OLIVE VIEW-UCLA MEDICAL CENTER
DEPARTMENT OF PATHOLOGY
POLICY & PROCEDURE

NUMBER: 11786
VERSION: 1

SUBJECT/TITLE: **POCT -15-02 IQCP FOR ACT TEST WITH THE HEMOCHRON SIGNATURE ELITE**

POLICY: IQCP – Activated Clotting Time with the Hemochron Signature Elite

TEST SYSTEM: The Hemochron® Signature Elite is a quantitative assay for monitoring heparin anticoagulation during various medical procedures. The system measures whole blood clotting times using Hemochron Jr. disposable single-use cuvettes, ACT-LR. The Hemochron utilize a mechanical endpoint clotting mechanism in which clot formation occurs within the disposable ACT-LR cuvette. Following whole blood sample introduction, the instrument precisely measures 15 microliters of blood and automatically moves it into the test channel within the ACT-LR cuvette. Sample/reagent mixing and test initiation are performed automatically, requiring no operator interaction. After mixing with the reagent, the sample is then moved back and forth within the test channel and monitored clot formation.

The clot detection mechanism consists of a series of LED optical detectors aligned with the test channel of the cuvette. The speed at which the blood sample moves between the detectors is measured. As clot formation begins, blood flow is impeded and the movement slows. The instrument recognizes that the clot endpoint has been achieved when the movement decreases below a predetermined rate. The instruments report the Celite equivalent ACT value in seconds.

QUALITY REVIEW:

Electronic Quality Control (EQC)

EQC was tested from April 15 to May 31, 2019 and data was reviewed. There were no instances recorded of electronic control failure.

External Liquid Quality Controls (directCheck Whole Blood Controls)

Liquid controls were tested from April 15 to May 31, 2019, for two lot numbers each for Normal and Abnormal controls run on four Hemochron Signature Elite devices. QC results were compared to acceptable ranges for each lot that have been established at the manufacturer's facility. QC results were all within the established reference ranges. Mean, standard deviation and coefficient of variation were calculated. Studies showed that test results produced a coefficient of variation of approximately 14% or less throughout the study.

RISK ASSESSMENT

Information Used to Conduct Risk Assessment

- Regulatory and accreditation requirements
  1. Checklists from accrediting agency – College of American Patholigists (CAP)
     COM.50200 List of IQCP
     COM.50300 Risk Assessment
     COM.50400 QCP Approval
     COM.50500 QCP Elements
     COM.50600 QA Monitoring
  2. Centers for Medicare and Medicaid Services IQCP Memorandum
- Hemochron IQCP Risk Assessment Tool
- Manufacturer's Operator Manual
- Manufacturer's test cuvette package inserts
- Testing personnel qualifications, training and competency assessment
- Quality control data
- Interviews with staff nurses
- CAP and IQCP webinars

Determination of Risk Assessment

Our facility utilized the Hemochron IQCP Risk Assessment Tool and comments for Risk Mitigation that helps identify the risk-mitigation features and control methods associated with the Hemchron Signature Elite system. The risk assessment tool presents potential risks in the testing process, potential failures, and potential related failure causes by identifying the hazard, target failure mode and risk mitigation features. This tool also identifies areas of the Hemochron Operator's Manual and other documents to review for specific risk related information. Additonal facility specific potential risks were discovered during research for creating the IQCP and were added to the tool.

Our facility utilized the Hemochron IQCP Risk Assessment Tool to document the laboratory's determination of the Risk with frequency of occurrence, severity of harm and residual risk score. This determination was based on information gathered during the investigation for creating the IQCP.

INDIVIDUALIZED QUALITY CONTROL PLAN

In summary, the Quality Control Plan requirements for the Hemochron Signature Elite, ACT testing includes:

Risk Assessment

Pre-Analytic Phase

- Temperature checks of room and refrigerator
- Maintenance of instrument
- Calibration
- Operator's Training
- Proficiency Testing
- Specimen collection

Analytic Phase

- Electronic Quality Control (EQC) every 8 hours
- directCheck Normal and Abnormal Controls (LQC) once a week
- Testing sample

Post-Analytic Phase

- Reporting of result electronically

Quality Control Plan:

- Pre Analytic Phase
- Analytic Phase
- Post Analytic Phase

Quality Assessment monitoring process will include:

- EQC and LQC review
- Room and refrigerator temperature logs
- 20 runs of QC for new lot
- Procedure and policy review
- Proficiency testing records
- Maintenance records
- Chart review
- Competency assessment

SEE ATTACHED DATA

References: IQCP Individualized Quality Control Plan. Developing an IQCP A Step-By-Step Guide. CDC.CMS CAP Common Checklist August 21, 2017 http://www.cdc.gov/clia/.	
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