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Subject	Attachments
Internal Quality Control Policy	☐ Yes ☒ No
Key words Quality Control, Internal QC, Quality Assessment, QSE 6	**Number** **GHI-PC-LAB-AD-Internal QC Policy v. 03-2009**
Category Provision of Care (PC)	**Effective Date** **October 2007**
Manual Central Laboratory Policy and Quality Assessment Manual HPMG Clinic Laboratory Procedure Manual	**Last Review Date** **March 2014**
Issued By Laboratory Administration	**Next Review Date** **March 2015**
Applicable Laboratory Staff	**Origination Date** **June 1994**
	Retired Date
Review Responsibility Laboratory Administration	**Contact** Lab Administration

I. PURPOSE

This policy ensures the measuring and maintaining of accurate and precise performance of lab tests through quality control.

II. POLICY

Methods:

1. Quality control plans will be reviewed and individualized to include risk assessment of potential process and human errors associated with test categories.

2. There are specific quality control (QC) procedures for each test performed that incorporates the recommendations from EP 23: Laboratory Quality Control Based on Risk Management. These may include the use of assayed control materials, reagent checks, and equipment checks.

3. For tests that do not have quality control material (i.e., wright stain slides, post vasectomy test), specific qualitative parameters are indicated in the test-specific procedure.

4. Controls must not be used beyond their expiration date.

5. Lot-to-lot, unassayed, and daily quality control is performed according to manufacturers and regulatory requirements. QC requirements will be indicated on test-specific procedures and worksheets at the Clinic and Central labs.

6. In the event that expected QC values are not attained, begin troubleshooting and/or notify the Lab Technical Consultants (TC) or Central Laboratory Lead.
    - Patient results **will not** be reported until the Quality Control is acceptable.
    - In the event that a test becomes delayed due to QC failure, refer to the specific test procedure and notify the TC or Lead.

- In the event that testing is delayed due to QC failure, notify the TC or Lead and the Clinic supervisory staff of potential delays in patient results. See the Notification of Delay in Testing Policy.
- In the event that QC is determined to be outside of established limits and patient results have already been reported, the Central Lab Lead or TC will notify the Laboratory Medical Director and collaboratively decide the action steps and recommendations on the potential impact to patients. The Central Lab Lead or TC will direct any repeat or other testing to confirm patient results.
- The Central Lab Lead or TC will communicate with providers regarding the possibility of compromised test results. The Laboratory Medical Director will be involved in communicating with providers as necessary.
- The Central Lab Lead or TC will contact Laboratory Leadership to evaluate any Risk Management involvement.
- Once the QC is performing as expected, testing can be performed and patient results reported.

7. Document QC problems and resolutions on the worksheet or troubleshooting log.

8. Comparison testing between the clinic labs, Central lab, and Regions will be performed on a regular basis for certain instruments and/or assays. See the individual test procedures for the frequency of comparison testing.

Documentation:

1. All QC results will be documented on worksheets or entered into the Sunquest, Unity Software, and other QC management files as appropriate.

    - Verify quality control information on worksheets or entered into the Sunquest QC file each day of use (i.e., lot #s, expiration dates, etc.).

2. Documentation will include QC results, and corrective action as necessary. The TC or Lead will actively review these worksheets.

3. All QC records/worksheets/logs must be kept for 2 years or for the next accreditation inspection cycle, whichever is longer.

4. Test kits/reagents/controls will be handled in the following manner:

    - Record received date, date opened, and expiration date (if different from manufacturers expiration date), on the kit and/or control vials as appropriate.
    - Give the material package inserts (heme, UA and ESR) to the TC or Lead. All other package inserts should be kept with the kit until discarded.

5. If any information is different then what is listed on the worksheet or in Sunquest, document new lot numbers and expiration dates and run controls before reporting patient values.

III. DEFINITIONS

Sunquest: Laboratory Information System

IV. COMPLIANCE

Failure to comply with this policy or the procedures may result in disciplinary action, up to and including termination.

V. ATTACHMENTS

VI. OTHER RESOURCES

Manufacturers' package inserts, instrument manuals

CLSI Approved Guideline NCCLS Document C24-A:Internal Quality Control Testing: Principles and Definitions.

CLSI Approved Guideline EP23: Laboratory Quality Control Based on Risk Management

VII. APPROVAL(S) Director, Laboratory Services

VIII. ENDORSEMENT Laboratory Administration