Quest Diagnostics

TRAINING UPDATE

Lab Location:	All	**Date Distributed:**	6/1/2012
Department:	Mgmt & QA staff	**Due Date:**	6/30/2012

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
Policy for Compliance with the College of American Pathologists (CAP) Terms of Accreditation QDNQA726, V 2.0
Description of change(s):
Section 5 – revised wording to harmonize with CAP Terms of Accreditation. See yellow highlighted areas

EMPLOYEE SIGNATURES

I have read and understand the procedure described above:

Name	**Signature**	**Date**

Employee signatures are not necessary. Document your compliance with this training update by taking the quiz in the MTS system.

Non-technical SOP

Title	**Policy for Compliance with the College of American Pathologists (CAP) Terms of Accreditation**
Prepared by	Jill Hittinger, Karen Rupke 5/1/2012

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:**	5/7/2012
Print Name and Title	**Signature**	**Date**
Karen Rupke **Director, Corporate Quality Management -CP**	*On File*	5/1/2012
Stephen C. Suffin, M.D. **V.P and Chief Laboratory Officer**	*On File*	4/23/2012

Retirement Date:	
Reason for retirement/replacement:	

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1. PURPOSE

This document sets forth the policy for compliance with the College of American Pathologists (CAP) Laboratory Terms of Accreditation.

2. SCOPE

This policy applies to all CAP accredited Quest Diagnostics owned or managed laboratories as well as those seeking initial CAP accreditation.

3. RESPONSIBILITY

- The **Laboratory Director** is responsible for:
  - Approving the initial release of this document and any subsequent revisions.
  - Ensuring the terms and obligations required for accreditation by the College of American Pathologists are met and remain in compliance.
- The **Laboratory Director or designee** is responsible for:
  - The recurring review of this policy document.
  - The implementation, coordination, management and oversight of each CAP accreditation term and obligation listed.

4. DEFINITIONS

College of American Pathologists (CAP) Accreditation Program: The CAP Laboratory Accreditation Program is an internationally recognized program that helps laboratories achieve the highest standards of excellence to positively impact patient care. The Centers for Medicare and Medicaid Services (CMS) have granted the CAP Laboratory Accreditation Program deeming authority to inspect and grant certifications for individual laboratory operations.

CAP Certification Mark: The logo symbolizing CAP accreditation achievement.

College of American Pathologists (CAP): A medical society of physicians and laboratory personnel throughout the world, fostering and advocating excellence in the practice of pathology and laboratory medicine.

Laboratory Director: The person whose name is on the CLIA certificate.

Proficiency Testing Program: Proficiency Testing (PT) is the process used to demonstrate a laboratory's ability to provide accurate and reliable results in its patient testing system by testing "unknown" samples from an approved PT provider. The process incorporates elements of pre-analytical, analytical, and post-analytical phases.

Quality Management Plan: A strategy for systematic monitoring of the ongoing and overall quality of the total testing process (pre-analytic, analytic and post-analytic phases). It is the process through which problems or errors are identified, corrective action implemented and the effectiveness of the corrective action is later evaluated and monitored.

5. POLICY

CAP accredited Quest Diagnostics laboratories will comply with the terms and obligations set forth by the College of American Pathologists which includes the following:

- Compliance with all applicable federal, state, and local laws.
- Notification to the CAP office within two working days, whenever the laboratory finds itself the subject of an investigation by a government entity or other oversight agency, or the subject of adverse media attention related to laboratory performance. This notification must include all complaint investigations conducted or warning letters issued by any oversight agency (e.g., CMS, State Department of Health, The Joint Commission, FDA, OSHA, AABB).
  - **NOTE**: See also *Notification of Federal and State Agency Laboratory Performance Investigations, Complaints or Adverse Media* SOP (QDMED724)
- Notification to the CAP if the laboratory becomes the subject of a validation inspection (e.g., CMS, State).
- Notification to the CAP if the laboratory discovers actions by laboratory personnel that appear to violate federal, state, or local laws or regulations that govern laboratories.
- Complying with Quest Diagnostics Duty to Report Policy and posting required signage (CAP Poster and Quest Diagnostics CheQline posters) so that employees understand their available options to communicate concerns to management or the CAP about quality and safety issues. Corrective or preventative actions taken in response to quality and safety issues are incorporated into the laboratory's Quality Management Plan.
- Providing an inspection team comparable in size and scope to that required for its own inspection if requested by the regional and/or state commissioner at least once during the two-year accreditation period.
- Participation in a CAP accepted proficiency testing program for each analyte as applicable.

- Notification to the CAP office in writing of changes in location, ownership, or directorship no later than 30 days prior to the change(s). In the case of unexpected changes, notification must occur no later than two days afterwards.
- Notification to the CAP office when there are additions or deletions in the laboratory's test menu. For additions, notify CAP of additions prior to starting new patient testing.
- Authorizing the CAP to release inspection and proficiency testing data to the appropriate regulatory or oversight agencies.
- Conducting an interim self inspection, documenting the correction of identified deficiencies, and the review of these findings by responsible personnel.
- Accepting and adhering to the *Certification Mark Terms of Use/Agreement for CAP Accredited Mark and Design*, if the laboratory is using or will use the CAP Certification Mark of accreditation. **NOTE**: Use of the CAP Certification Mark must be done following Quest Diagnostics Brand Identity Guidelines. http://questnet1.qdx.com/Business_Groups/bus_mgmt/cpa/corp_identity/corp_identity.htm
- Submitting only documents and other materials to the CAP that have been de-identified of all protected health information (PHI) in accordance with the requirements of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 unless the PHI is critical to the supporting documents (e.g., patient complaints).
- Cooperating in any CAP investigation or inspection.
- Refraining from copying or distributing the CAP Checklists or any content thereof except for use by inspectors in conducting a CAP inspection and by the laboratory in preparing for such an inspection.
- Adhering to CAP personnel qualification requirements for all personnel engaged in the pre-analytic, analytic and post-analytic phases of testing. (See the CAP website for specific requirements based on test complexity and job function.)
- Maintaining the necessary documentation to confirm that each employee's qualifications meet the CAP requirements. Refer to *Policy for the Documentation of Testing Personnel Qualifications in PeopleSoft*™ (QDMED717).

6. RECORDS MAINTENANCE

Records are maintained in accordance with the requirements published in the Quest Diagnostics *Records Management Program Reference Guide*.

7. RELATED DOCUMENTS

- *Policy for the Documentation of Testing Personnel Qualifications in PeopleSoft*™ (QDMED717)
- *Notification of Federal and State Agency Laboratory Performance Investigations, Complaints or Adverse Media* (QDMED724)
- Compliance Policies and Procedures:
  - Cooperation with Government Inspections and Inquiries
  - Duty to Report
  - Licenses and Accreditation

- Privacy of Protected Health Information (PHI)
  Legal / Compliance Policies/Procedures & Supporting Documents

- Quest Diagnostics Brand Identity Guidelines.
  http://questnet1.qdx.com/Business_Groups/bus_mgmt/cpa/corp_identity/corp_identity.htm

8. REFERENCES

- College of American Pathologists Laboratory Accreditation Program (cap.org)
- Code of Federal Regulations, Title 45, § 164.514(b)

9. DOCUMENT HISTORY

Version	Date	Section	Revision	Revised By	Approved By
1.0	7/2010		N/A-Corporate policy document issued		
1.0	8/23/10		Footer: Remove file name and date, add local version Supersedes local version GEC/SGAH/WAH. QA14.000	L. Barrett	C. Bowman
2.0	5/2012	5	Policy updated to harmonize with CAP Terms of Accreditation	K Rupke	K. Rupke
A	5/15/12	Footer Page 1	Adopting corporate issued version 2.0 Additional local revisions: Add local version Add SOP type designation to reflect local terminology and electronic approval.	L. Barrett	C. Bowman

10. ADDENDA

Addenda	File Name	Title
	NA	