Quest Diagnostics

TRAINING UPDATE

Lab Location:	All	**Date Distributed:**	5/10/2012
Department:	Management & QA	**Due Date:**	6/1/2012

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Management of Vendor Notifications GEC / SGAH / WAH. QA43 v000

Description of change(s):

New SOP to define process for handling recalls or other issues reported by a vendor or manufacturer.

No.	Learning Objective
1	Reads and understands procedures associated with job assignment.
2	States definition of vendor notifications - product recalls, market withdrawals, or software patches and upgrades.
3	Describes process when a vendor notification is received. • Staff give notification to Lab management or QA • Management informs Lab QA and vice versa • Lab QA informs Chantilly QA
4	Review documentation process • QA and Lab management prepare and submit vendor response, if required • QA and Lab management work together on corrective action, if required • QA maintains electronic documentation

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.

Approved draft for training all sites (version 000)

Non-Technical SOP

Title	**Management of Vendor Notifications**	
Prepared by	Amanda Engles/Rachel Strother	Date: 9/26/2011
Owner	Cynthia Bowman-Gholston	Date: 4/24/2012

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:	

12 month (or new) management review and approval: Signature acknowledges SOP version remains in effect with NO revisions.		
Print Name	**Signature**	**Date**

Form revised 3/31/00

TABLE OF CONTENTS

1. PURPOSE

The purpose of this policy is to establish a process to further notify end users and manage notifications (including recalls, defects, or general issues) from vendors for their products (hard or soft) that may affect patient care.

2. SCOPE

This procedure applies to all Laboratory personnel.

3. RESPONSIBILITY

1. The Quality Assurance (QA) department is responsible for:
   a. The maintenance and periodic review of this SOP
   b. The maintenance and retention of any notification documentation and any resolutions and/or responses.

2. It is the responsibility of the department directors, managers and supervisors
   a. To forward vendor notifications to the QA department
   b. To act on any vendor required response through the QA department

4. DEFINITIONS

Notifications – Documents that may take the form of product recalls, market withdrawals, or software patches and upgrades. Notifications can come directly from the manufacturer or as a corporate correspondence.

5. PROCEDURE

1. Upon receipt of vendor notifications, by the affected department, the department will forward them to the Quality Assurance department. The hospital QA staff will notify the QA staff in Chantilly. If applicable, QA, in conjunction with the department, will prepare confirmation responses to be returned to the vendor.

2. If the notifications are initially received by the QA department, they will be forwarded to the appropriate department and the Chantilly QA department. If applicable, QA, in conjunction with the testing department, will prepare confirmation responses to be returned to the vendor.

3. The Quality Assurance department will maintain notification documentation and any resolutions and/or responses. Documents will be scanned and saved electronically on the shared drive.

4. The Quality Assurance staff will collaborate with the department, if any corrective actions pertaining to the notification are necessary. Corrective action may include but is not limited to physician (client) notification, alternate testing sites (test referred out), alternate test methodologies (different kit or instrument), etc.

6. RELATED DOCUMENTS

- QDMED708 – Process for Notification of Reportable Quality Issues
- QDMED706 – Guidelines for Communication of Medical Quality Events to Corporate Personnel
- QDCMQ700 – Process for Complying with FDA Regulations Requiring Device User Facilities to Report MDR Reportable Events (Medical Device Reporting)

7. REFERENCES

College of American Pathologists (CAP) Checklist

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By

9. ADDENDA AND APPENDICES

N/A

Form revised 3/31/00