TITLE: Microbiology 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 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 activity 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.

Media

Quality Control Plan:

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| Type of Quality Control | Frequency | Criteria for Acceptability  (Range of Acceptable Results) |
| Temperature Checks  Room temp lab  Refrigerator | Daily | Between 15 – 30⁰C  Between 2 – 8⁰C |
| Verify media sterility and visual acceptability. | With each shipment or lot number | |  | | --- | | Refer to Media Quality Control SOP |   Monitor expiration dates. |
| External QC | |  | | --- | | Each new lot/shipment with appropriate ATCC organisms. | | |  | | --- | | Acceptable ranges – Growth or No growth  Results must be recorded on quality control log sheet prior to reporting results. | |

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| Training | |  | | --- | | With each new testing personnel and when indicated. | | |  | | --- | | Successful demonstration of test performance.  Document training activities |   Refer to Plating SOP. |
| 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 | Corrective Action When Indicated |
| Temperature Checks  Room Temp lab  Refrigerator | Daily | Between 15 - 30ºC  Between 2 - 8ºC | Contact clinical engineering or plant ops if problem persists. |
| Verify Media and visual Inspection | Each new lot and shipment  Monthly | Review media shipment and variance logs  Review of manufacturer’s CoAs and PIs and media alerts.  Monitor for trending organisms (possible contamination) | Contact manufacturer and discontinue use.  Contact manufacturer and discontinue use.  Contact manufacturer and discontinue use. |
| External QC – ATCC organisms | Each new lot and shipment | Monthly review of logs. | Contact manufacturer and discontinue use. |
| Training | Each new hire | With each new testing personnel and when indicated. | Successful demonstration of test performance.  Document training activities. |
| Competency | 6 months, 1 year, and annually thereafter. | Meet all six CLIA elements for competency assessment | Retrain and no testing performed by that staff member until competence is met. |

Cepheid - GeneXpert

Quality Control Plan:

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| Type of Quality Control | Frequency | Criteria for Acceptability (Range of Acceptable Results) |
| Temperature  Checks  Room Temperature  Instrument function checks | Daily  With each test | Between 15 - 30º C  Pass or Fail |
| Verify specimen acceptable | Each specimen | Refer to MICRO-725, MICRO-724, MICRO-723, MICRO-721,MICRO-(SA NASAL COMPLETE) |
| Verify patient ID | With each step of process | For written procedures regarding specimen labeling and entry of patient results in LIS. |
| Perform PT Surveys | 2 – 4 times annually (per CAP requirement) | Follow written procedure for handling CAP PT surveys and the test specific instructions with each shipment. |
| Internal QC | Each specimen | Internal control must be valid. Results are observed and recorded for each specimen. |
| External QC- (2 or 3 organisms) | Each new lot or shipment | Acceptable Ranges – Positive or Negative  Results must be recorded on the appropriate log. |
| Result Reporting | Each result at time of entry.  Each result during worksheet review.  As needed. | Follow written procedures and record results appropriately.  Results on worksheet must match result entered in LIS.  Investigate complaints and remediation ASAP. |
| Training | With each new testing personnel and when indicated. | Successful demonstration of test performance.  Document training activities. |
| Competency Assessment | 6 months and 1 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 | 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 | Replace if changes are indicated and update procedure | |
| Review, temperature logs, QC, lot to lot logs, and instrument function checks. | Monthly | Logs are reviewed and signed off. Any issues are noted.  Unexpected errors are investigated immediately and remediated if needed. | 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 and specimen integrity. | With each specimen  Daily  With each specimen | Monitor during competency assessment.  During review of manual worksheets. | Correct identified errors, errors monitored. Adjust QCP if issues arise.  Inadequate specimens are entered into SZP and reviewed by management. | |
| 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 Reporting review | Daily  As needed  Monthly | Laboratory investigation of errors. Review manual result entry. Ensure result printout matches result recorded manually in LIS. Ensure valid internal QC.  Complaint investigation and remediation.    Calculate CT/NG positivity rate to detect potential false positive due to cross contamination. | | Errors monitored. Adjust QCP if issues arise.  Enter into SZP as required. |
| Training | With each new hire. | With each new testing personnel and when indicated. | | Successful demonstration of test performance.  Document training activities. |
| 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. |

C. diff Quik Chek

Quality Control Plan:

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| Type of Quality Control | Frequency | Criteria for Acceptability (Range of Acceptable Results) |
| Temperature  Checks  Refrigerator  Room Temperature | Daily | Between 2 - 8ºC  Between 15 - 30º C |
| Verify specimen acceptable | Each specimen | Refer MICRO-725 and MICRO-722 |
| Verify patient ID | With each step of process | For written procedures regarding specimen labeling and entry of patient results in LIS. |
| Internal QC | Each specimen | Internal control must be valid. Results are observed and recorded for each specimen. |
| External QC- (2 levels) | Each new lot or shipment  If same lot, QC performed every 31 days, when new operator. | Acceptable Ranges – Positive or Negative  Results must be recorded on the appropriate log. |
| Perform PT Surveys | 2 – 4 times annually (per CAP requirement) | Follow written procedure for handling CAP PT surveys and the test specific instructions with each shipment. |
| 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 result entered in LIS. |
| Training | With each new testing personnel and when indicated. | Successful demonstration of test performance.  Document training activities. |
| Competency Assessment | 6 months and 1 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 | 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 | Replace if changes are indicated and update procedure | |
| Review temperature logs, QC, lot to lot logs, and instrument function checks. | Monthly and with each new lot and/or shipment | Logs are reviewed and signed off. Any issues are 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 and specimen integrity. | With each specimen  Daily  With each specimen | Monitor during competency assessment.  During review of manual worksheets. | Correct identified errors, errors monitored. Adjust QCP if issues arise.  Inadequate specimens are entered into SZP and reviewed by management. | |
| 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 | Daily  As needed | Review manual result entry. Ensure result printout matches result recorded manually in LIS. Ensure valid internal QC.  Complaints investigated and remediated. | | Errors monitored. Adjust QCP if issues arise.  Enter into SZP if needed. |
| Training | Each new hire | With each new testing personnel and when indicated. | | Successful demonstration of test performance.  Document training activities. |
| 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. |

ImmunoCard STAT EHEC

Quality Control Plan:

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| Type of Quality Control | Frequency | Criteria for Acceptability (Range of Acceptable Results) |
| Temperature  Checks  Refrigerator  Room  Incubator  Temperature | Daily | Between 2 - 8ºC  Between 15 - 30ºC  Between 33 - 35ºC |
| Verify specimen acceptable | Each specimen | Refer MICRO-725 and MICRO-722 |
| Verify patient ID | With each step of process | For written procedures regarding specimen labeling and entry of patient results in LIS. |
| Internal QC | Each specimen | Internal control must be valid. Results are observed and recorded for each specimen. |
| External QC- (2 levels) | Each new lot or shipment  If same lot, QC performed every 31 days, when new operator. | Acceptable Ranges – Positive or Negative  Results must be recorded on the appropriate log. |
| 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 result entered in LIS. |
| Training | With each new testing personnel and when indicated. | Successful demonstration of test performance.  Document training activities. |
| Competency Assessment | 6 months and 1 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 | 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 | Replace if changes are indicated and update procedure | |
| Review temperature logs, QC, lot to lot logs, and instrument function checks. | Monthly and each new lot number and/or shipment | Logs are reviewed and signed off. Any issues are 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 and specimen integrity. | With each specimen  Daily  With each specimen | Monitor during competency assessment.  During review of manual worksheets. | Correct identified errors, errors monitored. Adjust QCP if issues arise.  Inadequate specimens are entered into SZP and reviewed by management. | |
| 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 | Daily  As needed | Review manual result entry. Ensure result printout matches result recorded manually in LIS. Ensure valid internal QC.  Complaints investigated and remediated. | | Errors monitored. Adjust QCP if issues arise.  Entered in SZP as needed. |
| Training | With each new hire | With each new testing personnel and when indicated. | | Successful demonstration of test performance.  Document training activities. |
| 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. |

ImmunoCard STAT CAMPY

Quality Control Plan:

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| Type of Quality Control | Frequency | Criteria for Acceptability (Range of Acceptable Results) |
| Temperature  Checks  Refrigerator  Room Temperature | Daily | Between 2 - 8ºC  Between 15 - 30º C |
| Verify specimen acceptable | Each specimen | Refer MICRO-725 and MICRO-722 |
| Verify patient ID | With each step of process | For written procedures regarding specimen labeling and entry of patient results in LIS. |
| Internal QC | Each specimen | Internal control must be valid. Results are observed and recorded for each specimen. |
| External QC- (2 levels) | Each new lot or shipment  If same lot, QC performed every 31 days, when new operator. | Acceptable Ranges – Positive or Negative  Results must be recorded on the appropriate log. |
| 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 result entered in LIS. |
| Training | With each new testing personnel and when indicated. | Successful demonstration of test performance.  Document training activities. |
| Competency Assessment | 6 months and 1 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 | 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 | Replace if changes are indicated and update procedure | |
| Review temperature logs, QC, lot to lot logs, and instrument function checks. | Monthly or with new lot and/or shipment. | Logs are reviewed and signed off. Any issues are 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 and specimen integrity. | With each specimen  Daily  With each specimen | Monitor during competency assessment.  During review of manual worksheets. | Correct identified errors, errors monitored. Adjust QCP if issues arise.  Inadequate specimens are entered into SZP and reviewed by management. | |
| 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 | Daily  As needed | Review manual result entry. Ensure result printout matches result recorded manually in LIS. Ensure valid internal QC.  Investigate and remediate complaints as needed. | | Errors monitored. Adjust QCP if issues arise.  Enter into SZP as needed. |
| Training | With each new hire | With each new testing personnel and when indicated. | | Successful demonstration of test performance.  Document training activities. |
| 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. |

Vitek 2 Compact 2 AST

Quality Control Plan:

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| Type of Quality Control | Frequency | Criteria for Acceptability (Range of Acceptable Results) |
| Temperature  Checks  Refrigerator  Vitek 2  Room Temperature | Daily | Between 2 - 8ºC  Between 34.5 – 36.5ºC  Between 15 - 30º C |
| Optics | Daily | Pass or Fail |
| Verify specimen acceptable | Each specimen | Refer to MICRO-755, MICRO-107, MICRO-605, MICRO-754, MICRO-106, MICRO-105 |
| Verify patient ID | With each step of process | For written procedures regarding specimen labeling and entry of patient results in LIS. |
| Internal QC | Each specimen | There must be sufficient growth in the positive growth well. |
| External QC- (streamline ATCC organisms) | Each new lot, shipment and  weekly | Acceptable Ranges – MIC must be within acceptable range. Refer to package insert.  Results are monitored and stored in the Vitek QC notebook. |
| Result Reporting | Each result at time of entry. | Follow written procedures and record results appropriately. |
| Training | With each new testing personnel and when indicated. | Successful demonstration of test performance.  Document training activities. |
| Competency Assessment | 6 months and 1 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 | 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 | Replace if changes are indicated and update procedure | |
| Review temperature log, QC, optics, and instrument function checks. | Weekly  Monthly | QC results are reviewed and filed. Refer to MICRO-106 and MICRO-105  Logs are reviewed and signed off. Any issues are noted.  Review monthly turbidity calibration. | Review at Quality Meeting and adjust QCP if issues arise. Testing appropriate strains against any new antimicrobial agent added to a panel 30 consecutive days with no errors prior to resuming weekly QC. | |
| 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 and specimen integrity. | With each specimen  Daily  With each specimen | Monitor during competency assessment.  During review of manual worksheets. | Correct identified errors, errors monitored. Adjust QCP if issues arise.  Inadequate specimens are entered into SZP and reviewed by management. | |
| 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 | Daily  Monthly  As needed | Patient and QC Prelim and final reports are reviewed for valid internal QC (positive growth well) and accuracy by tech and/or section lead.  Length of time of specimen collection to final result beyond 7 days.  Investigate and remediate complaints as needed. | | Correct identified errors and document.  Investigate and document.  Enter into SZP as needed. |
| Training | With each new hire | With each new testing personnel and when indicated. | | Successful demonstration of test performance.  Document training activities. |
| 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:

QM-150 IQCP

MICRO-755 VITEK 2 ORGANISM IDENTIFICATION AND SUSCEPTIBILITY RESULTS

MICRO-107 VITEK SALINE STERILITY

MICRO-605 VITEK 2 MAINTENANCE

MICRO-754 DENSICHECK PLUS

MICRO-106 WEEKLY VITEK 2 QC

MICRO-105 VITEK 2 ENTERING AND RUNNING NEW LOT CARDS

MICRO- MEDIA QC

MICRO-725 C.DIFF ASSAY BY PCR

MICRO-724 MRSA PCR

MICRO-723 XPERT FLU

MICRO-721 CT/NG ASSAY PCR

MICRO- SA NASAL COMPLETE

MICRO-722 C.DIFF QUIK CHEK COMPLETE

MICRO-707 IMMUNOCARD STAT EHEC

MICRO-706 IMMUNOCARD STAT CAMPY

SUPPLEMENTAL MATERIALS/ADDENDUM:

Risk Assessment for each test/test system

Individualized Quality 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-150

SOP Title: Microbiology Quality Control Plan (QCP) and Quality Assessment Plan (QAP) of the Individualized Quality Control Program (IQCP)

Written By: Jacee Farmer and Shaye Yarbrough

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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