TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	10/9/2016
Department:	Mgmt, QA	**Due Date:**	10/31/2016
		Implementation:	**10/13/2016**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
Corporate Quality Assessment Internal Inspection Policy SGAH.QDNQA719 v3.1 *(system SOP)*
Description of change(s):
Revised corporate version issued in 2015 being adopted. Refer to SOP Document History (section 12) for changes. This revised SOP will be implemented on October 13, 2016

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:**	3/2/15
Print Name and Title	**Signature**	**Date**
Dianne Zorka **Director, Corporate Quality Assessment**	*On file*	3/2/15
Lee Hilborne, M.D., MPH **Corporate Medical Director**	*On file*	3/2/15

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

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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 phases of Clinical Pathology (CP) testing in:

- Regional, Support and Esoteric Laboratories
- Rapid Response Laboratories (RRLs)
- Clinical Trials
- Employer Solutions
- Majority-owned joint venture laboratories
- Patient Service Centers (PSC)
- National Operations Centers (NOC)

This policy does not apply to:

- Anatomic Pathology
- Waived testing sites
- Hospital laboratories
- Minority-owned joint ventures (inspected by invitation only)

3. RESPONSIBILITY

- **Corporate Quality Assessment (CQA)** is responsible for:
  - Implementation of the CQA Internal Inspection Program
  - Conducting inspections
  - Distributing written report within 25 calendar days of the inspection date
  - Assessing laboratory corrective actions
  - Conducting additional inspections, as required, to ensure corrective actions are complete and sustained
- 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
- 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 corrective actions to ensure they are effective and sustained
  - Ensuring confidential retention and handling of CQA inspection reports.
- 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 the inspection process
  - Coordinating inspection corrective action responses
  - Creating and/or managing the remediation/corrective action plan for deficiencies in Lab General and submitting 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 on the IMT Responder List
- 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 the inspection processes in the department
  - Creating or managing the remediation/corrective action plan for the inspection deficiencies and submitting to laboratory management for approval
  - Handling and retaining inspection information in a confidential manner.

4. DEFINITIONS

- **Inspection Management Tool (IMT)**: 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.
- **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.
- **Repeat Systemic Deficiency:** A systemic deficiency from the most recent CQA, CAP, and/or state inspection that is cited again during the current CQA inspection.
- **Reportable Quality Issue (RQI):** A quality issue with known or potential impact on current or future 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.
- **Systemic Deficiency:** The same non-conformance cited three or more areas

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 policies

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
  - Any and 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, an electronic or a printed copy may be shared with limited 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 the reports must be notified by the Laboratory Director **that these electronic copies may not be distributed, disseminated, reproduced and/or forwarded without prior approval.**

- **CQA inspection reports may NOT be reviewed by or distributed to any outside regulatory agency (e.g., CLIA, CAP or state agency).**
- Corrective action responses to each deficiency must be transmitted to CQA via the Inspection Management Tool (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 wording **Privileged and Confidential - Quality Assurance Privilege** in the subject line and at the beginning of the e-mail message.

7. GENERAL INSPECTION PROCESS

- CQA may perform an inspection at any time
- All inspections include the following**:**
  - 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)
  - If a serious quality problem is encountered 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 the total number of deficiencies
- A color rating is also assigned to Regional, Support, Esoteric and Rapid Response Laboratories. (Refer to 8.3)
- Challenges to a deficiency must be must be communicated to CQA as soon as possible. All challenges must be resolved before the written inspection report is issued.
- **Regional, Support, Esoteric, Rapid Response Laboratories, and PSCs:**

- Inspectors perform an inspection of testing departments using CAP requirements, CLIA standards, and Quest Diagnostics standard policies.
- Inspectors use Quest Diagnostics Non-Technical Department Checklists for Logistics, Warehouse, Specimen Processing, Tech Ops and Referral Testing, as applicable.
- The inspection process includes:
  - CQA Inspection
  - Corrective Action for deficiencies cited during the CQA Inspection

- **Employer Solutions:**
  - Inspectors use CAP requirements and Quest Diagnostics standard policies
  - Inspections consist of the CQA inspection only
- **Clinical Trials:**
  - Inspectors use CAP requirements, GLP, and Quest Diagnostics standard policies
  - Inspectors may also examine compliance with protocols involved in particular trials
  - Inspections consist of the CQA inspection only.
- **National Operations Centers:**
  - Inspectors use the Quest Diagnostics Non-Technical Department Checklist for Client Service & Customer Solutions
  - Inspections consist of the CQA inspection only

8. INSPECTION PROCESS

8.1 CQA INSPECTION

8.1.1 Pre Inspection

Step	Action
1	CQA creates a preliminary inspection schedule and determines the inspection team composition.
2	CQA contacts the laboratory QA Director/Manager to determine date(s) for the inspection.
3	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.
4	CQA confirms the inspection date and time by sending an email to the laboratory QA Director/Manager, Laboratory Director, and Laboratory Operations Director/Manager. The email includes a tentative inspection schedule.

8.1.2 Inspection

1	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 • The summary meeting (including CQA, Laboratory Director, Laboratory Operations Director/Manager, laboratory QA Manager) is scheduled.
2	At the summary meeting, the inspectors review: • All deficiencies • IMT process • Key due dates • Process for challenging deficiencies
3	The following documentation is provided to the QA Director/Manager at the end of the inspection: • Deficiency forms • Key Reminders

8.1.3 Post Inspection

1	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 • Laboratory Operations Manager / Director • CQA Managers

2	The written Inspection Report includes:
	• Deficiencies listed in each department
	  • The deficiency is referenced to the specific standard or regulatory requirement that is not met.
	  • Repeat deficiencies are noted.
	• Systemic Deficiencies listed in Lab General
	  • The deficiency is also noted in each department where it is found
	• Total number of deficiencies

8.2 CORRECTIVE ACTION

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	Systemic Deficiencies must be addressed by each department cited AND by the laboratory as a whole, typically by the QA department.
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 of the corrective action plan
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 SCORING AND COLOR GRADES

8.3.1 SCORING

The laboratory inspection score is determined using a combination of 2 components.

1. Total Number of Deficiencies
   - A deficiency that is NOT included in a systemic issue is counted as 1 deficiency.
2. Total Number of Systemic Deficiencies
   - Each Systemic Deficiency is counted separately (and listed in Lab General)
     EXAMPLE: Reagent labeling deficiencies are found in Hematology, Microbiology and Immunology = 1 Systemic Deficiency
   - A Repeat Systemic Deficiency is counted as an **additional** Systemic Deficiency

8.3.2 COLOR GRADES

Color grades are assigned based on the most stringent (highest) score, as specified in the following tables:

Total # Deficiencies	Grade
<15 (NO systemic)	Blue
15-29	Green
30-45	Yellow
>45	Red

Systemic Deficiencies	
1-2	Green
3-5	Yellow
>5	Red

9. RECORDS MAINTENANCE

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

10. 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
- *Procedure for Handling Inappropriate Referral of Proficiency Material or Inter/Intra-laboratory Communication of Proficiency Test Information* (QDNQA712),
- *Proficiency Test Handling and Result Submission* (QDNQA711)
- *Priority Results Reporting Policy* (QDMED704)
- CQA Inspection Reminders Document

11. REFERENCES

Not Applicable

12. DOCUMENT HISTORY

Version	Date	Section	Revision	Revised By	Approved By
1.0	11/18/09		Refer to Document History for retired version 2		
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
2	3/3/14	4	• Eliminated definitions for Phase I and II standards. • Added RQI and RPI.	K. Grimes	D. Zorka
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

Version	Date	Section	Revision	Revised By	Approved By
3	2/6/15	All	• Removed all references to Levels 1-4, Follow-up Inspections, focused inspections, and points. • Revised verbiage throughout the document to correspond to the current process.	P. McLeod	D. Zorka
3	2/6/15	2	Updated Scope to include PSCs and NOC	P. McLeod	D. Zorka
3	2/6/15	3	Changed to descending order for Responsibilities	K. Grimes	
3	2/6/15	4	• Deleted Coincidental Finding, Normalized Points, Repeat Deficiency and Test System • Added Repeat Systemic Deficiency and Systemic Deficiency	P. McLeod	D. Zorka
3	2/6/15	6	• Added inspection reports may NOT reviewed by or distributed to outside regulatory agencies. • Revised verbiage for privileged labeling in emails.	K. Grimes	D. Zorka
3	2/6/15	7 & 8	• Revised with new process for all inspections. • Changed grading from points to number of deficiencies.	P. McLeod	D. Zorka
3	2/6/15	8.3	Added new scoring and color grades	P. McLeod	D. Zorka
3	2/6/15	11	Modified format for Related Documents	K. Grimes	D. Zorka
3	9/28/16	Page 1	Adopting corporate version 3. Added non-technical SOP designation per local document control.	L. Barrett	C. Bowman-Gholston

13. ADDENDA

Addendum	Title