TRAINING UPDATE

Lab Location:	SGMC, WAH & GEC	**Date Distributed:**	1/28/2019
Department:	Mgmt & QA	**Due Date:**	2/12/2019
		Implementation:	**2/12/2019**

DESCRIPTION OF REVISION

Name of procedure:

Corporate Quality Assessment Internal Inspections
SGMC.QA2001 v1

Description of change(s):

This is a 'new' SOP that replaces our previous NQA version. It is very similar to the old SOP but has been converted to our local SOP format. A few minor changes were made:

- Removed the Quest list of departments under Scope
- Changed 'QA manager/supervisor' to QA designee or QA staff through out
- Removed references / exceptions for NY labs

Note: This new version is processed thru Media Lab. SOP numbers for new shared documents are prefixed with SGMC (not SGAH) and initial version is 1 (not 0).

This SOP will be implemented on February 12, 2019

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

Non-Technical SOP

Title	**Corporate Quality Assessment Internal Inspections**
Prepared by	Leslie Barrett Date: 1/23/2019
Owner	Cynthia Bowman-Gholston Date: 1/23/2019

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 describes the process utilized the Quest Diagnostics Corporate Quality Assessment personnel 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 the clinical laboratory.

3. RESPONSIBILITY

Responsible Party	Task
Corporate Quality Assessment (CQA)	• Implementation of the CQA Internal Inspection Program • Conducting inspections • Distributing written report within 25 calendar days of the inspection date • Assessing laboratory preventive actions • Conducting additional inspections, as required, to ensure corrective actions are complete and sustained
Laboratory Director	• 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 preventive actions for all deficiencies • Monitoring of corrective actions to ensure they are effective and sustained

Responsible Party	Task
	• 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
Laboratory Operations Director/Manager	• 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 preventive actions for all deficiencies • Monitoring of preventive actions to ensure they are effective and sustained • Ensuring confidential retention and handling of CQA inspection reports.
Quality Assurance Staff / Designee	• 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 preventive 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 preventive 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
Department Manager/Supervisor	• 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 /corrective / preventive action plan for the inspection deficiencies and submitting to laboratory management for approval • Handling and retaining inspection information in a confidential manner.

4. DEFINITIONS

Term	Definition
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.
CAPA	Corrective Action / Preventive Action
Deficiency	An indication that an outcome or process has not met the specified requirement, standard or policy.
Major Issue	A serious quality problem that may greatly impact patient safety or pose a serious risk • Failure to maintain specimen integrity in each step of all processes (includes confirmation of positive patient identification at each step of all processes) • Critical value not called • Critical testing not completed / resulted • Blatant falsification of records • Discovery of any unreported RQI
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
- 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 / preventive actions (CAPA). 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).**
- CAPA responses to each deficiency must be transmitted to CQA via the Inspection Management Tool (IMT). Supporting documentation for corrective actions or 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. TYPES OF INSPECTIONS

- Routine inspections, at a frequency to be determined by CQA
- Pre-CAP accreditation inspections, prior to on-site approval inspections by CAP, as needed or requested
- Follow-up of most current inspection, as determined by CQA
- For-cause inspections, as needed, per request from Chief Laboratory Officer, Sr. Medical Director of Medical Quality, corporate legal counsel or CP Regional Medical Director
- Due diligence for a proposed laboratory acquisition, as requested

8. GENERAL INSPECTION PROCESS

- CQA may perform an inspection at any time but are typically scheduled in advance.
- All inspections include the following**:**
  - Evaluation of compliance to standards.
  - Explanation of deficiencies cited.

- Evaluation of CAPA taken in response to previous deficiencies
- Implementation verification of BPT initiatives.
- Verification that CAPA 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 / preventive 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 9.3)
- Challenges to a deficiency must be must be communicated to CQA within 18 days of the inspection. All challenges must be resolved before the written inspection report is issued.
- **Laboratories:**
  - Inspectors perform an inspection of testing departments using applicable regulatory standards (i.e., CLIA regulations, CAP requirements) and Quest Diagnostics standard policies.
  - Inspectors use Quest Diagnostics Non-Technical Department Checklists for Specimen Processing and Referral Testing, as applicable.

9. INSPECTION PROCESS

9.1 CQA INSPECTION

9.1.1 Pre-inspection

Step	Action
1	CQA creates a preliminary inspection schedule and determines the inspection team composition.
2	CQA contacts the laboratory QA Designee 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 Designee and Laboratory Director. The email includes a tentative inspection schedule.

9.1.2 Inspection

Step	Action
1	The inspection begins with an introductory meeting: • Recommended laboratory attendees include the Laboratory Director, Laboratory Operations Director/Manager, laboratory QA staff, 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, and laboratory QA staff) is scheduled.
2	At the summary meeting, the inspectors review: • All deficiencies • All Required Process Improvements • IMT process • Key due dates • Process for challenging deficiencies
3	The following documentation is provided to the QA Designee at the end of the inspection: • Deficiency forms • Key Reminders

9.1.3 Post-inspection

Step	Action
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 Designee • Chief Laboratory Officer • CQA Corporate Medical Director • Vice President of Laboratory Operations (International) • Regional Vice President/General Manager • Regional Laboratory Director • Regional Operations Director • Laboratory Operations Manager / Director • CQA Director

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 separately
	  • The deficiency is also noted in each department where it is found
	• Total number of deficiencies

9.2 CORRECTIVE ACTION / PREVENTIVE ACTION

Step	Action
1	The laboratory QA staff coordinates the CAPA 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: • Corrective 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) • Preventive 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 preventive 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.

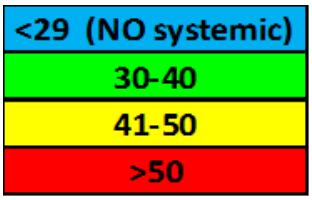
9.3 SCORING

- The laboratory inspection score is determined using a combination of points.
- The overall point total may be reduced if the IMT response(s) to any Systemic Deficiency (including Repeat Systemic) is accurate, complete and timely.

DEFICIENCY	POINTS	INCENTIVE FOR GOOD CAPA*
Department deficiency	1	
Repeat Deficiency	2	
Systemic Deficiency	2	-2
Repeat Systemic Deficiency	4	-2
Major Issue	5	
Repeat Major Issue	10	

9.4 COLOR GRADES

Color grades are assigned based on the total number of points, as specified in the follow table:



10. RECORDS MANAGEMENT

Records generated as a result of this policy/process/procedure may have different retention requirements. Refer to the Quest Diagnostics *Records Management Program Reference Guide*. http://questnet1.qdx.com/Business_Groups/legal/records/schedule.htm

11. RELATED DOCUMENTS

- CAP Laboratory Accreditation Program (LAP) Checklists
- 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, QA procedure
- Proficiency Test Handling and Result Submission, QA procedure
- Critical Values, Laboratory procedure
- CQA Inspection Reminders Document

12. REFERENCES

Not Applicable

13. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SGAHQDNQA719v4.1		

14. APPENDICES

None