents or supplies that may affect patient care/client services.
- Records associated with this policy shall be retained according to the *Retention of Laboratory Records, Specimen, and Materials* policy.

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Storage and Handling of Reagents and Other Material Related to Laboratory Testing, Continued

Reagent Storage and Handling for Waived Tests

- This section block contains the requirements for waived tests. Requirements described throughout the rest of this policy apply only to nonwaived tests.
- For waived tests, the laboratory follows manufacturer instructions for handling and storing reagents, cartridges, test cards, etc.
  - There is no requirement to routinely label individual containers with "date opened"; however, a new expiration date must be recorded if opening the container changes the expiration date, storage requirement, etc.
  - If the manufacturer defines a required storage temperature range, the temperature storage areas must be monitored daily.
- If the laboratory identifies a problem with a reagent that was used for patient testing (e.g., expired vial or reagent subjected to unacceptable storage conditions, etc.), the laboratory must evaluate the potential impact on patient test results and retain records of the evaluation and actions taken.

Labeling Requirements

- Reagents, calibrators, controls, stains, chemicals, and solutions are properly labeled, as applicable and appropriate, with the following elements:
  1. Content and quantity, concentration or titer
  2. Storage requirements
  3. Date prepared, filtered or reconstituted by laboratory
  4. Expiration date
- The above elements may be recorded in a log (paper or electronic), rather than on the containers themselves, providing that all containers are identified so they are traceable to the appropriate data in the log.
- While useful for inventory management, labeling with "date received" is not routinely required. There is no requirement to routinely label individual containers with "date opened"; however, a new expiration date must be recorded if opening the container changes the expiration date, storage requirement, etc. For containers with multiple individual reagent units (e.g., cartridges), the expiration date must be recorded on each unit if stored outside of the original container.
- Precautionary labels are present on the containers of all hazardous chemicals, indicating type of hazard and what to do if accidental contact occurs.

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Storage and Handling of Reagents and Other Material Related to Laboratory Testing, Continued

Storage and Temperature Requirements

- Reagents (chemicals, stains, controls, media, antibodies, test strips, testing cartridges, etc.) must be stored and handled in a manner that will prevent environmentally induced alterations that could affect reagent stability and test performance, following the manufacturer's instructions.
- Prepared reagents must be discarded when stability parameters are exceeded.
- If the manufacturer defines a required storage temperature range, the temperature of storage areas must be monitored daily using a calibrated thermometer.
- If reagents and supplies are stored in a centralized area outside of the laboratory, they are stored and handled in accordance with the manufacturer's instructions.
- Supplies of flammable and combustible liquids are reasonable for the laboratory's needs and are properly stored.
- Storage areas and/or rooms where volatile solvents are used are adequately ventilated.
- Supplies of concentrated acids and bases are stored safely. Consider the following:
  1. Storage must be below eye level. Storage near the floor is recommended.
  2. Strong acids and bases must not be stored under sinks, where contamination by moisture may occur.
  3. Storage containers of acids and bases should be adequately separated to prevent a chemical reaction in the event of an accident/spill/leak.
  4. Bottle carriers are used to transport all glass containers larger than 500 mL that contain hazardous chemicals.

Expiration Dates

- All reagents (chemicals, stains, controls, medica, antibodies, test strips, testing cartridges, etc.) are used within their indicated expiration date. They shall not be used if they have deteriorated or are of substandard quality.
- Transfusion services laboratories may use rare reagents (i.e., rare antisera and selected panel cells to determine the specificity of red cell antigens and antibodies) beyond their expiration date if appropriate positive and negative controls are run each day of use and react as expected. The laboratory must have in-date reagents for routine antigen typing and antibody panel testing.
- For histology and cytology, laboratories may satisfy confirmation of ongoing acceptable performance of stains until the expiration date by technical assessment of case material containing suitable material for evaluation of stains, or by use of suitable control specimens.

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Storage and Handling of Reagents and Other Material Related to Laboratory Testing, Continued

Expiration Dates, continued

- The laboratory must assign an expiration date if an expiration date is not provided by the manufacturer. The laboratory must base the assigned expiration date on the following and perform a risk assessment annually. Refer to *Evaluation of Reagents Lacking Manufacturer-Assigned Expiration Dates* form.
  1. Known stability
  2. Frequency of use
  3. Storage conditions
  4. Risk of deterioration
- The laboratory/testing department may use reliable literatures or reference documents to support the length of time when assigning the expiration date.

New Reagent Lots and Shipments

New reagent lots and shipments are checked against previous reagent lots or with suitable reference material before or concurrently with being placed in service.

- This applies to reagents that provide a chemical or biological reaction to detect and/or measure a target analyte and does not apply to inert ingredients (e.g., reagent water, saline) or materials used for specimen preparation.
- The purpose of new reagent lot and shipment confirmation of acceptability is to confirm that the use of new analytic reagent lots and shipments do not affect patient results.
- The minimum extent of the reagent check if described in the following section blocks; however, the check must be at least as extensive as described in the manufacturer's instructions. The laboratory may determine the number of specimens tested.

New Reagent Lot and Shipment Confirmation of Acceptability - Qualitative

- For qualitative nonwaived tests, minimum cross-checking includes retesting at least one positive and negative sample with known reactivity against the new reagent lot. Utilization of a weakly positive sample is recommended in systems where patient results are reported in that fashion.
- Examples of suitable reference materials for qualitative tests include:
  - Positive and negative patient samples tested on a previous lot;
  - Previously tested proficiency testing materials;
  - External quality control (QC) materials tested on the previous lot;

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Storage and Handling of Reagents and Other Material Related to Laboratory Testing, Continued

New Reagent Lot and Shipment Confirmation of Acceptability - Qualitative, continued

- Control strains of organisms or previously identified organisms for microbiology reagents used to detect or evaluate cultured microorganisms;
- If none of the above options is available, control material provided by the assay manufacturer with the new test kit.

- There may be more specific requirements in laboratory sections for some types of qualitative testing, such as flow cytometry antibodies and reagents, microbiology media and stains, disk/strips, antimicrobials, and reagents, and immunohistochemistry antibody and detection system reagents.

New Reagent Lot and Shipment Confirmation of Acceptability - Quantitative

- For quantitative nonwaived tests, patient specimens should be used to compare a new lot against the previous lot, when possible. Manufactured materials, such as proficiency testing (PT) or QC materials may be affected by matrix interference between different reagent lots, even if results show no change following a reagent lot change. The use of patient sample confirms the absence of matrix interference.
- The following materials may be used:
  1. Patient specimens tested on a previous lot;
  2. Reference materials or QC products provided by the method manufacturer with method specific and reagent lot specific target values
  3. Proficiency testing materials with peer group established means
  4. QC materials with peer group established means based on interlaboratory comparison that is method specific and includes data from at least 10 laboratories
  5. Third-party general-purpose reference materials if the material is affirmed in the package insert or by the method manufacturer to be commutable with patient specimens for the method.
  6. QC material used to test the current lot is adequate alone to check a new shipment of the same reagent lot, as there should be no change in potential matrix interactions between the QC material and different shipments of the same lot number of reagents.
- For hematology analyzers, reservoirs containing testing reagents and cleaning/decontaminating solutions must be checked according to manufacturer's instructions.

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Storage and Handling of Reagents and Other Material Related to Laboratory Testing, Continued

Non-Controlled Documents

The following non-controlled documents support this policy.

CLIA Requirements, 42 CFR, Part 493.492
College of American Pathologists Laboratory General, All Common, and Flow Cytometry Checklists

Controlled Documents

The following controlled document supports this policy.

Policy
Retention of Laboratory Records, Specimen, and Materials
Antibody Identification – How to Interpret Test Results

Form
Evaluation of Reagents Lacking Manufacturer-Assigned Expiration Dates

Signature Manifest

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