TRAINING UPDATE

Lab Location:	GEC, SGAH & WAH	**Date Distributed:**	9/16/2014
Department:	Mgmt, QA & Technical Specialist	**Due Date:**	10/14/2014
		Implementation:	**10/15/2014**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Instrument Relocation Validation and Verification of Performance Specifications
GEC / SGAH / WAH.QA49 v1

Description of change(s):

Added Section 5.5 “Vendor Supported Verifications” as per CQA BPT rollout; re-numbered subsequent sections

Section 11: Updated location terminology for Appendices C & D.

App E: Updated minimum functionality requirements for incubators and refrigerators / freezers

This revised SOP will be implemented on October 15, 2014

Document your compliance with this training update by taking the quiz in the MTS system.

Non-Technical SOP

Title	**Instrument Relocation Validation and Verification of Performance Specifications**
Prepared by	Cynthia Bowman-Gholston, Leslie Barrett Date: 8/1/2013
Owner	Cynthia Bowman-Gholston Date: 8/1/2013

Laboratory Approval		
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		
Local Issue Date:	Local Effective Date:	

Review:		
Print Name	**Signature**	**Date**

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1. PURPOSE

This procedure provides a standardized process for documenting that previously verified or established test/test system performance specifications continue to meet laboratory criteria for acceptability after test/test system relocation.

2. SCOPE

This procedure applies to analytical test and test systems that are relocated within the same laboratory (CLIA number).

> **NOTE:** *Performance specifications for new methods or new test offerings must be verified or established according to standard "method validation" processes.*

When multiple analytes are performed on the same instrument EACH analyte must be verified.

This process applies to "loaner" equipment, when the instrument is the same make and model, and the test methodology is the same as used by the laboratory.

The criteria and processes for Microbiology and certain other unique tests individually defined.

This process for verification of functionality of equipment peripherally involved with patient testing (e.g. incubators, centrifuges, safety cabinets, autoclaves) is addressed in Appendix E.

3. RESPONSIBILITY

It is the responsibility of the **Laboratory Director** for the approval of the initial document and any subsequent revisions.

It is the responsibility of the **Laboratory Director** to ensure that testing systems used for each of the tests performed in the laboratory provide quality services for all aspects of testing performance.

It is the responsibility of the **Laboratory Director** to ensure that verification procedures used are adequate to determine the accuracy, precision and other pertinent performance characteristics of the method. This responsibility may be delegated to a Technical Supervisor.

It is the responsibility of the **Technical Supervisor**/ **Department Manager** (or designee) to ensure compliance with this procedure, and to ensure the process is complete, appropriately documented and acceptable, and approved, prior to patient testing.

It is the responsibility of the **Quality Assurance Director** to ensure compliance with this procedure.

4. DEFINITIONS

Accuracy: The closeness of a measurement to the true concentration, trueness.

Measurement Range (AMR) – is the span of test result values over which the laboratory can establish or verify the accuracy of the instrument or test system measurement response.

Analytic Measurement Range (AMR) – is the span of test result values over which the laboratory can establish or verify the accuracy of the instrument or test system measurement response.

Calibration – is the process of testing and adjusting an instrument or test system to establish a correlation between the measurement response and the concentration or amount of the substance that is being measured by the test procedure.

Calibration Verification – Is the assaying of calibration materials with known relationship to a predictable linear or nonlinear line in the same manner as patient specimens to confirm that the calibration of the instrument, kit, or test system has remained stable throughout the laboratory's reportable range for patient test results.

Instrument: A piece of equipment used to prepare or analyze a patient sample or batch of samples in order to produce a test result.

Peripheral Equipment: Equipment used in support of the testing process.

Precision: The agreement among replicate measurements. Precision is not typically represented as a numerical value but is expressed quantitatively in terms of imprecision; the SD or CV or results in a set of replicate measurements, also referred to as imprecision, where the higher the imprecision, the higher the SD.

Qualitative Test System: A test system that reports observations in the form of interpretive comments. Results can also be an alpha result such as "Positive" or "Negative" or "Reactive" or Nonreactive".

Quantitative Test System: An assay that produces measurement in continuous numerical values based on a standard curve and on a signal (e.g. light) measured by an instrument (e.g. relative light units). These measurements are reported to, and interpreted by, the treating physician, based on numerical cutoff (e.g. reference ranges) provided to the treating physician.

Semi-Quantitative Test System: An test system that produces a signal that is measured and interpreted by laboratory staff based on laboratory cutoffs without a standard curve and reported to the treating physician as qualitative statements (e.g. "Negative", "Positive", "Equivocal", Titers, etc.)

Total Allowable Error (TEa): refers to the maximum allowable total error of the assay.

Total Error: The combination of random and systemic analytical errors; an estimate if the magnitude of error that might occur in a single measurement.

5. PROCEDURE

PROCESS OVERVIEW

Prior to moving a test/test system, the criteria and steps required to evaluate performance acceptability after the move must be defined. For most tests, this is accomplished by defining/verifying existing precision and documenting known accuracy.

Precision and accuracy, for quantitative tests, are defined in terms of C.V. and/or Total Allowable Error (TEa).

Precision and accuracy, for qualitative and/or semi-quantitative tests, may be defined in terms of concordance with known results.

Performance acceptability must include (as applicable) an assessment of:

Instrument functionality

- Accuracy
- Precision
- AMR
- Calibration/calibration verification
- Carryover
- Patient replicate testing
- LIS interface
- Accuracy of calculation(s)

Acceptability of each moved test, test system and analyte must be documented prior to patient testing.

For Microbiology, test performance is deemed acceptable when the laboratory demonstrates the ability to detect growth (recover) known patient organisms or (QC and ATCC strains).

5.1 PREPARATION TO RELOCATE

The individual coordinating the move (Project Move Coordinator and/or the Technical Supervisor/ Department Manager) is responsible for:

a) Reading the instrument manual and making note of manufacturer's recommendations for installation. The following procedure will describe the minimum verification that must be performed. If the manufacturer recommends procedures that are not included below, it is the coordinating personnel's responsibility to ensure that they are performed.
b) Contacting the supplier if an instrument is involved.
   i. Discuss take-down procedure.
   ii. It is recommended that all instruments be moved by the supplier or by Quest Diagnostics personnel under the direction of the supplier.
   iii. The relocation schedule should be designed so that the process interferes minimally with production.
c) Designing the relocation in conjunction with Biomedical Engineering Department and Information Resources Departments.
d) Appendix A and/or B may be used to aid in coordinating the relocation process.

5.2 INSTRUMENT FUNCTION AND MAINTENANCE CHECKS

a) Function checks, where applicable, should be performed and documented by the supplier in accordance with the manufacturer's recommendations and the instrument manual.
   Examples: probe alignment, reagent dispensing, optics, power supply, computer/disk drives, printers/copy units, water supply/decontamination, gamma counter efficiency, etc.
b) For peripheral test equipment verification, refer to SOP QDNQA730.
c) Water supply: Verify that the water tap has been tested for bacterial contamination, silicate and conductivity.
d) Safety equipment that is moved must be revalidated, for example eye wash fountains, exhaust hoods, Class II biological safety hood, fire alarms, sprinkler systems, safety valves or pressurized tanks.
e) Maintenance Checks: All instrument maintenance recommended by the manufacturer must be performed and documented before operation.

5.3 INSTRUMENT ANALYTICAL PERFORMANCE VERIFICATION

NOTE: Some of the steps may be accomplished simultaneously. When instrument vendors assist in the process, laboratory staff will perform (at a minimum) QC and patient replicate testing.

5.3.1 Collect sufficient number of samples to meet study requirements, keeping into account sample stability and volume.

a) Required **Accuracy Verification:** After relocating instrument, re-calibrate if necessary, and assay QC materials. Compare the QC results obtained with the assigned range for each control tested. If results are within the assigned range, accuracy is considered to be verified. If the results are not within the assigned range, corrective action procedures are taken.
See "Accuracy" Tab of Appendix C. Alternatively see "Analyte Specific" Tab C of Appendix C.

b) Required **Precision Verification:** After relocating instrument, assay a minimum of 5-10 replicates of each level of control. Calculate mean, SD and CV for all levels. The achieved CV must be less than or equal to the assigned CV.
See "Precision" Tab of Appendix C. Alternatively see "Analyte Specific" Tab C of Appendix C.

c) Required **Patient Correlation:**

i. Select 5 (at a minimum) -10 specimens, spanning the reportable range of the assay.
Quantitative: When possible, select samples that span the AMR, including a low (within +/- TEa of the lower limit), mid, and high (within +/- TEa of the upper limit).
Semi-Quantitative: Samples must include 'weakly reactive' test results, with values around the cut-off or decision point, and/or samples that span the reportable titer.
Qualitative: Samples must include both positive and negative test results. Samples with known quantitative values may be used to verify the accuracy of a qualitative test (e.g. hCG).
Immunohematology: A minimum of two samples are required for each comparison. Samples must include A Pos, A Neg, B Pos, B Neg, O Pos, O Neg, AB Pos, AB Neg.
Microbiology: If known patient samples are not available for targeted organisms, QC or ATCC organisms may used.

ii. Assay specimens before relocating instrument, and again after relocation.
Note: *Store specimens between testing according to stability requirements.*

iii. Using the appropriate Appendix, perform calculations on the results. Acceptable results are:
Quantitative: Test performance is deemed acceptable when the individual sample difference using replicate testing for each sample is within TEa and the patient repeat means (Estimate of Bias) are </= TEa/4. When the TEa for an analyte is not defined the test performance is deemed acceptable when the individual sample difference using replicate testing for each sample is within the average QC CV and the patient repeat means (Estimate of Bias) are </= CVX1.5.
If the results show unacceptable test performance, corrective action procedures are taken.
See "Patient Correlation TEa defined" Tab of Appendix C or "Patient Correlation no TEa" Tab of Appendix C. Alternatively see "Analyte Specific" Tab of Appendix C.
Qualitative or Semi-Quantitative: 100% concordance (with 5 samples) 90% concordance (with 10 samples) Titers agree +/-1 categories. See Appendix D
Microbiology: Test performance is deemed acceptable when the laboratory demonstrates the ability to grow (recover) known organisms from previously tested patients (QC and ATCC strains).
Medical Director Approval: As necessary, the medical director retains the option to define the acceptability criteria in any instance that does not meet the acceptance criteria specified in this procedure, based upon clinical judgment and in accordance with the age of the equipment.

d) If applicable — **AMR Validation/Calibration/Reportable Range Verification:** After an instrument is moved, carefully review Accuracy Verification Data, and assess whether any additional AMR/Calibration/Reportable Range verification studies should be performed. This procedure should be performed if a shift is seen in QC materials and re-calibration fails to produce in-control results, or after a major preventative maintenance or replacement of critical parts. If required, *See* "Calibration and AMR Verification" SOP #QA48.

e) If applicable — **Carryover**: If the instrument has an integrated pipetting system, evaluate for possible carryover within 72 hours. If required, *See* "Carryover Studies" SOP # QDNQA723.

5.4 FOR STAINS

a) Collect at least one each positive and negative sample (reference material may be used).
b) Stain each sample and record the results.
c) Store samples in accordance with established sample stability.

5.5 VENDOR SUPPORTED VERIFICATIONS

A vendor may participate in the laboratory's post-move verification of analytical tests, test systems, and instruments under supervision of the technical supervisor or designee; including running samples under the direction of testing personnel.

Tasks or steps that involve judgment or manual methods must be performed by testing personnel. Judgment involves evaluating calibration and quality control, and judgment of adequacy of validation studies.

5.6 FOR THE LIS INTERFACE

The LIS Interface for all instruments that are on-line must be verified after relocation, to ensure that results are reporting correctly. This must be done in conjunction with the local Information Resources Department.

a) Build a load and assay on the instrument. This can be done in conjunction with the instrument analytical performance verification.
b) Review the worklist, and make sure that results are reporting in the correct fields.
c) If the correct information appears in the correct fields, indicate that the interface is acceptable, and sign and date.

5.7 FOR COMPUTER CALCULATIONS

This procedure must be performed following a LIS system or database change, and periodically thereafter, in accord with CAP requirements. *See* "Calculation Validation" SOP# IT.32.

5.8 FOR INSTRUMENT TO INSTRUMENT VERIFICATION

For those test systems that have more than one instrument relocated, instrument-to-instrument verification must be performed only if this verification is not current (completed within the last six months).
The department may use additional aliquots of samples collected as described above.
The criteria and process for instrument-to-instrument will follow that defined in "Process for Comparison of Intra/Inter Laboratory Test Results".

6. DOCUMENTATION

All supporting data and evaluation documents should be kept and information should be recorded.
Final verification packages should be stored in the appropriate Document Control Validation departmental vault.
Final verification packages must be retained according to the Quest Diagnostics Records Management Program Reference Guide.

7. SAFETY

All applicable safety precautions should be followed pertaining to electrical, biological, radiation, etc.
Protection of the Instrument: The supplier should be familiar with precautions to prevent damage during the move and should take responsibility for any damage incurred.
Quest Diagnostics personnel should not attempt to perform procedures that may cause harm to themselves, other employees, or the instrument

8. RELATED DOCUMENTS

"Calibration and AMR Verification" QA48
"Laboratory Method Validation for Quantitative and Semi-Quantitative Methods" SOP QDQC710
"Calculation Validation" IT32
"Process for Comparison of Intra/Inter Laboratory Test Results" QA16

9. REFERENCES

"Verification of Performance Specification for Relocated Test Systems" QDNQA731
"Verification of Functionality of Relocated Instruments and Peripheral Test Equipment" SOP QDNQA730
"Instrument Relocation Validation and Verification of Performance Specifications" Chantilly Business Unit, QM.128, 2013

10. REVISION HISTORY

Version	Date	Reason for Revision	Revised by	Approved by
		Supersedes GEC/SGAH/WAH.QA36		
000	8/18/14	Added Section 5.5 "Vendor Supported Verifications" as per CQA BPT rollout; re-numbered subsequent sections Section 11: Updated location terminology for Appendices C & D. App E: Updated minimum functionality requirements for incubators and refrigerators / freezers Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L Barrett	C Bowman-Gholston

11. APPENDICES

Appendix	Location	Title
A	Page 11 of 14	Primary Equipment Movement/Validation Form
B	Page 12 of 14	Instrument Documentation Form
C	Attachment located on SOP document profile page.	Instrument Analytical Performance Accuracy Verification: See “Accuracy” Tab of Appendix C
		Instrument Analytical Performance Precision Verification: See “Precision” Tab of Appendix C
		Instrument Analytical Performance Patient Correlation Verification: See “Patient Correlation TEa defined” Tab of Appendix C
		or see “Patient Correlation no TEa” Tab of Appendix C
D	Attachment located on SOP document profile page.	Instrument Analytical Performance Verification for Qual/Semi-Quant Results
E	Page 13 of 14	Verification of Functionality of Relocated Peripheral Test Equipment

APPENDIX A: Primary Equipment Movement/Validation Form

Primary Equipment Movement/Validation

Date to move: _____
Date to validate: _____
Date completed: _____

Instrument to be moved

Make: _____
Model: _____
Serial Number: _____

Relocation:

Department Contacted: _____

Vendor BioMed Facilities IT

Who to move:
Vendor contact (if applicable) _____

Work order completed and contact (BioMed) _____

Work order completed and contact (Facilities) _____

Work order completed and contact (IT) _____

Validation

SOP version _____
Analyte (s) involved _____
TEa if applicable _____

Tech responsible for testing _____

Review of data validation _____

APPENDIX B: Instrument Documentation Form

Instrument Documentation Form

FUNCTION/SYSTEM CHECKS

☐Pass ☐Fail Corrective action if Fail: _____

INSTRUMENT ANALYTICAL PERFORMANCE VERIFICATION PERFORMED

☐YES ☐NO Corrective action if NO: _____

LIS INTERFACE TRANSFERRED CORRECTLY

☐YES ☐NO LOAD NUMBER _____

COMPUTER CALCULATIONS CHECKED

☐YES ☐NO ☐N/A Accession Number: _____

DOCUMENTATION ATTACHED if applicable
(ex. Function Check, Accuracy, Precision, Patient Correlation)

☐YES ☐NO Corrective action if NO: _____

Verified by: _____ Date: _____

Technical Supervisor: _____ Date: _____

APPENDIX E: Verification of Functionality of Relocated Peripheral Test Equipment

A. AT OLD LOCATION

1. Each item (Peripheral Equipment) must be uniquely identified.
2. Identify the peripheral equipment as out of service.
3. Complete decontamination (per EHS instructions) and document on instrument with "Decontamination Sticker" noted with date performed and initials of person completing the decontamination.
4. Notify IT department. IT department takes action to ensure proper data transfer and integrity.
5. Move instrument per manufacturer's direction (for large instruments), per direction of manager/supervisor or in cooperation with facilities move team.

B. AT NEW LOCATION: Verify Functionality

1. Visually inspect each item. Do not use if damaged, notify your department supervisor / manager.
2. Ensure that the new physical location is suitable for the peripheral equipment. For example: all applicable electrical safety checks have been performed.
3. When possible, the manufacturer should perform and document function checks in accordance with the manufacturer's recommendations and the instrument manual. These checks may include, probe alignment, reagent dispensing, optics, power supply, computer/disk drives, printers/copy units, water supply/decontamination, etc.
   Note: If the manufacturer is not performing these checks, the user must following manufacturer's instructions for set-up.
4. Perform and document all manufacturer-recommended instrument maintenance prior to operating the instrument.
5. Document satisfactory completion of all required function checks (both those defined by manufacturer and those defined in Section 6 below).
6. Perform and document all required instrument calibration.
7. If any or all of the above steps are not achieved, **DO NOT USE FOR TESTING**, notify your department supervisor / manager.
8. If the instrument / peripheral equipment is suitable for use, remove the decontamination and out of service stickers.

C. MINIMUM CRITERIA FOR FUNCTIONALITY VERIFICATION

PERIPHERAL EQUIPMENT	REQUIREMENT
AUTODILUTORS	• Verify functionality per each assay specification. • Autodilutors may be checked in synchronization with test. • Documentation may be included with test verification documents.
BALANCES	Balances must be verified with certified weights prior to use as defined in standard SOP.
CELL WASHER	Must be verified according to test specific SOP.

PERIPHERAL EQUIPMENT	REQUIREMENT
CENTRIFUGES	• Each centrifuge must have RPM/RCF verified prior to use (see Centrifuge SOP and in accordance with test specific SOPs). • Documentation of verification must be noted on centrifuge.
HOODS	Biological and/or chemical fume hoods must be validated by an outside vendor prior to use.
INCUBATORS	• Verify that each incubator can maintain requirements (e.g. temperature range, gas, etc.). • Documentation must include three consecutive appropriate measurements prior to use. Measurements must be at least one hour apart if incubator is used as a single short-term step in patient testing. • Incubators with built in temperature monitoring systems may be placed in service when required temperature range is reached.
MICROMETERS	Verify that micrometers are accurate.
MICROSCOPES	Visually inspect microscope. Lens must be clean and intact. Do not use if damaged.
pH Meter	pH Meter must be verified with standard material (according to established procedure) prior to use as defined in standard SOP.
PIPETTES	• Visually inspect each pipette. Do not use if damaged. • Each pipette must have current calibration documented on the pipette (see Pipette SOP for specifics)
REFRIGERATORS and FREEZERS	• Verify that each moved refrigerator/freezer can maintain required temperature range. Documentation must include three consecutive appropriate temperatures prior to use. • Refrigerators with built in temperature monitoring systems may be placed in service when required temperature range is reached.
ROTATORS	Rotators must have speed verified (per established test specific SOP) prior to use with patient testing.
STAINERS	Replicate patient testing or known organisms must be run to verify acceptability of staining characteristics.
THERMOMETER	• Visually inspect each thermometer. Do not use if damaged. • Each thermometer must have current certification.
TIMER	Visually inspect timers. Do not use if damaged.
WATER BATHS/HEAT BLOCKS	• Verify that each water bath / heat block can maintain required temperature range. • Documentation must include three consecutive appropriate temperatures prior to use. (Note: temperatures must be at least one hour apart.)

D. DOCUMENTATION

1. If the current process is to document on a form, clearly indicate the first day of relocation and functionality verification either on the current form OR alternatively on a new form that begins on first day of relocation.
2. If current process is to document directly on the item, clearly indicate the first day of relocation and functionality verification.
3. Note: When moved by manufacturer, records supplied by the manufacturer are stored with Instrument records. A copy should be included in the verification package.