TITLE: Quality Control Plan (QCP) and Quality Assessment Plan (QAP)

of the Individualized Quality Control Program (IQCP)

PURPOSE: The Quality Control Plan - defines all aspects monitored based on risk assessment. The Quality Control Plan (QCP) is the laboratory’s standard operating procedure describing the practices and resources to ensure quality for a test system. The Quality Assessment Plan (QAP) is the laboratory’s policy for monitoring the effectiveness of the IQCP.

SCOPE: Applies to all non-waived testing within the laboratory that does not have two or more levels of controls run each day of testing.

PROCEDURE: The Quality Control Plan is followed for each test/test system as outlined in the Quality Control Plan charts below. Routine troubleshooting and investigation must be performed and documented for any outliers as outlined in the specific quality control procedures for each test/test system.

The Quality Assessment Plan for each test/test system is outlined in the charts below and includes the activiy to monitor and the frequency. If and when error(s) occurs, that is unacceptable, a formal investigation must take place to see if there are any steps that could be either added or change existing ones to better *reduce\** error and suite testing needs.

Alere Determine Rapid HIV-1/2 Ag/Ab Combo

Quality Control Plan:

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| Type of Quality Control | Frequency | Criteria for Acceptability  (Range of Acceptable Values) |
| Temperature Checks  Room temp lab  Room temp storage room | Daily | Between 15 – 30⁰C  Between 2 – 30⁰C |
| Verify specimen acceptable (cloudy samples are centrifuged) | With each specimen | |  | | --- | | Refer to Specimen type and handling in sop | |
| Verify patient ID | With each step of process | Follow written procedures regarding specimen labeling and entry of patient results in LIS |
| Internal QC | Each specimen | Internal control must be valid, Result is observed and recorded for each specimen. |
| External QC – 2 levels | |  | | --- | | At least every 31 days, when a new operator performs testing, a new test kit lot/shipment is to be used, if the temperature of the test storage area falls outside of 2 - 30⁰C, or if the temperature of the testing area falls outside of 15 - 30⁰C assay positive and negative levels of quality control. | | |  | | --- | | Acceptable ranges – POSITIVE and NEGATIVE    Results must be recorded on quality control and reagent lot verification log sheet prior to reporting results. | |
| Result Reporting | Each result at time of entry  Each result during worksheet review | Follow written procedures and record results appropriately  Results on worksheet must match value entered in LIS |

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| Training | |  | | --- | | With each new testing personnel and when indicated. | | |  | | --- | | Successful demonstration of test performance.  Document training activities | |
| Competency Assessment | |  | | --- | | Six months and one year after initial training, annually thereafter. | | |  | | --- | | All testing personnel must successfully meet all six CLIA elements for competency assessment | |

Quality Assessment Plan

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| QA Activity to Monitor | Frequency | |  | | --- | | ASSESSMENT OF QA ACTIVITY  (Was there variation from established policy and procedures?) | | |  | | --- | | CORRECTIVE ACTION (WHEN INDICATED) | |
| Review package inserts | Each new lot to ensure any changes are incorporated into procedures.  Checked Monthly to ensure | Package insert is kept and filed for each new lot received. | Pull new sheet if new lot is not located. |
| |  | | --- | |  |   Review QC, lot to lot logs | Monthly | Logs are signed off after review and issues noted | Review at Quality meeting and adjust QCP if issues arise |
| Review PT surveys   |  | | --- | |  | | Each survey upon receipt of results | Take note of unacceptable results and follow PT failure process | Review at Quality meeting and adjust QCP if issues arise |
| Verify patient id | With each specimen –  Each shift | Monitor during competency assessment  During review of manual worksheets – | Correct identified errors, errors monitored. Adjust QCP if issues arise |
| Verify all reagents/cassettes are within date range and stored appropriately | Periodically  Daily | When each new lot/shipment arrive and external QC is performed (storage), record dates  Cassette expiration date checked with use | Correct identified errors by removing expired product. Adjust order schedule. Adjust QCP if issues continues. |
| Result review | Each shift - | Review manual result entry. Ensure result printout matches result recorded manually in LIS | Errors monitored. Adjust QCP if issues arise |
| Competency Assessment | Annually after first year of employment | Meet all six CLIA elements for competency assessment | Retrain and no testing performed by that staff member until competence is met. |
| Discuss QA findings | Quarterly | Quality Meeting – QCP assessment will be discussed | Adjust QCP based on new risks not previously identified |
| Revise policies and procedures | As needed and every 2 years | Procedure review performed every 2 years. Inserts are reviewed for changes each lot and other changes are identified from manufacturer or as identified by product notification memos from the manufacturer | Adjust QCP based on revisions identified. |

RELATED PROCEDURES:

SERO-711 Alere Determine HIV ½ Ag/Ab Combo

QM-150 IQCP

SUPPLEMENTAL MATERIALS/ADDENDUM:

Risk Assessment for each test/test system

Individualized Qualy Control Plan Summary for each test/test system

List of Individualized Quality Control Plans

REFERENCES:

Current CAP Checklist

Published Power Point Presentation for CAP by Lyn Wielgos, MT(ASCP), December 8, 2015

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HISTORY PAGE

SOP Number: QM-151

SOP Title: Quality Control Plan (QCP) and Quality Assessment Plan (QAP)

of the Individualized Quality Control Program (IQCP)

Written By: Wendy Turner

Manual in which Hard Copy of this SOP is located: Quality Management

Distribution: no other locations

Supersedes Procedure:

SOP CHANGE CONTROL

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