SIEMENS

Urgent Field Safety Notice

10816857

October 2013

CentraLink™ Data Management System

Disabled Test in CentraLink System or Aptio System May Become Enabled in CentraLink System

Our records indicate that you are running CentraLink™ Data Management System Version 14.0.4, 14.0.5, or 14.0.8 (catalog numbers10810210, 10811596, 10814296, 10814298, 10814877, 10815474) that is interfaced to an Aptio™ Automation System.

Reason for Corrective Action

Siemens Healthcare Diagnostics is conducting a Field Correction for CentraLink Version 14.0.4, 14.0.5, and 14.0.8 System Software only when interfaced to an Aptio Automation System. It has been confirmed that under extremely rare circumstances a patient result for a test that had been previously disabled may be released.

This condition will occur when the following sequence of events are all in place:

- The operator uses the Test Enable / Disable feature from either the Aptio system or CentraLink system and indicates a “Disabled” status for a test.
- The operator places reagent on the instrument that is necessary for analysis of the disabled test, thereby changing the reagent status from 0 to a positive number.
- The test will remain disabled on the Aptio system, but will automatically be set to “enabled” in the CentraLink system.
- If a sample with an order for the disabled test arrives at the instrument, the disabled test is processed. The sample will only be routed to the instrument if it contains at least one request that is different from the request for the disabled test.
- When the test is processed, if there are no instrument-generated Result Flags, QC, Delta Norms, or Normal Range severities that would prevent the result from being released, the test result is then released to the LIS.

Your local Siemens representative will be contacting you to schedule a service visit to implement an interim solution, which will do the following:

- Prevent the release of unrequested test results to the LIS
- Automatically disable the test that was inadvertently enabled.

Siemens Healthcare Diagnostics

511 Benedict Avenue
Tarrytown, New York 10591

www.siemens.com/diagnostics

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GPF-003 -11 V2.0 Effective: 2013-03-25
Related Procedure: GP-003 DX- Field Correction Action

Risk to Health

If this issue occurs, there is a very small risk that a result could be released without proper review.

A review of previously generated results is *not* required. This letter should be discussed with the Laboratory Director.

Actions to Be Taken by the Customer

Until a service visit is scheduled, please do the following:

- Instruct the laboratory staff to recognize this sequence of events (as listed on the first page)
- Ensure that whenever the operator disables a method on an Aptio system or a CentraLink system and replenishes reagent for that method, the operator then confirms that the method remains disabled in the CentraLink system or disables it again. The operator must allow up to five minutes to verify that the test remains disabled.

After a service visit is performed and an interim solution is implemented, the laboratory staff will be trained on this update to understand the minor but necessary changes in the workflow.

Please retain this letter with your laboratory records, and forward this letter to those who may have received this product.

We apologize for the inconvenience this situation has caused. If you have any questions, please contact your Siemens Customer Care Center or your local Siemens representative.

Trademark Information

Aptio and CentraLink are trademarks of Siemens Healthcare Diagnostics.

FIELD CORRECTION EFFECTIVENESS CHECK

Disabled Test in CentraLink System or Aptio System May Become Enabled in CentraLink System

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice dated October 2013 regarding Disabled Test in CentraLink System or Aptio System May Become Enabled in CentraLink System 10816857. Please read each question and indicate the appropriate answer. Fax this completed form to
Siemens Healthcare Diagnostics at the fax number indicated at the bottom of this page.

1. I have read and understand the Urgent Field Safety Notice instructions provided in the October 2013 letter.	Yes ☐	No ☐
2. I confirm this site has a CentraLink/Aptio system. (Please check inventories before answering.)	Yes ☐	No ☐
Name and Title of person completing questionnaire:		

Product Description (if applicable) Product Catalog# / SMN # / Lot #	**Quantity Discarded**	**Replacement Quantity Required**

Institution:	Instrument Serial Number:	
Street:		
City:	State:	Phone:
Customer Sold To #:	Customer Ship To #:	

PLEASE FAX THIS COMPLETED FORM TO THE CUSTOMER CARE CENTER AT _____.

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