AHC.QA40 Quality Control Program

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7.0	Approved and Current	Major revision	7/18/2022	7/18/2022	Indefinite
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5.0	Retired	Initial version	2/6/2019	4/1/2019	9/21/2020

Linked Documents

- AG.F187 Patient Look-Back Log
- AG.F209 Vista QC Schedule WOMC
- AG.F 536 QC Max SD Calculator
- AG.F 543 Dimension EXL QC Schedule
- AG.F 598 Atellica Solution QC Schedule

Non-Technical SOP

Title	**Quality Control Program**	
Prepared by	Robert SanLuis	Date: 8/18/2011
Owner	Cynthia Bowman-Gholston	Date: 8/18/2011

Laboratory Approval		
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		
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1. PURPOSE

This procedure establishes the guidelines for implementation and management of the laboratory's Quality Control (QC) program. Deviation from these guidelines must be approved by the Laboratory's Medical Director and must be documented in the standard operating procedure for the particular procedure.

2. SCOPE

Both qualitative and quantitative laboratory tests require quality control. This procedure provides guidelines for the frequency and any corrective actions necessary in the event of failed or out of range quality control.

2.1 QUANTITATIVE

A. QC materials provide objective assessment of method accuracy and precision and laboratory techniques. They also contribute an integral part of good laboratory practice.
B. QC testing ensures that laboratories report accurate and reliable test results. These materials best represent actual patient specimens and contain analytes with concentrations that approximate realistic values.

C. QC testing provides a performance check on the entire testing system: instrument function, operator competence, inventory management, and environmental conditions; all contribute to a successful quality control system. These attributes should be considered when quality control testing is questionable.
D. The quantitative QC assessment at Quest Diagnostics at Adventist HealthCare Laboratories relies upon the verification of each new lot of control material against the manufacturer's ranges or the peer group performance.
E. The Laboratory QC Module, functions through a series of rules which are applied to QC results to evaluate acceptable, using the two standard deviation range that falls within the manufacturer's published range or compares with a peer group on the same system. Technologists document all corrective actions in the Laboratory QC Module (LIS, Data Innovation [DI], or Bio-Rad Unity Real Time).
F. The supervisors evaluate QC statistics for assay specific controls from data gathered under similar operating conditions as patient testing, or based upon the manufacture's specifications.

2.2 QUALITATIVE

A. For kits that have internal and external qualitative control requirements, the frequency of control is in accordance with the manufacturer's guidelines, unless otherwise stated within the respective operating procedure for the assay. An Individualized Quality Control Plan (IQCP) is performed when necessary (refer to Quality Management Plan for detailed information). The external material will be as close in nature as the patient sample.
B. If external material ships with the kit, this material will be the primary control.
C. For kits or assays without accompanying external material, the QC material will still reflect the consistency of the patient sample, i.e. the control for the urine pregnancy will be a urine control material.
D. For microbiology, quality control materials such as ATCC strains of bacteria are selected to best represent (as possible) actual patient specimens and to approximate realistic results. The QC program also includes testing and monitoring of media.

3. RESPONSIBILITY

3.1 General Guidelines

A. Each testing person for qualitative or quantitative testing must ensure that quality control adheres to the specified requirements for control frequency as specified in the SOP for each test.
B. Each testing person will ensure that the QC met the acceptable performance limits prior to reporting patient results. **No patient results can be reported until the method has been validated using the established QC rules**.
C. Each testing person will ensure QC material will be analyzed at established intervals and in the same manner as patient samples.

D. Each testing person will ensure that all unacceptable QC results are investigated and appropriate actions documented electronically or on the QC/Action Log as appropriate.
E. Each testing person will ensure the recording of all control results on the worksheet (paper), in the instrument (automatic process), LIS, or DI/Bio-Rad Unity Real Time. Where applicable, instrument printouts and manual control records will be retained for 2 years (5 years for Blood Bank QC records).
F. **THE TESTING PERSON WILL VERIFY THAT THE LOT NUMBER AND EXPIRATION DATE OF ALL QC MATERIAL IS CURRENT AND WITHIN DATE PRIOR TO RELEASING PATIENT RESULTS.**
G. The testing person will ensure the documentation of control results in accordance with the guidelines for the particular test being performed. (See test-specific procedure)
H. Refer to the procedure QC Responsibilities and Review for additional details.

4. DEFINITIONS

A. Action Codes – standard remedial / corrective descriptions for failed QC established in Sunquest, DI, and Bio-Rad Unity, refer to attachment A.
B. Analytical Run – the interval within which the accuracy and precision of the measuring system is expected to be stable.
C. Assayed controls – the manufacturer has tested the control material in replicate and provided lot-specific mean values (along with upper and lower limits). Individual laboratory means should fall within the manufacturer's calculated limits. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents, or by modification of the manufacturer's test method.
D. Comment Codes – descriptions used to explain rationale for repeating QC. May be used in conjunction with an Action Code but never used solely to describe remedial action.
E. Control Limits – the upper and lower values for acceptable control performance. Any test value outside of these limits must be considered a QC failure.
F. Bracketing **-** the placement of control materials at the beginning and the end of a batch of patients' specimens. When runs are performed sequentially in continuous processing placing control material in the first cup of the next batch can be considered as the control for the end of the previous batch. Note this applies only for continuous processing.
G. Peer Group – any group of laboratories, using the same instrumentation and reagents, and testing the same lot number of quality control material.
H. Unassayed controls – the control material has not been tested by the manufacturer to establish mean values. Each laboratory must test the material to establish its own mean values and statistically acceptable limits. All of the same analyzers within this laboratory system contribute values to the determination of the internal mean value.
I. Quantitative Results – numeric values that correspond to the actual amount of analytes present.
J. Qualitative Results – indicate only the presence or absence of a substance.

K. TEa – Total Allowable Error; TEa is the amount of error that can be tolerated without invalidating the medical usefulness of the analytical result.
L. Look Back – the term used for the process to determine the accuracy of prior reported test results, after discovery of an "out of control" analytical run (1:3S or 2-levels >2SD). Qualitative methods require look back when QC falls outside of the acceptable range.
M. Standard Deviation (SD) – is a mathematical calculation that measures the average distance to the mean for a given set of values, based upon instrument performance. A small SD indicates that most of the values, within a set of data, fall close to the mean. A large SD indicates that most values are farther away from the mean.
N. Unacceptable QC results (for Quantitative Assays) – any QC that exceeds 1:2S requires investigation and resolution before continuation of testing.
O. "Out of control" QC results for quantitative methods – 2-Levels >2SD or 1:3S; Perform Look Back. Exception: certain scenarios do not require Look Back, refer to action codes in attachment A.
P. "Out of control" QC results (for Qualitative Assays) – any value less than 100% compliance with manufacturers expected results.
Q. Acceptability Limits (AL) – the points beyond which an assay qualifies as out of control.

5. PROCEDURE

5.1 PERFORMING QUALITY CONTROL

A. General Guidelines
Performance of QC is specific to the testing procedure. The applicable SOP should always be reviewed for specific quality control guidelines regarding:
1. the type, name, and product number of QC material used
2. preparation and handling instructions
3. levels to be run and their frequency
4. documentation of QC results and corrective action
5. reagent preparation
6. instrument maintenance

B. Establishment of Quality Control Acceptability Limits (QC-AL)
General Considerations
1. QC-AL must be established on the analyzers within "the system" or the manufacturer's limits must be verified for each new lot of control material.
2. When establishing in-house AL ranges for assayed controls, the in-house mean should fall within the manufacturer's published range
3. When establishing an in-house range for unassayed controls, the QC-AL should be compared to a peer group using the same test system.
4. The QC settings must be evaluated using TEa to ensure the SD limits meet the Sigma requirements. The performance goal is 6 sigma or better but a score of 4 is acceptable. A 3 sigma value must be approved by the Medical Director.
   a) The QC Max SD Calculator template is used to check the performance by entering the assay, TEa (percent and absolute, as applicable) and the QC mean.

b) The template displays values for 3, 4 , 5 and 6 sigma
c) Utilize the 'Achieved X and SD' to verify actual performance
d) The second tab of the template may be used to calculate CV and the 2SD and 3SD ranges for QC products.

5. Quality control material should mimic patient specimens and be focused at the clinical decision levels whenever possible.
6. If quality control testing is performed on multiple shifts, then establishment of QC–AL will include testing from multiple shifts.
7. New lots of QC will be tested against existing lots of QC material before being placed into service.
8. QC material will not be used beyond its expiration date, including the open vial stability.
9. Control material should also be purchased in sufficient volumes to minimize changes in lot numbers (purchase of quality control lots in yearly increments is recommended). In general, lot numbers for quality control material should not be changed at the same time as reagent lot numbers.
   Note: In chemistry, where reagent lots change in 30-40 day cycles, the supervisors may need to establish QC ranges over two or more lots.
10. Mishandling of control material, i.e. improper long term storage (freezer outside the manufacturer's recommended storage temperature) or day-to-day mishandling through prolonged exposure to room temperature, will affect the stability and performance of the control material. These storage and handling practices should be controlled to ensure successful QC performance.

5.2 HANDLING QUALITY CONTROL MATERIAL

A. Quantitative Controls
   1. Establishing QC-AL for a new lot number of controls with expiration dates greater than 2 months.
      a) Analyze the new lot of QC material in conjunction with the current lot number.
      b) Collect at least 30 data points (for each level) from at least 20 separate runs over 5 to 30 days. *(Each instrument can be considered a separate run).* Calculate the mean for the new control lot. Establish and accept the new mean if it falls within the assay range (for assayed controls) or peer group range (unassayed controls).
   2. Establishing ranges for a new lot number of assayed controls with short expiration dates, e.g., hematology controls.
      a) Analyze each level of control simultaneously with the current lot of controls once per shift for 3 days.
      b) After the 3 days, compare the in-house derived mean and SD to the manufacturer's assigned mean and SD.
      c) If the mean is within the manufacturer's range, accept the manufacturers mean and SD as the established mean and SD.
      d) If the mean is outside the manufactures range, then **do not proceed with patient testing, test a level of a current QC lot to ensure**

analyzer accuracy and notify the supervisor on duty. Proceed with instrument troubleshooting, when applicable.

3. Verifying new shipment of a current lot.
   a) When a new shipment of a current lot number is received, the control name, lot number and date of receipt will be logged in the reagent inventory log. *(Complete all sections on the log)*
   b) Each level of the control will be analyzed simultaneously with the current in-house control, as soon as practical.
   c) All results must be within the laboratory's AL for all the analytes for it to be acceptable.
4. Establishing control ranges, when no current control lot is available.
   a) Analyze each level of new control 10 times and calculate the mean.
   b) If the new control lot is an assayed control, compare the calculated mean to the manufacturer's published range. If this value is within manufacturer's range, use the calculated mean along with the historic SD to calculate the new acceptability limits. If the calculated range is outside the manufacturer's range, **do not proceed with patient testing and notify the supervisor on duty**.
   c) If the new control lot is an unassayed control, compare the in-system calculated mean to the peer group control performance on the same test system. If the mean is within the peer group AL, use the calculated mean and our historic SD to establish the new AL. If the calculated mean is outside of the peer group AL, do not proceed with patient testing and notify the supervisor on duty.
5. If commercial control material is unavailable through any means, notify the supervisor on duty immediately. The following methods may be employed to verify the reliability of patient results.
   - Split samples and send to a reference laboratory (accuracy).
   - Exchange specimens with another accredited laboratory (accuracy).
   - For labile specimens, have multiple technologists perform analysis (precision).
   - With the guidance of the supervisor, selected patient samples can be re-tested using a comparison of obtained results to total allowable error as a method of validating new patient testing in the absence of available control material.
   - Any of these methods will not be used without written documentation and approval of the supervisor.

B. Qualitative Controls
   General Considerations
   1. For tests in which numerical values are not generated, at minimum, the analytic run and external QC frequency is defined per procedure. In addition, tests with internal QC will require documentation of said internal QC before reporting patient results per procedure.
   2. For specific details on microbiology media, refer to the procedure Media Quality Control.

C. Other Methods of Assessing Test Quality
   1. Instrument Comparison
      a) In situations where multiple analyzers are used for the same analytes (at the same site) patient specimens are run on both analyzers and the results are compared based on TEa of the given analyte. Specimens are chosen to represent the clinically appropriate range. Alternatively, specimens may be purchased from a qualified vendor that utilizes traceable testing material.
      b) Instrument comparison testing must be performed at least twice a year, but can be performed at more frequent intervals as determined by the section supervisor, Medical Director, or designee. Refer to Comparison of Intra-laboratory Test Results procedure for details.
   2. Primary versus Secondary Modes
      a) On instruments that have multiple-sampling modes, specimens will be analyzed through each mode and the results are compared.
         - Tea/4 is accepted and requires no additional approval.
         - Tea/3 is acceptable with Medical Director Approval.
      b) This is performed during instrument correlations. See the appropriate SOP for complete details.
   3. Positivity Monitoring for Molecular Tests
      1. Positivity Monitoring.
         - Positivity is monitored monthly against historical and seasonal trends as appropriate. Unexpected increases or difference across sites are investigated.
      2. Physician/Customer Concern – Any concerns or questions regarding positivity will be investigated and addressed immediately. Repeat testing will be performed, when possible, to confirm the patient result.
      3. Wipe Testing - Wipe Testing is performed semi-annually on to ensure proper decontamination procedures are in place. In addition, Wipe Testing may also be utilized to investigate other potential contamination concerns, as needed.
         - Wipe Test procedure see ATTACHMENT B

5.3 REVIEWING QC RESULTS

Refer to QC Responsibilities and Review SOP

5.4 ACTION FOR UNACCEPTABLE QC RESULTS

Note: All unacceptable and "Out of Control QC" results must be investigated and acceptable QC results must be obtained.

- All corrective action must be documented in the QC module (LIS, DI or Unity Real Time) and in the Look-Back Binder, before testing patient samples or reporting patient results.

- "Out of Control" QC result will initiate the patient Look-Back process, after acceptable QC results have been obtained. Exception: certain scenarios do not require Look-Back, refer to action codes in attachment A.
- For qualitative methods Look-Back is required when QC exceeds the acceptable limits.
- An evaluation of results already reported from the affected run must be documented by recording either 'no patient impact' or 'reports corrected'.

A. Quantitative or Semi-quantitative Determinations (with numerical values)
   1. Discontinue patient testing on the analyzer.
      Note: Valid patient results are a priority. Immediately perform patient look-back on another instrument, if available, before beginning QC failure investigation. Refer to step 7.
   2. Check to make sure reagents are not expired and there are no obvious signs of reagent contamination.
   3. Use the freshest control material, re-pour and reanalyze the control. If the QC result is within the AL, document your actions in the appropriate QC Module along with the acceptable control value and initiate the patient look-back procedure prior to resuming patient testing, as applicable. If the QC issue persists, go to step 4.
   4. Repeat testing using fresh reagent. If the QC result exceeds the AL, then go to step 5. If the QC result is in range, go to step 6.
   5. Evaluate the method for systematic errors by reviewing the following as applicable:
      a) Instrument maintenance logs, changes in reagent or control lots, instrument function checks and operator competency.
      b) Check parameters of instrument function as is appropriate, i.e., up to date maintenance, check/correct temperature, timer correct, etc. If any deviation from the acceptable practice is noted, correct the situation and **document all corrective action in the appropriate manner: LIS manual QC log, or instrument maintenance log.** Be sure to include your initials, date/time, problem identification, actions taken, persons notified, and resolution, if any. Repeat the QC. If the QC result is still outside of the AL, call Hotline and notify the section supervisor/designee.
   6. If the repeat QC is acceptable, proceed with patient testing. Proceed to step 7 (unless look-back was already completed on another instrument).
   7. Patient Look-Back
      a) Repeat the last three patient samples that were reported before the QC failure. Record the instrument, test and results (original and repeat) on the Patient Look-Back Log and indicate if the results are within the TEa.
      b) All three repeated results must be within the TEa for the assay. If acceptable, proceed to step H for documentation guidance.
      c) If one or more results exceed the TEa, select and repeat testing on the lesser number of patients from either the 10 next most recent patient

samples or all patient samples that have been tested since the last successful QC result.

d) If nine out of the above 10 samples fall within the TEa of the original assay values, further look back will not be necessary.
   - If 90% of the look back is acceptable, within the TEa range, collect data and attach to the daily bench log for the supervisor or designee to review and file in the Patient Look Back Binder.

e) Patient results outside of the TEa must be corrected. (See the Error Detection and Correction procedure)

f) If two (2) or more patient values fall outside of the TEa, perform an extended patient look-back.
   - If less than 90% is acceptable continue patient look back with 20 additional patients or the entire run, whichever is fewest.
   - If 95% match within the TEa, collect the data and present to the supervisor.
   - If less than 95% of the values fall within the acceptable range, perform a full look-back of all patient samples tested from the last successful QC. Correct any report where the repeat value differs from the original reported value by greater than the TEa.

g) Document all actions taken on the corrective action log.

h) Using the "-" function in the LIS, append the comment **LOOKB** "Repeat/Look Back performed and satisfactory" to the previous corrective action documentation on the within-limit QC result. If no patient samples were tested prior to this failed QC, use the "-" and append **NPTR** "No patients run between successful and failed QC run." For assays processed through DI/Unity Real Time select the appropriate code / description from the remedial actions listed (Attachment A).

i) Staple and place all documentation of the QC printouts to the Patient Look-Back Log and attach to the daily bench log for the supervisor or designee to review and file in the Patient Look Back Binder.

B. Qualitative or Semi-Quantitative Determinations (no numerical values)

1. Repeat control. If control value is acceptable, accept run and proceed with patient testing. If control value is unacceptable proceed to step 2.
2. Ensure that the reagent/test kit and controls are within date, and that the test kit components have not been inappropriately combined. Verify the selection of the appropriate lot and control material. Check parameters of testing system as appropriate, i.e., up to date maintenance, correct temperature, timer correct, etc. If everything is in order, obtain new control material and repeat control. If control is unacceptable, proceed to step 3.
3. Check reagent/test kit and QC for obvious signs of contamination. Take the reagent/test kit out of service and document findings. Open a new reagent/test kit, run QC, if acceptable, repeat testing using new reagent/kits and assess the need to perform a patient look-back. If control value is unacceptable, proceed to step 4.

4. Have another trained staff member review your work and repeat controls. If controls are acceptable assess the need to perform a patient look-back. If control values are still unacceptable notify supervisor/manager that testing is suspended and the problem is unresolved. Follow up with technical support to determine if there are reports of reagent/test kit problem or product recall, proceed to step 5. *(Upon resolution of the "out of control" event assess the need to perform a patient look-back).*
5. Document all corrective action in the appropriate log: LIS, DI/Unity Real Time, manual QC log, or instrument/equipment maintenance log. Be sure to include your initials, date/time, problem identification, actions taken, persons notified, and resolution.

C. Unresolved QC Issues
1. If the QC problem does not resolve after all actions are performed, the section supervisor/designee must be notified.
2. Run patient samples using an alternate method, if available. If an alternate method is unavailable, patient testing must be suspended until QC problem is resolved.

D. Molecular Positivity Concerns.
1. Unexpected increases in positivity from monthly statistics should be reported to the technical supervisor and quality variance completed. Investigations may include wipe testing.
2. Physician/Customer concerns regarding positivity should be reported to the technical supervisor and quality variance completed. Investigations may include wipe testing.
3. Wipe Test failures should be reported to the technical supervisor and quality variance completed.

6. RELATED DOCUMENTS

QC Responsibilities and Review, QA procedure
Quality Management (QM) Plan, QA procedure
Comparison of Intra-laboratory Test Results, QA procedure
Error Detection and Correction, Laboratory policy
Data Innovations Instrument Manager, Laboratory policy
Bio-Rad Unity Real Time 2.0, Chemistry procedure
Reagent Parallel Testing, QA procedure
Media Quality Control, Microbiology procedure
Vista QC Schedule, SGMC (AG.F208)
Vista QC Schedule, WOMC (AG.F209)
XPAND QC Schedule (AG.F210)
Patient Look-Back Log (AG.F187)
QC Max SD Calculator (AG.F536)

7. REFERENCES

A. Clinical and Laboratory Standards Institute. *Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions; Approved*

Guideline-Third Edition. CLSI document C24-A3 [ISBN 1-56238-613-1]. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2006.

B. Tietz, Textbook of Clinical Chemistry, 6th Edition, Carl A Burtis, Edward R Ashwood & David E Bruns, 2008
C. College of American Pathologists, CAP Accreditation Program, section specific checklists, www.cap.org
D. Guidelines for Troubleshooting Quality Control Issues, QDQC707 v1.0, Quest Diagnostics intranet
E. QC Frequency for Batch, Random Access and STAT Testing, QDQC705 v1.2, Quest Diagnostics intranet

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SGAH-WAH L002.003		
000	4/23/2013	Section 2.1, 3.1: update programs for corrective action documentation Section 5.2.A: add each instrument as separate run Section 5.2.B: add internal QC Section 5.2.C: revise TEa acceptability approval Section 5.4: update program, add Look-Back log Section 6: add DI, Unity Real Time and Reagent Parallel Testing SOPs Section 9: add attachments C-F, revised A	R SanLuis	C Bowman
001	8/11/2015	Section 2: remove Nichols Institute Section 6: move schedules & forms from section 9 Section 9: retitle description column to include DI and Bio-Rad Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L Barrett R SanLuis	C Bowman
2	1/19/2017	Header: add other sites Section 2.2: add IQCP Section 3.1.C: update reference to QC charts Section 5.4.A: add immediate look-back testing on another instrument	L Barrett R SanLuis	C Bowman
3	9/28/2017	Section 3.1: remove reference to QC chart, specify action documentation, add QC responsibility SOP Section 3.2: delete (duplicates QC responsibility SOP) Section 5.2.C: remove comparison approval and reference SOP Section 6: delete QC frequency chart	L Barrett R SanLuis	C Bowman-Gholston
4	1/31/19	Header: updated facility Section 4: added Action & Comment Codes and exception for look-back Section 5.4: added exception for look-back Attach A: added new codes	L Barrett	C Bowman-Gholston

Version	Date	Reason for Revision	Revised By	Approved By
5	8/18/20	Header: changed WAH to WOMC Section 5.1: added SD and sigma criteria Section 5.4 & 6: updated correction policy title Section 6: updated titles of Vista schedules, added max SD calculator	L Barrett R SanLuis	C Bowman-Gholston
6	7/18/22	Header: Changed to All Laboratories Footer: Changed prefix to AHC Section 5.2,C.3: Added positivity monitoring Section 5.4.D: Added molecular positivity concerns Attachment B: Added Wipe test procedure	D Collier R SanLuis	C Bowman-Gholston

9. ADDENDA AND APPENDICES

Attachment A: QC Action Codes and Comment Codes
Attachment B: Wipe Testing Procedural Steps

ATTACHMENT A

QC Action Codes and Comment Codes

	Sunquest / DI / Bio-Rad Unity Description
Action Codes	AC. Control: repeated level 1-Accept
	AC. Control: repeated level 2-Accepted
	AC. Control: repeated level 3-Accepted
	AC. Instrument problem identified detail on QC summary report, issue resolved
	AC. Patient Lookback not indicated.(No patients tested since last acceptable QC)
	AC. Patient Lookback performed and acceptable
	AC. Patient testing suspended
	AC. Patient testing suspended/hotline called, supervisor/TIC informed
	AC. Reagent change, lookback not indicated.(No patients tested since last acceptable QC)
	AC. Reagent change, lookback performed and acceptable
	AC. Repeat control with freshly poured QC accepted
	AC. Repeat control with new QC vial accepted
	AC. Test recalibrated, lookback performed and acceptable
	AC. Test recalibrated, lookback not indicated, no patients tested since last acceptable QC
	AC. Test/assay repeated QC in range
	AC. Wrong Control Level-QC Repeated and Accepted.(No lookback indicated)
	AC. New lot calibration done, reagent lot suspended for QC range adjustment
	AC. Control repeat with fresh QC failed. Troubleshooting - Patient testing suspended.
	AC. Control repeat with fresh reagent failed. Troubleshooting - Patient testing suspended.
	AC. Establishing range for new lot of QC not in use, no lookback indicated
	AC. Troubleshooting by FSE
	[redacted]
Comment Codes	CC. Calibrated with new lot. QC issue resolved
	CC. Calibrator changed. QC issue resolved
	CC. Instrument calibrated
	CC. Instrument serviced see summary report
	CC. Instrument: bleached
	CC. Instrument: electrode/cartridge/IMT change
	CC. New mean established
	CC. QC vial QNS, no patient lookback indicated
	[redacted]
QC Codes	QC: reviewed for day
	QC: reviewed for month
	QC: reviewed for week

Note: Utilize only the above defined Action Codes to document corrective / remedial action taken for QC failures.

ATTACHMENT B

Wipe Test Procedure

1. Wipe Testing should be performed semi-annually at minimum for all molecular testing. Semi-annual Wipe testing will be placed in the recurring calendar binder. Wipe Testing results as part of troubleshooting a positivity concern will be attached to the Quality Variance form when needed.
2. Dip a swab into appropriate transport media and wipe along the surfaces you wish to test.
3. Place the swab back into the transport media and tighten the cap.
4. Vortex the sample for 60 seconds before the sample is run on the instrument.
5. Attach all instrument print outs to the back of the Wipe Test worksheet and place in the appropriate binder.
6. The Technical Supervisor or designee will review the Wipe Test within a month of it being performed.