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Automated Chemistry IQCP Geenius HIV 1/2

Document Type: Policy

I. PURPOSE AND OBJECTIVE:

A. As stated by Centers for Medicare/Medicaid Services (CMS), "The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations require a laboratory to have quality control (QC) procedures to monitor the accuracy and precision of the complete testing process. A QC option is now available that provides you the opportunity to tailor an individualized quality control plan (IQCP) for your unique testing environment and your patients. The IQCP option offers your laboratory flexibility for meeting regulatory QC requirements appropriate for the testing you perform and when you add a new test."

B. IQCP is an all-inclusive approach to assuring quality. It includes many practices that the laboratory already uses to ensure quality testing, beyond requiring that a certain number of QC materials be tested at a designated frequency. As of January 1, 2016, IQCP is a CMS requirement for non-waived test systems for which external controls are run less frequently than the CLIA requirement (2 levels every day of patient testing). Furthermore, the College of American Pathologists (CAP) requires that IQCP tests have an internal (electronic/procedural/built-in) quality control system.

II. IQCP: RISK ASSESSMENT DOCUMENT REVIEW:

A. Test System: Geenius HIV 1/2; Manufacturer: BioRad

	IQCP Binder	Date Reviewed
Manufacturer instructions	Y Refer to Manufacturer's Package Insert	6/10/2016
Manufacturer IQCP guidance document	Y	6/3/2016
Instrument manuals	S:\ClinPathChem\Automated Chemistry\Document Control Library\NEW INDEX AND TEMPLATE\CSL Chemistry_Stat Lab\MT - Manual Tests\Master Geenius HIV-1/HIV-2 Supplemental Test - *New Shipment* Verification Log (Attachment A) Geenius HIV-1/HIV-2 Supplemental Test - *New*	

	Lot Verification Log (Attachment B)	
Manufacturer alerts, bulletins	Y	6/3/2016
FDA alerts	Y	6/10/2016
Lab procedure and worksheets	Y	6/3/2016
Laboratory Test Directory entry	Y	10/17/2016
Method validation data	Refer to S:\ClinPathChem\Automated Chemistry\Method-Instrument Validation\Manual Testing\BioRad Geenius	10/17/2016
Historical QC data (all locations	Y	10/17/2016
PT results	Y (summary)	10/17/2016
Personnel training records (all locations)	Refer to: Medical Technologist II (MTII) Office Clinical Instructor	10/17/2016
Competency records (all locations)	Refer to: Medical Technologist II Office Clinical Instructor	10/17/2016
Physician/client complaints (all locations)	Y	10/17/2016
Canceled tests (all locations)	Y SOFT Laboratory Information System (LIS)	10/17/2016
Corrected reports (all locations)	Y S:\ClinPathChem\Automated Chemistry\IQCP\Corrected Reports-Cancellations	10/17/2016
Regulatory requirements	Y	6/10/2016
Scientific publications	Y	6/10/2016

B. **Summary of findings from supporting data:**

1. **Manufacturer recommendations for QC**: Each Geenius HIV 1/2 Supplemental assay cassette contains a control band that is used to determine the validity of the assay and confirm that sample has been added to the cassette. The control band must be present for the test to be valid. External QC is available for the Geenius HIV 1/2 assay. One positive and one negative control must be tested under the following circumstances:
    a. When opening a new test kit lot
    b. Whenever a new shipment of test kits is received
    c. If the temperature of the test storage area falls outside of 2-30 degrees C
    d. If the temperature of the testing area falls outside of 18-30 degrees C
    e. At periodic intervals as indicated by the user facility.

2. **Historical QC**: SOFT LIS Total QC (TQC): Quality Control results are available through Total QC in SOFT LIS. Total QC provides kit lot numbers, expiration dates, and acceptable ranges/means for each testing parameter.
3. **Proficiency Testing**: CAP Surveys: AHIV-A 2016 (01-05), AHIV-B 2016 (06-10) were acceptable compared to peer group from CAP.
4. **Training and Competency:** S:\ClinPathChem\Automated Chemistry\SUPERVISOR\Garcia\Training Master Autochem Training Checklist Updated Oct 2016. Each new employee is provided a training checklist which must be completed and signed by a supervisor or Lead Med Tech before testing can be performed by the individual. A competency review will be given to the new employee around 6 months after training has been completed. An annual competency will then be performed each year after.
5. Physician Complaints: NA
6. Corrected reports and canceled tests: Canceled Test Reports 2016 SOFT LIS saved under S:\ClinPathChem\Automated Chemistry\IQCP\Corrected Reports-Cancellations

III. IQCP: RISK ASSESSMENT:

A. The risk assessment summary was completed for the BioRad Geenius HIV 1/2 Test; refer to Automated Chemistry IQCP Attachment A, IQCP Risk Assessment. The risk assessment identifies and evaluates potential failures and sources of errors in the testing process. It includes an evaluation of the following five components:

1. Specimen
2. Test System
3. Reagent
4. Environment
5. Testing personnel

IV. IQCP: QUALITY CONTROL PLAN:

A. The quality control plan defines all aspects of the test system monitored based on potential errors identified during the risk assessment. The components of the quality control plan must meet regulatory and CAP accreditation requirements and be in compliance with the manufacturer instructions and recommendations, at minimum. The quality control plan must control the quality of the test process and ensure accurate and reliable test results.

B. **Quality controls (number, types, and frequency) and acceptability criteria**

1. Internal controls: BioRad Geenius HIV 1/2 has an internal control band on each test cartridge. If this control band does not appear during testing, the test is invalid.
2. External controls: CAP requirement: External control material samples must be analyzed at least every 31 days and with new lots and shipments of reagents or more frequently if indicated in the manufacturer's instructions. One positive and one negative serum control are to be used every time there is a newly trained operator as part of training (before patients have been resulted), new test cartridge lot, new quality control lot, new shipment, storage temperature of the cartridges or quality controls falls outside of specified ranges, temperature of testing area falls outside of specified ranges, and once per month.

C. **Documentation of complaints and testing errors (preanalytical, analytic, and post analytic)**
An IQCP Problem Documentation log will be located at the Geenius work bench for documentation of errors/problems, etc; refer to Automated Chemistry IQCP, Attachment D, IQCP Problem Documentation Log. This log will be reviewed by appropriate Lead Medical Technologist on a monthly basis, summarized into a QA Monthly Monitoring Log and scanned in to the S: / drive. Any complaints will also be documented on the Quality Safety Reports form (QSR) and followed up with and recorded on the S: / drive log.

D. **Monitoring of the testing environment and reagents**
Geenius HIV 1/2 cartridges are stored in the core lab Chemistry walk in. Testing is performed on the bench top in core lab Chemistry. The temperature of the walk-in unit and the room temperature is monitored and recorded daily. (Refer to: Temperature Log Book - Core Lab Chemistry). The walk-in unit also has a temperature monitor which tracks the temperature consistently. New lots and new shipments are marked with “New Lot” or “New Shipment” tags until the QC requirements are completed.

E. **Specimen quality**
Geenius HIV 1/2 testing is not affected by the presence of interfering substances such as hemolysis and lipemia. Samples should not be used if they have incurred more than 5 freeze-thaw cycles. It is recommended that samples be centrifuged to remove gross particulate matter. Any problems with specimen quality will be documented on the IQCP Problem Documentation Log, which will be located at the Geenius bench. Refer to Automated Chemistry IQCP, Attachment D, IQCP Problem Documentation Log. SOFT LIS Modification after Verification reports will also be reviewed monthly by the appropriate Lead Medical Technologist.

F. **Instrument calibration, maintenance, and function checks**
The Geenius HIV 1/2 reader system performs a self-calibration and function checks when the system is started. The calibration status reports are located on the system in the Archived section. Daily and weekly maintenance is logged on the Geenius Reader Maintenance log located at the testing bench. Refer to Attachment C, Geenius Reader Maintenance Log.

G. **Training and competency of testing personnel**
Training is completed with a training checklist when a new tech is trained on the Geenius procedure. Competency is evaluated twice in the first year of employment and annually thereafter, so long as the employee is employed in the Automated Chemistry department.

H. **Provisions for multiple identical devices, variations in use of the test system, multiple testing locations**
A lot to lot is performed before using a new cartridge lot with one positive patient and one negative patient, as well as positive and negative external controls.

V. IQCP: QUALITY ASSESSMENT MONITORING:

A. Ongoing quality assessment monitoring ensures that the quality control plan is effective in mitigating the identified risks for the IQCP. If ongoing assessments identify failures in one or more components of the quality control plan, the laboratory must investigate the cause and consider if modifications are needed to the quality control plan to mitigate potential risk. The CAP requires the following for quality assessment monitoring:

B. **Monthly review of quality control and instrument/equipment maintenance and function check data**
Appropriate Lead Medical Technologist reviews monthly quality controls in SOFT LIS TQC and

maintenance log located at the Geenius bench.

C. **Evaluation of errors relating to preanalytic, analytic, and post analytic phases of the testing process**
IQCP Problem Documentation Log located at the Geenius bench. This log is reviewed on a monthly basis by the appropriate Lead Medical Technologist and summarized into an IQCP QA Monthly Monitoring Log. Refer to Automated Chemistry IQCP, Attachment E, IQCP QA Monthly Monitoring Tool.

D. **Review of complaints from clinicians and other healthcare providers regarding the quality of testing to confirm the clinical efficacy of testing**
Quality Safety Reports (QSR) related to Geenius HIV 1/2 testing. IQCP QA Monthly Monitoring Log prepared by Lead Medical Technologist documenting complaints from various sources, reviewed on a monthly basis. Refer to Automated Chemistry IQCP, Attachment D, IQCP Problem Documentation Log.

E. **Evaluation of corrective actions taken if problems are identified**
On a monthly basis, the Lead Medical Technologist will review the IQCP QA Monthly Monitoring Log, refer to Automated Chemistry IQCP, Attachment D, IQCP Problem Documentation Log, and check for previous monthly documented corrective actions. The Lead Medical Technologist will then decide if the correct action was taken or if more follow-up is needed for a resolution.

F. **Biennial reapproval of the quality control plan by the laboratory director or designee**
Near the designated 24-month period end date, the Lead Medical Technologist will prepare an IQCP binder for the medical or technical director to review the IQCP QA Monthly Monitoring Log data that had been prepared and reviewed on a monthly basis by the Lead Medical Technologist. Refer to Automated Chemistry IQCP, Attachment D, IQCP Problem Documentation Log.

VI. REFERENCES:

1. CMS Step by step guide to IQCP (SC15-39 02 IQCP Workbook)
2. College of American Pathologists, 5 May 2015 - IQCP Frequently Asked Questions
3. IQCP Implementation Guide for Geenius HIV 1/2 Supplemental Assay

Attachments

Attachment C - Geenius Reader Maintenance Log.pdf
Attachment B - Geenius HIV 1-2 New Lot Verification Log.pdf
Attachment A - Geenius HIV 1-2 New Shipment Verification Log.pdf

Approval Signatures

Step Description	Approver	Date
Medical Director	Ann Marie Blenc: System Med Dir, Hematopath	11/18/2021
Policy and Forms Steering Committee Approval (if needed)	Gail Juleff: Project Mgr Policy	11/18/2021
Policy and Forms Steering Committee Approval (if needed)	Colette Kessler: Mgr Laboratory	11/17/2021

Step Description	Approver	Date
Lab Chemistry Best Practice Committee	Elizabeth Sykes: System Med Dir, Chemistry	11/17/2021
Lab Chemistry Best Practice Committee	Qian Sun: Tech Dir, Clin Chemistry, Path	11/17/2021
	Colette Kessler: Mgr Laboratory	11/17/2021

Applicability

Royal Oak