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-microbiology 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.

TCA – Siemens Syva RapidTest

Quality Control Plan:

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| Type of Quality Control | Frequency | Criteria for Acceptability(Range of Acceptable Values) |
| Temperature ChecksRoom temp labRoom temp storage roomRefrigerator (liquid QC) | Daily | Between 15 – 30⁰C Between 15 – 30⁰C Between 2 – 8⁰C |
| Verify specimen acceptable (cloudy samples are centrifuged) | With each specimen |

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| Refer to Specimen type and handling of TCA sop  |

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| 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 |

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| Weekly and with Each new lot/shipment assay positive and negative levels of quality control.  |

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| Acceptable ranges – POSITIVE and NEGATIVE  Results must be recorded on quality control log sheet prior to reporting results. *Once complete, record the new shipment/new lot control results on the NEW REAGENT LOT VERIFICATION and EXTERNAL QC log and tape the control printout on the Calibration and External QC form located on the clipboard behind the QC log.**Tape the monthly control results to the fFN Analyzer, fFN Cassette, TCA Cassette QC Log* |

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| Result Reporting | Each result at time of entryEach result during worksheet review | Follow written procedures and record results appropriatelyResults on worksheet must match value entered in LIS |

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| Training |

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| With each new testing personnel and when indicated.  |

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| Successful demonstration of test performance. Document training activities  |

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| Competency Assessment |

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| Six months and one year after initial training, annually thereafter.  |

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| All testing personnel must successfully meet all six CLIA elements for competency assessment  |

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Quality Assessment Plan

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| QA Activity to Monitor | Frequency |

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| ASSESSMENT OF QA ACTIVITY (Was there variation from established policy and procedures?)  |

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| CORRECTIVE ACTION (WHEN INDICATED) |

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| Review package inserts | Each new lot to ensure any changes are incorporated into procedures.Checked Monthly to ensure | Package inserts are kept and reviewed for each new lot received and replaced if changes are made | Pull new sheet if new lot is not located. |
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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

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 | 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 assessmentDuring 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 | PeriodicallyDaily  | When each new lot/shipment arrive and external QC is performed (storage), record datesCassette 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 | Adjsut QCP based on new risks not previously identified |
| Revise policies and procedures | As needed and every 2 years | Proceudre 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. |

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 ChecksRoom temp labRoom temp storage room | Daily | Between 15 – 30⁰C Between 2 – 30⁰C  |
| Verify specimen acceptable (cloudy samples are centrifuged) | With each specimen |

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| 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 |

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| 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.  |

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| Acceptable ranges – POSITIVE and NEGATIVE  Results must be recorded on quality control and reagent lot verification log sheet prior to reporting results.  |

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| Result Reporting | Each result at time of entryEach result during worksheet review | Follow written procedures and record results appropriatelyResults on worksheet must match value entered in LIS |

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| Training |

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| With each new testing personnel and when indicated.  |

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| Successful demonstration of test performance. Document training activities  |

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| Competency Assessment |

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| Six months and one year after initial training, annually thereafter.  |

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| All testing personnel must successfully meet all six CLIA elements for competency assessment  |

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Quality Assessment Plan

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| QA Activity to Monitor | Frequency |

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| ASSESSMENT OF QA ACTIVITY (Was there variation from established policy and procedures?)  |

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| CORRECTIVE ACTION (WHEN INDICATED) |

 |
| Review package inserts | Each new lot to ensure any changes are incorporated into procedures.Checked Monthly to ensure | Package inserts are kept and reviewed for each new lot received and replaced if changes are made | Pull new sheet if new lot is not located. |
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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

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 | 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 assessmentDuring 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 | PeriodicallyDaily  | When each new lot/shipment arrive and external QC is performed (storage), record datesCassette 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. |

ACT Hemochron Signature Elite

Quality Control Plan:

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| Type of Quality Control | Frequency | Criteria for Acceptability(Range of Acceptable Values) |
| Temperature ChecksRoom temp labRefrigerator (liquid QC) | Daily | Between 15 – 30⁰C Between 2 – 8⁰C |
| Cuvette storage | Daily | All items should be within expiration date range |
| Verify patient ID | Specimen collection | Follow written procedures regarding specimen labeling and entry of patient results in LIS |
| Electronic QC | Every 8 hours | PASS |
| External QC – 2 levels |

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| Every 28 days, reagent lot correlations |

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| Acceptable ranges are published on back page of package insert in each box of QC material  |

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| Result Reporting | Each result at time of entryDaily | Follow written procedures and record results appropriatelyDaily review of the accuracy of result recording in the electronic medical record will be conducted on the previous working day’s ACT results. Confirmation that this review has been completed will be recorded on the daily crash cart review sheet. Results should match. |

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| Training |

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| With each new testing personnel and when indicated.  |

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| Successful demonstration of test performance. Document training activities  |

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| Competency Assessment |

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| Six months and one year after initial training, annually thereafter.  |

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| All testing personnel must successfully meet all six CLIA elements for competency assessment  |

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Quality Assessment Plan

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| QA Activity to Monitor | Frequency |

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| ASSESSMENT OF QA ACTIVITY (Was there variation from established policy and procedures?)  |

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| CORRECTIVE ACTION (WHEN INDICATED) |

 |
| Review package inserts | Each new lot to ensure any changes are incorporated into procedures.Checked Monthly to ensure | Package inserts are kept and reviewed for each new lot received and replaced if changes are made. | Pull new sheet if new lot is not located. |
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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

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 | 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 – daily | Monitor during competency assessmentDuring 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 | PeriodicallyDaily  | When each new lot/shipment arrive and external QC is performed (storage), record datesCuvette 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, staff counseled. 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 | Adjsut QCP based on new risks not previously identified |
| Revise policies and procedures | As needed and every 2 years | Proceudre 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. |

FFN – Adeza TLi

Quality Control Plan:

|  |  |  |
| --- | --- | --- |
| Type of Quality Control | Frequency | Criteria for Acceptability(Range of Acceptable Values) |
| Temperature ChecksRoom temp labStorage room tempRefrigerator (liquid QC) | Daily | Between 15 – 30⁰C Between 15 – 30⁰C Between 2 – 8⁰C |
| Cuvette storage | Daily | All items should be within expiration date range |
| Verify patient ID | Specimen collection | Follow written procedures regarding specimen labeling and entry of patient results in LIS |
| Calibration | Each New Cassette Lot number | SYSTEM CALIBRATED |
| TLi QCette | Daily | SYSTEM PASS |
| Internal QC | Each test | Valid = PASS |
| External QC – 2 levels |

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| Monthly and reagent lot correlations |

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| Positive and Negative  |

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| Result Reporting | Each result at time of entryDaily | Follow written procedures and record results appropriatelyDaily review of the accuracy of result recording in the LIS will be conducted each shift |

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| Training |

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| With each new testing personnel and when indicated.  |

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| Successful demonstration of test performance. Document training activities  |

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| Competency Assessment |

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| Six months and one year after initial training, annually thereafter.  |

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| All testing personnel must successfully meet all six CLIA elements for competency assessment  |

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Quality Assessment Plan

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| QA Activity to Monitor | Frequency |

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| --- |
| ASSESSMENT OF QA ACTIVITY (Was there variation from established policy and procedures?)  |

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| CORRECTIVE ACTION (WHEN INDICATED) |

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Review QC, calibration and 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

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 | 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 – daily | Monitor during competency assessmentDuring 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 | PeriodicallyDaily  | When each new lot/shipment arrive and external QC is performed (storage), record datesCuvette expiration date checked with use | Correct identified errors by removing expired product. Adjust order schedule. Adjust QCP if issues continues. |
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RomPlus Fetal Membrane Rupture

Quality Control Plan:

|  |  |  |
| --- | --- | --- |
| Type of Quality Control | Frequency | Criteria for Acceptability(Range of Acceptable Values) |
| Temperature ChecksRoom temp labRoom temp storage roomRefrigerator (liquid QC) | Daily | Between 15 – 24⁰C Between 4 – 24⁰C Between 2 – 8⁰C |
| Verify specimen acceptable  | With each specimen |

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| --- |
| Refer to Specimen type and handling 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 |

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| Each new lot and/or shipment or monthly – whichever comes first, new operator, and with suspicious results assay positive and negative levels of quality control.  |

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| Acceptable ranges – POSITIVE and NEGATIVE  Results must be recorded on quality control log sheet prior to reporting results.  |

 |
| Result Reporting | Each result at time of entryEach result during worksheet review | Follow written procedures and record results appropriatelyResults on worksheet must match value entered in LIS |

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| Training |

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| With each new testing personnel and when indicated.  |

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| Successful demonstration of test performance. Document training activities  |

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| Competency Assessment |

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| Six months and one year after initial training, annually thereafter.  |

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| All testing personnel must successfully meet all six CLIA elements for competency assessment  |

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Quality Assessment Plan

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| QA Activity to Monitor | Frequency |

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| ASSESSMENT OF QA ACTIVITY (Was there variation from established policy and procedures?)  |

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| CORRECTIVE ACTION (WHEN INDICATED) |

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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

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 | 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 assessmentDuring 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 | PeriodicallyDaily  | When each new lot/shipment arrive and external QC is performed (storage), record datesCassette 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 |
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| 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:

CHEM-120 Quality Control Procedure (Chemistry)

CHEM-755 Fetal Fibronectin

TCA Stepwise procedure

SERO-711 Alere Determine HIV ½ Ag/Ab Combo

UA-716 ROMPlus Fetal Membrane Rupture Test

COAG-701 ACT – Activated Clotting Time

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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| Review Date | Signature | Mgmt. | Director |
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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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|   | Approvals |   | Action | In |
| Mgmt. | Date |  Director | Date |   | Effect |
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