Beaumont Laboratory
Clinical Pathology
Royal Oak, MI 48073

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Related Documents:
RC.CH.LOP.QCQA.PY.021A

Automated Chemistry IQCP TEG 6s

RC.CH.LOP.QCQA.PY.021

Introduction

As stated by 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."

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 CAP requires that IQCP tests have an internal (electronic/procedural/built-in) quality control system.

IQCP Risk Assessment Document Review

Test System: TEG 6s
Manufacturer: Haemonetics

	IQCP Binder	Date Reviewed
Manufacturer instructions	Y	4/9/2018
Mf IQCP guidance document	Y	4/9/2018
Instrument manuals	Refer to _STAT lab Manuals Bench	4/9/2018
Manufacturer alerts, bulletins	Y	4/9/2018
FDA alerts	Y	4/9/2018
Lab procedure and worksheets	Y	6/21/2019
LTD entry	No entry in LTD at this time	N/A
Method validation data	Refer to _STAT lab MTII office	6/20/2019
Historical QC data	None – new method	N/A
PT results	Y – with validation data	7/2/2019

Personnel training records	Refer to STAT lab MTII office	6/21/2019
Competency records	Refer to STAT lab MTII office	At annual review
Physician/client complaints (all locations)	Y	5/31/2019
Canceled tests (all locations)	Y	5/31/2019
Corrected reports (all locations)	Y	5/31/2019
Regulatory requirements	Y	4/9/2018
Scientific publications	Y	4/9/2018

Summary of findings from supporting data:

Manufacturer recommendations for QC:

- The TEG 6s analyzer performs an internal QC check during the pretest when the cartridge is inserted.
- Assayed liquid controls each time a new lot or new shipment is to be used and at least monthly.
- Haemonetics IQCP guidance reviewed and incorporated into in-house risk assessment

Historical QC:

- Not available, as this test is new to the laboratory
- Liquid QC was performed according to manufacturer's recommendations described above to assess the performance and stability of TEG analysis over the maximum interval between runs of external QC (one month)

Proficiency Testing:

- No historical proficiency testing results were available, as this is a new test for the STAT lab.
- Future proficiency testing will be performed using API survey material so that no shared surveys are tested (TEG 5000 uses CAP surveys).

Training and Competency:

- All operators completed the objectives defined in the TEG 6s assay training checklist.
- All operators complete a competency assessment checklist on a semi-annual basis during the first year of employment and annually thereafter.

Physician Complaints:

- Physicians in trauma and ECMO services initially requested TEG methodology. Complaints will be reviewed and documented as described herein.

Corrected reports and cancelled tests:

- Documentation in IQCP worksheets. LIS reports will be reviewed and saved in S:\ClinPathChem\Automated Chemistry\IQCP\Corrected Reports-Cancellations

IQCP: Risk Assessment

See RC.CH.LOP.QCQA.PY.021A Attachment A – TEG 6s Risk Assessment

IQCP: Quality Control Plan

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.

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

Internal controls: The TEG 6s Power-On Self-Test performs internal QC checks on all analyzer functions prior to cartridge insertion. The analyzer also performs internal QC checks during a pretest when the cartridge is inserted. This verifies that all electromechanical and pneumatic functions of the analyzer-cartridge combination are operating satisfactorily. When in use, the analyzer monitors critical operational parameters throughout the test. Failure of any internal QC will invalidate the test and an error message will display.

External controls: [CAP requirement: External control material samples must be analyzed with new lots and shipments of reagents and as indicated in the manufacturer's instructions]: One normal donor control (fresh citrate tube from lab volunteer meeting donor acceptability criteria defined by Haemonetics) and one abnormal control (manufactured control, commercially available from Haemonetics) are to be tested under these circumstances:

1) With every newly trained operator as part of training (before patients have been resulted)
2) New test cartridge lot or shipment
3) New quality control lot
4) Temperature of cartridges or quality control material falls outside of acceptable ranges
5) Temperature of testing area falls outside of acceptable ranges, and
6) At least once per month.

Normal control results must fall within reference ranges approved in the TEG 6s procedure. Abnormal liquid QC must fall within QC ranges specified by Haemonetics in the lot-specific ranges provided with the QC material.

II. Documentation of complaints and testing errors (preanalytical, analytic, and post analytic)

An IQCP Problem Documentation log will be located at the TEG 6s work bench for documentation of errors/problems; refer to RC.CH.LOP.QCQA.PY014 Attachment D. Problems will be reviewed in real time by the bench technologist and STAT lab supervisor. The IQCP Problem Documentation log will be reviewed by the appropriate MTII 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.

III. Monitoring of the testing environment and reagents

TEG 6s cartridges and quality control materials are stored in the Stat Lab walk-in refrigerator. Testing is performed on the bench top in Stat Lab. The temperature of the walk-in unit and the room temperature is monitored and recorded by an electronic system. New lots and new shipments are marked with "New Lot" or "New Shipment" tags and not used for patient testing until the external liquid QC demonstrates acceptability.

IV. Specimen quality

Samples performed on the TEG 6s system should not be checked with wooden sticks for clots. Potential assay interferences will be documented where possible for patient specimens. According to Haemonetics, the CK assay interferences are hemolysis and hemodilution above 20%. Interferences for CRT assay include hemodilution above 20%. For the CKH assay, protamine concentrations above 0.062 mg/mL were found to interfere. For the CFF assay, heparin concentrations of 1 IU/mL and hemodilution above 30% interfere.

V. Instrument calibration, maintenance, and function checks

The TEG 6s analyzer performs internal QC checks during a pretest when the cartridge is inserted. This verifies that all electromechanical and pneumatic functions of the analyzer-cartridge combination are operating satisfactorily.

VI. Training and competency of testing personnel

Training is completed with a training checklist when a new tech is trained on the TEG 6s 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.

VII. Provisions for multiple identical devices, variations in use of the test system, multiple testing locations

The STAT lab has two of the same model of TEG 6s at the same bench and are used interchangeably, with the same operators, and under the same conditions. Both will be tested with the same lot of external liquid QC.

IQCP: Quality Assessment Monitoring

Ongoing quality assessment monitoring ensures that the quality control plan is effective in mitigating the identified risks for the test system. 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:

I. Monthly review of quality control and instrument/equipment maintenance and function check data

Appropriate MTII reviews monthly quality controls in Unity and maintenance log located at the TEG 6s bench.

II. Evaluation of errors relating to preanalytic, analytic, and post analytic phases of the testing process

IQCP Problem Documentation Log (RC.CH.LOP.QCQA.PY.014 Attachment D) is located at the TEG 6s bench and used daily by technologists to document errors. Errors addressed in real time are documented here, and the log is reviewed on a monthly basis by the appropriate MTII and summarized into an IQCP QA Monthly Monitoring Log (RC.CH.LOP.QCQA.PY.014 Attachment E).

III. Review of complaints from clinicians and other healthcare providers regarding the quality of testing to confirm the clinical efficacy of testing

Healthcare provider complaints and Quality Safety Reports (QSR) related to TEG 6s testing are addressed in real time and documented on the IQCP QA Monthly Monitoring Log

(RC.CH.LOP.QCQA.PY.014 Attachment E), which is prepared by the appropriate MTII and reviewed on a monthly basis.

IV. Evaluation of corrective actions taken if problems are identified

On a monthly basis, the MTII will review the prior months' IQCP QA Monthly Monitoring Log (RC.CH.LOP.QCQA.PY.014 Attachment E) and evaluate planned corrective actions and determine if more follow-up is needed for resolution.

V. Annual reapproval of the quality control plan by the laboratory director or designee

Near the end of the designated 12-month period, the MTII will summarize QC problems and other errors relating to pre-analytic, analytic, and post-analytic phases of the testing process using the IQCP annual assessment form (RC.CH.LOP.QCQA.PY.014 Attachment F), based on the monthly monitoring data collected throughout the year. After this review, the IQCP will be revised as necessary and reapproved by the medical or technical director annually, as indicated by signature of this document.

References

CMS Step by step guide to IQCP (SC15-39 02 IQCP Workbook)
CAP 5 May 2015 - IQCP Frequently Asked Questions
TEG 6s Platelet Mapping ADP package insert
TEG 6s Citrated: K, KH, RT, FF package insert
Haemonetics March 2015 IQCP Aid

Attachments

Attachment A: IQCP Risk Assessment Summary, TEG 6s

Authorized Reviewers

Initial Review – Medical Director, Beaumont Laboratory
Annual Review – Section Medical Director or Technical Director

Document Control

Location of Master: Master electronic file stored on the Beaumont Laboratory server under S:\ClinPathChem\Automated Chemistry\Document Control Library\NEW INDEX AND TEMPLATE\LOP Laboratory Operations\QCQA\Master
Master printed document stored in Chemistry Procedure Manual
Number of Controlled Copies posted for educational purposes: 0
Number of circulating Controlled Copies: 1
Location of circulating Controlled Copies: Stat Lab

Document History

Signature	Date	Revision #		Related Documents Reviewed/ Updated
Prepared by: Amber Macumber, MLS(ASCP)^{CM}, and Kelly Walewski, C(ASCP)^{CM}	05/31/2019	**r00**		
Approved by: Technical Director, STAT Lab Medical Director, Coagulation Medical Director, Beaumont Laboratory				
Reviewed by: (Signature)	**Date**	**Revision #**	**Modification**	**Related Documents Reviewed/ Updated**
