TRAINING UPDATE

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

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Corporate Quality Assessment Internal Inspection Policy GEC / SGAH / WAH. QDNQA719 v2.1

Description of change(s):

Section	Revision
All	• Reformatted to current template. • Changed document to a policy and updated the title. • Consolidated, renamed and rearranged sequence of Sections 6-16 of the previous version. • Updated terminology to reflect changes from NQA to CQA, categories of laboratories. • Changed nonconformance to deficiency
2	Updated Scope to current practice.
4	• Eliminated definitions for Phase I and II standards. • Added RQI and RPI.
8.1	Revised criteria for assigning points.
8.4	Revised grading criteria for Level 2 and Level 3.
12	Updated Related Documents

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	**Corporate Quality Assessment Internal Inspection Policy**
Prepared by	Kathy Grimes **Date: 1/10/14**

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

Review		
Print Name and Title	**Signature**	**Date**

Corporate Approval		**Corporate Issue Date:** 3/3/14
Print Name and Title	**Signature**	**Date**
Dianne Zorka Director, Corporate Quality Assessment **Owner**	*On file*	**3/3/14**
Lee Hilborne, M.D., MPH **Corporate Medical Director**	*On file*	**3/3/14**

Retirement Date:	*Refer to the SmartSolve EDCS.*
Reason for retirement/replacement:	

TABLE OF CONTENTS

1. PURPOSE

This document sets forth the Quest Diagnostics policy to monitor compliance with federal and state regulatory requirements as well as Quest Diagnostics' corporate and local policies and procedures by conducting on-site internal inspections of Clinical Pathology laboratories.

2. SCOPE

- This policy applies to all pre-analytic, analytic and post-analytic steps of Clinical Pathology (CP) testing in:
- Regional, Support and Esoteric Laboratories
- Rapid Response Laboratories (RRLs)
- Clinical Trials
- Quest Diagnostics managed hospital laboratories staffed by Quest Diagnostics employees (referred to as "hospitals" hereafter)
- Employer Solutions
- Majority-owned joint venture laboratories

- This policy does not apply to:
- Anatomic Pathology
- Patient Service Centers
- Waived testing sites
- Quest Diagnostics managed hospital laboratories staffed by non-Quest Diagnostics employees
- Minority-owned joint ventures (inspected by invitation only)

3. RESPONSIBILITY

- The **laboratory department Managers/Supervisor** is responsible for:
  - Working closely with the Operations Director and Quality Assurance Director/Manager to assure thorough and effective analysis of root causes of identified deficiencies
  - Ensuring their department preparedness for inspections
  - Participating in or managing both the Initial inspection and Follow-up inspection processes in the department
  - Creating or managing the remediation/corrective action plan for both the Initial and Follow-up inspection deficiencies and submitting to laboratory management for approval
  - Handling and retaining inspection information in a confidential manner.

- The laboratory **Quality Assurance Director/Manager** is responsible for:
  - Working closely with the Laboratory Director to assure the integrity of the inspection and response processes
  - Ensuring preparedness for inspections
  - Coordinating the laboratory's participation in both the Initial and Follow-up inspection process
  - Coordinating Initial and Follow-up inspection corrective action responses
  - Creating and/or managing the remediation/corrective action plan for Initial and Follow-up deficiencies in Lab General and submit to laboratory management for approval
  - Monitoring all corrective actions to ensure they are effective and sustained
  - Handling and retaining CQA inspection reports in a confidential manner
  - Submitting personnel information for the IMT responses on the IMT Responder List

- The **Laboratory Operations Director/Manager** is responsible for ensuring:
  - Preparedness for and participation in inspections
  - Responses to deficiencies are approved and submitted to the Laboratory Director prior to the deadline
  - Implementation and documentation of corrective actions for all deficiencies
  - Monitoring of Initial and Follow up corrective actions to ensure they are effective and sustained
  - Ensuring confidential retention and handling of CQA inspection reports.

- The **Laboratory Director** is responsible for ensuring:
  - Preparedness for and participation in inspections
  - Responses to deficiencies are submitted to CQA within 21 calendar days of receipt of the inspection report.
  - Implementation and documentation of corrective actions for all deficiencies
  - Monitoring of corrective actions to ensure they are effective and sustained
  - Confidential retention and handling of CQA inspection reports.
  - Personal access to and routine checking of Quest Diagnostics email for the purpose of receiving and responding to findings

- **CQA** is responsible for:
  - Implementation of the CQA Internal Inspection Program
  - Conducting Initial inspections
  - Distributing written report within 25 calendar days of the Initial and follow up inspection dates
  - Conducting Follow-up inspections, as required, to ensure corrective actions are complete and sustained

4. DEFINITIONS

- **Coincidental Finding:** An unrelated deficiency discovered during a Follow-up inspection. This finding is not related to the original finding. (CQA does not actively look for additional findings during Follow-up inspections but will cite them if seen.)
- **Inspection Management Tool**: A web-based system used to automate responses to inspection deficiencies. This includes the approval or rejection of corrective action responses.
- **Deficiency:** An indication that an outcome or process has not met the specified requirement, standard or policy.
- **Normalized Points:** A factoring system for inspection scores that accounts for the number of test systems reviewed. The average number of test systems inspected in a given year divided by the number of test systems inspected in a given laboratory equals the normalizing factor. The average number of test systems is re-baselined annually.
- **Repeat Deficiency:** A deficiency from the most recent CQA, CAP, and/or state inspection that is cited again in the same area during the current CQA inspection.
- **Reportable Quality Issue (RQI):** A quality issue with known or potential effect on current patient care that requires notification.
- **Required Process Improvement (RPI):** A finding, noted during an inspection that does not rise to the level of a deficiency but needs to be addressed / corrected.
- **Test System:** A standard grouping of "platforms" or assays that is used to normalize the scoring process across all laboratories, regardless of size or testing volume.

5. STANDARDS

The inspection process assesses conformance to requirements according to:

- State and federal regulatory standards
- CAP Laboratory Accreditation Program Checklists
- Quest Diagnostics Corporate Quality Assessment programs
- Quest Diagnostics standard policies, processes and procedures
- Quest Diagnostics Best Practice Team (BPT) standardization initiatives
- Corporate Medical Compliance standards
- Quest Diagnostics Environmental Health & Safety (EHS) Manual

6. DATA PRIVACY AND SECURITY

- CQA Inspection Reports fall under one or more of the following privilege categories:
  - Work Product Doctrine
  - Privilege of Self-Critical Analysis
  - Peer Review / Quality Assurance Privilege
  - All other applicable privileges
- The information included in CQA inspection reports is highly confidential and subject to Quality Assurance privilege. **The initial e-mailed report may not be redistributed, disseminated, reproduced and/or forwarded via email or otherwise without prior approval.** However, a printed copy of the report may be shared with individuals on a need-to-know basis for the purposes of responding to the reports or implementing any required corrective actions. The persons who receive printed copies must be notified by the Laboratory Director that **these printed copies may not be re-copied, distributed, disseminated, reproduced and/or forwarded without prior approval.**
- Corrective action responses to each deficiency must be transmitted to CQA via the IMT. Supporting documentation for corrective actions/process improvements must be maintained by the Quality Assurance department. If requested by CQA, this documentation can be submitted as an attachment to the IMT response.
- All reports received electronically, including printed or saved reports, IMT responses, and all final responses transmitted electronically must be retained in your personal e-mail folder under the recipient's password-protected access (e.g., not on a shared drive). Only final versions of laboratory responses may be retained, not draft versions. If responses are not submitted to CQA electronically, but instead are submitted by hard copy, paper copies must be retained in a confidential paper file segregated from other routine business files. Electronic or hard copies must be maintained consistent with the company's documentation requirements and/or any legal hold obligations.
  - E-mail questions regarding inspection reports must:
  - Contain the message "Quality Assurance Privilege" in the subject line.
  - Contain the wording "Confidential/Subject to Quality Assurance Privilege" at the beginning of the e-mail message.

7. GENERAL INSPECTION PROCESS

- CQA may perform an inspection at any time
- <u>All inspections include the following</u>**:**
  - Evaluation of compliance to standards.
  - Explanation of deficiencies cited.
  - Evaluation of corrective actions taken in response to previous deficiencies
  - Implementation verification of BPT initiatives.
  - Verification that corrective actions are complete and sustained for Reportable Quality Issues (RQI)
  - During an inspection, if a serious quality problem is noted that requires immediate corrective action:
    - The Laboratory Director is immediately notified
    - The Director of Corporate Quality Assessment is immediately notified.

        - Written notification of the problem is provided within 5 calendar days.
        - Documentation of corrective actions must be submitted within 10 calendar days of receipt of written notification.
    - At the end of the inspection, the inspector informs the department(s) or laboratory of any deficiencies and Required Process Improvements (RPI).
    - CQA generates a written report:
    - Reports are issued via company email within 25 calendar days of the inspection
    - Reports include a grade with total points
    - A color rating is also assigned to Regional, Support and Esoteric laboratories. (Refer to 8.4)
    - If a laboratory challenges a deficiency, the challenge must be communicated to CQA as soon as possible. All challenges will be resolved before the written inspection report is issued.
- **For Regional, Support and Esoteric Laboratories:**
    - Inspectors perform a focused inspection of one or more test systems and all associated documentation.
    - The focused inspection includes the broader quality systems that support the specific test systems.
    - Inspectors use Quest Diagnostics Non-Technical Department Checklists for Logistics, Warehouse, Specimen Processing, Tech Ops and Referral Testing, as appropriate.
    - Inspections are a three level process:
        - Level 1 – Initial CQA Inspection
        - Level 2 – Assessment of the laboratory's corrective action responses for the Initial inspection
        - Level 3 – Follow-up Inspection.
- **For RRLs:**
    - Inspectors use CAP requirements, CLIA standards, and Quest Diagnostics standard policies
    - Inspections are a one level process.
- **For Hospitals:**
    - Inspectors use CAP requirements, CLIA standards, Joint Commission, and Quest Diagnostics standard policies
    - Inspections are a one level process.
- **Employer Solutions:**
    - Inspectors use CAP requirements and Quest Diagnostics standard policies
    - Inspections are a one level process.
- **Clinical Trials:**
    - Inspectors use CAP requirements, GLP, and Quest Diagnostics standard policies
    - Inspections may also examine compliance with protocols involved in particular trials
    - Inspections are a one level process.

8. REGIONAL, SUPPORT AND ESOTERIC LABORATORY INSPECTION PROCESS

8.1 Level 1

Step	Action
1	CQA creates a preliminary inspection schedule and determines the inspection team composition.
2	CQA reviews Quality Indicators from the laboratory, including but not limited to, previous inspection reports (internal and external), proficiency test results (internal and external), Interlab QC, RQIs, agency complaints and results of other CQA managed quality programs.
3	CQA notifies the laboratory QA Director/Manager, Laboratory Director, or Laboratory Operations Director/Manager on the Friday before the inspection.
4	CQA sends an email to the laboratory QA Director/Manager, Laboratory Director, and Laboratory Operations Director/Manager confirming the inspection date and time. A tentative inspection schedule is included.
5	The inspection begins with an introductory meeting: • Recommended laboratory attendees include the Laboratory Director, Laboratory Operations Director/Manager, laboratory QA Manager, and department Managers/Supervisors. Those off site may be accommodated by phone. • The agenda is discussed and the inspection schedule is confirmed • An optional exit meeting is scheduled.
6	If an Exit meeting is requested, inspectors will summarize: • All deficiencies • IMT process • Key due dates • Process for challenging deficiencies
7	The following documentation is provided to the QA Director/Manager at the end of the inspection: • Deficiency forms • Key Reminders
8	An inspection report is issued via company email within 25 calendar days of the inspection to the following: • Laboratory Director • Corporate Legal Counsel • Laboratory QA Manager • Chief Laboratory Officer • CQA Corporate Medical Director • Vice President of Laboratory Operations (International or Hospital Services) • Regional Vice President of Laboratory Operations (for the laboratory's region) • Regional Laboratory Director • Regional Operations Director

Step	Action
	• CQA Managers
9	Each deficiency is assigned a point value which is included in the written report (See Step 10 below for points): • Points for the entire laboratory are totaled. • Total points for the laboratory are normalized to reflect the number of test systems inspected. • Total points are adjusted downward for more than an average number of test systems, upward for less than an average number of test systems.

10	**The point system is as follows:**
	• **Repeats:** 4 points + associated number of points for the deficiency (1-3)
	• **10 points:** A deficiency repeated for the 3rd consecutive time
	• **3 Points**:
	  • Results released with out of limits QC
	  • Failed competency that was not resolved and the employee is still performing the task or job assignment
	  • Failure to call a Priority 1 result according to the corporate *Priority Result Reporting Policy*
	  • Procedures are incomplete and written procedures for two or more test systems in a department do not match actual practice
	• **2 points**:
	  • Any deficiency related to QC (other than results released with out of limits)
	  • Any deficiency related to incomplete/ineffective corrective action
	  • Expired reagents in use
	  • No maintenance performed
	  • Release of test results with QC out of range without adequate supporting documentation for the over-ride
	  • Priority Result Reporting Policy / practice does not match procedure (e.g., failure to implement monthly summary; failure to document critical calls with name of contact; failure to document the value was read back by recipient)
	  • Inappropriate Proficiency Test (PT) Handling (e.g., failure to handle PT material as patient sample to the extent possible, such as duplicate PT testing when patients are routinely tested only once; calibrating immediately prior to performing PT samples; running QC in a manner that does not match the SOP; laboratory has not performed PT for a given analyte (including Alternative Performance Assessment)
	  • Lack of initial or annual training or lack of documentation of training on the Corporate procedures for PT handling (QDNQA711) and inappropriate PT referral or communication (QDNQA712), for all appropriate employees.
	  • Written procedures for two or more test systems do not match practice OR written procedures are incomplete and one written

Step	Action
	procedure does not match actual practice • Problems are identified with the Laboratory Director's delegation documents and unqualified individuals are listed on the documents. (This is cited under the Team Leader section. A single point is also assessed in the department for failing to meet supervisor qualification requirements.) • When the same deficiency is cited three or more times across the laboratory, a 2-point systemic deficiency (quality system failure) is also cited in the Laboratory General section. • **1 Point**: All other deficiencies

8.2 Level 2 – INITIAL CORRECTIVE ACTION RESPONSE

Step	Action
1	The laboratory QA Manager/Director coordinates the corrective action process for the deficiencies.
2	The laboratory documents deficiency responses in the Inspection Management Tool (IMT). • IMT responses must be submitted within 21 calendar days of issue of the final inspection report • Supporting documentation must be maintained by the laboratory • Attachments in the IMT are discouraged
3	Points are added or subtracted based on timeliness and completeness of the responses (Refer to 8.4.1)
4	Responses to all deficiencies must address: • Remedial Action [immediate steps taken to correct the deficiency(ies)] • Patient Impact (describe steps taken to minimize patient impact or explain why there was no patient impact) • Root Cause (why the existing process failed) • Root Cause Analysis (**brief** description of investigation) • Corrective Action Plan (steps taken to remove the root cause) • Replication (within or among other departments) • Monitoring (to ensure implemented process improvements are sustained) • Date Completed or Target Date for Completion
5	CQA reviews the IMT responses and determines acceptability. • If a response is unacceptable, it is rejected. • Additional information may be requested
6	When all responses are approved, CQA sends e-mail notification to the Laboratory Director and Laboratory Operations Director/Manager acknowledging the completion of the inspection process. The Laboratory QA Manager is copied.

8.3 LEVEL 3 – FOLLOW-UP INSPECTIONS

Step	Action
1	Level 3 inspections are unannounced; no advance notice is given.
2	The inspection begins with a brief introductory meeting. • A schedule is discussed with the QA department and key laboratory personnel.
3	Inspectors focus on the corrective actions to the deficiencies cited during the Initial inspection. This assessment includes: • Ensuring that corrective actions are complete, or on target for completion, by the established date • Assessing whether corrective actions are effective and maintained • Determining whether corrective actions were replicated to similar processes • If discovered, coincidental findings (new deficiencies) are also cited.
4	Deficiencies that have not been fully addressed, or require additional corrective action, are discussed with responsible laboratory personnel. The Follow-up Inspection report details any additional corrective action that is required.
5	A written Follow-up Inspection report is issued via company email within 25 calendar days of the inspection to the following distribution list: • Laboratory Director • Corporate Legal Counsel • Laboratory QA Manager • Chief Laboratory Officer • CQA Corporate Medical Director • Vice President of Laboratory Operations (International or Hospital Services) • Regional Vice President of Laboratory Operations (for the laboratory's region) • Regional Laboratory Director • Regional Operations Director • CQA Managers
6	For deficiencies that require additional corrective action, the laboratory manages the corrective action response process as described in 8.2. • Responses are due within 21 calendar days of receipt of the Follow-up Inspection report. • Corrective action is not required for original deficiencies that are complete or on target for completion.
7	When the follow up responses are reviewed and deemed appropriate, CQA sends electronic notification to the Laboratory Director and Laboratory Operations Director/Manager, acknowledging the completion of the inspection process. The Laboratory QA Manager is copied.
8	Follow-up for Level 3 corrective actions is performed by the laboratory's CQA Mentor.

8.4 GRADING PROCESS

8.4.1 Grading is comprised of three levels and each level will receive a score or grade.

- Level 1 is the Initial CQA Inspection. Points are assigned based on the number and types of deficiencies cited.
- Level 2 assesses the laboratory's corrective action responses to the deficiencies. Points are added or subtracted based on timeliness and completeness of the responses.

IF	THEN
Responses are received within 21 calendar days of receipt of Initial inspection report	15 points are subtracted from the laboratory's cumulative score
Responses are received more than 21 calendar days after receipt of Initial inspection report	20 points are added to the laboratory's cumulative score
A response is rejected (IMT fields missing, root cause not addressed, superficial response, etc.)	2 points per rejected response are added (Responses are rejected if they are unacceptable, not if minor clarifications are needed.)

- Level 3 is the CQA Follow-up Inspection. Points are subtracted (or in some cases added) based upon the implementation and monitoring of the laboratory's corrective actions.

8.4.2 SCORING AND COLOR GRADES

Level 1

Color Grade	Level 1 Score	Level 1 Cumulative
Green	0 to 80 *	0 to 80 *
Yellow	81 to 120 *	81 to 120 *
Red	>120 *	>120 *

Level 2

Color Grade	Level 2 Score	Level 2 Cumulative
Green	- 4 to -15	0 to 80 *
Yellow	-3 to +6	81 to 120 *
Red	>6	>120 *

Level 3 – No color grade is assigned

Level 3 Score
85% or more of original points removed
70% to 84.99% of original points removed
Less than 70% of original points removed

$$\text{Level 3 Percentage} = \frac{\text{* Corrected Points (Points Removed) - Added Points}}{\text{* Original Points}} \times 100$$

***** Normalized points based on number of test systems inspected (points removed are also normalized)

9. RRL INSPECTIONS

Levels 1 through 4 do not apply to RRLs

Step	Action
1	All RRL deficiencies count as 1 point; there is no weighting of any particular deficiency.
2	Any **Repeat Deficiency is** 2 points
3	The laboratory QA Manager/Director coordinates the corrective action process for the deficiencies.
4	The laboratory documents deficiency responses in the Inspection Management Tool (IMT). • IMT responses must be submitted within 21 calendar days of issue of the final inspection report • Supporting documentation must be maintained by the laboratory • Attachments in the IMT are discouraged **NOTE:** Points are removed if all responses are received within 21calendar days.

5	Responses to all deficiencies must address: • Remedial Action [immediate steps taken to correct the deficiency(ies)] • Patient Impact (describe steps taken to minimize patient impact or explain why there was no patient impact) • Root Cause (why the existing process failed) • Root Cause Analysis (**brief** description of investigation) • Corrective Action Plan (steps taken to remove the root cause) • Replication (within or among other departments) • Monitoring (to ensure implemented process improvements are sustained) • Date Completed or Target Date for Completion
6	CQA reviews the IMT responses and determines acceptability. If a response is unacceptable, it is rejected. Additional information may be requested if needed.
7	When all responses are approved, CQA sends e-mail notification to the Laboratory Director and Laboratory Operations Director/Manager acknowledging the completion of the inspection process. The Laboratory QA Manager is copied.

10. HOSPITAL INSPECTIONS

Only Level 1 and Level 2 apply to Hospital Laboratories

Step	Action
1	Level 1 is the Initial CQA Inspection. Points are assigned based on the number and types of deficiencies cited. Laboratories are given a score of total points assessed
2	Level 2 assesses the laboratory's corrective action responses to the deficiencies. Points are added or subtracted based on timeliness and completeness of the responses.
3	Follow-up Inspections are not routinely performed in Hospital Laboratories.

11. RECORDS MAINTENANCE

Records are maintained according to the requirements published in the Quest Diagnostics *Records Management Program Reference Guide*.

12. RELATED DOCUMENTS

- CAP Laboratory Accreditation Program (LAP) Checklists (www.cap.org)
- Quest Diagnostics CQA Non-Technical Department Checklists
- Rapid Response Laboratory Quality Oversight Program
- Interpretive Guide for RRL Inspection Checklist

- SOP QDCQA712, *Procedure for Handling Inappropriate Referral of Proficiency Material or Inter/Intra-laboratory Communication of Proficiency Test Information*
- SOP QDCQA711, *Proficiency Test Handling and Result Submission*
- SOP QDMED704, *Priority Results Reporting Policy*
- CQA Inspection Level 1 Reminders Document
- CQA Inspection Level 3 Reminders Document

13. REFERENCES

N/A

14. DOCUMENT HISTORY

Version	Date	Section	Revision	Revised By	Approved By
QDCQA716 Ver. 3.0	1/24/08		Revised SOP title and ID number (previously CQA0202_CPIntInspProcess_SOP.doc)	Ruthi Breazeale	
QDCQA719 Ver. 1.0	11/18/09	All	**Document number reassigned**. See Revision History of the 2009 retired document (version 3.1) for all prior revisions.	Don Bennett	R. Breazeale
1.0		3	Added reference to Follow-up inspections and BU QA Manager responsibilities	Don Bennett	R. Breazeale
		4	Added definitions of IMT, coincidental finding, normalized points, and test systems	Don Bennett	R. Breazeale
		6	Added unannounced inspections	Don Bennett	R. Breazeale
		8	(Pre-Inspection) Renumbered section, moved Scoring section, included unannounced inspections	Don Bennett	R. Breazeale
		9	(Inspection) Renumbered and included unannounced, focused process	Don Bennett	R. Breazeale
		10	(Post-Inspection) Added time limit for challenging non-conformances	Don Bennett	R. Breazeale
		11	(Inspection Report) Added 21 calendar day report receipt expectation	Don Bennett	R. Breazeale
		12	(Corrective Action) Added specific corrective action information required, added IMT references	Don Bennett	R. Breazeale
		13	(Follow-up Inspections) New process, added entire section	Don Bennett	R. Breazeale
		14	(Scoring) Added revised evaluation criteria	Don Bennett	R. Breazeale
		15	(IMT) Added section for overview of new management tool.	Don Bennett	R. Breazeale
		16	(Privacy and Security) Reworded to reflect current report verbiage.	Don Bennett	R. Breazeale

		17	(Related Documents) Added IMT Instructions.	Don Bennett	R. Breazeale
		20	Section 20: Added Appendix	Don Bennett	R. Breazeale
2	3/3/14	All	• Reformatted to current template. • Changed document to a policy and updated the title. • Consolidated, renamed and rearranged sequence of Sections 6-16 of the previous version. • Updated terminology to reflect changes from NQA to CQA, categories of laboratories. • Changed nonconformance to deficiency	K. Grimes	D. Zorka
2	3/3/14	2	Updated Scope to current practice.	K. Grimes	D. Zorka
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2	3/3/14	8.1	Revised criteria for assigning points.	K. Grimes	D. Zorka
2	3/3/14	8.4	Revised grading criteria for Level 2 and Level 3.	K. Grimes	D. Zorka
2	3/3/14	12	Updated Related Documents	K. Grimes	D. Zorka
2	8/18/14	Page 1	Adopting corporate version 2. Added non-technical SOP designation per local document control.	L. Barrett	C. Bowman-Gholston

15. ADDENDA

Addendum	Title