SIEMENS

Urgent Field Corrective Action

CI-16-01.A.OUS

November2015

ADVIA Centaur®

ADVIA Centaur® XP

Potential Vacuum Leaks at the Glass Rod Sensor on the Waste Reservoir

Our records indicate that your facility has received the following product:

Table 1. ADVIA Centaur and ADVIA Centaur XP Affected Product

Product	Siemens Material Number (SMN)
ADVIA Centaur Instrument	10284980, 10286140, 10309524, 10309525, 10310210, 10313282, 10314322, 10316248, 10316372, 10316968, 10317060, 10317403, 10319111, 10319433, 10320929, 10321568, 10322149, 10322731, 10323204, 10325015, 10326217, 10327008, 10327379, 10328250, 10328647, 10329364, 10330873, 10331013, 10332617, 10334139, 10334759, 10337512, 10337526, 10339677, 10340551, 10340737, 10341051, 10341110, 10361010, 10361011, 10361012
ADVIA Centaur XP Instrument	10285219, 10316507, 10317207, 10317284, 10319668, 10320757, 10323213, 10324519, 10327135, 10327836, 10328940, 10329339, 10336292, 10338631, 10364455, 10388696, 10471899

Reason for Communication:

Siemens Healthcare Diagnostics is conducting a field corrective action for the ADVIA Centaur and ADVIA Centaur XP Immunoassay systems, glass rod sensor (SMN 10327638) in the waste reservoir.

A potential vacuum leak may occur around the Glass Rod Sensor in the Waste Reservoir, caused by the gasket on the housing of the Glass Rod Sensor sliding out of position.

Risk to Health:

With the alerts generated by the instrument for this issue, the operator will be aware that a sample may not have been processed and can take action.
Siemens recommends discussing the content of this letter with your laboratory director.

511 Benedict Ave.
Tarrytown, NY 10591
www.siemens.com/diagnostics

Potential Vacuum Leaks at the Glass Rod Sensor on the Waste Reservoir

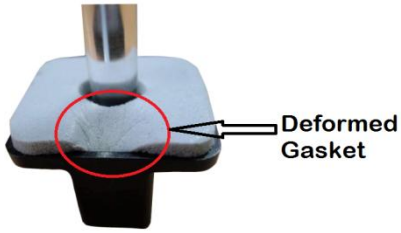
Actions to be taken by the Customer

- If your system stops running due to a low vacuum error - Error code 600 13 24, verify that the gasket under the Glass Rod Sensor housing on the Waste Reservoir is positioned properly.

The illustrations below shows the bottom view of the gasket properly seated and not properly seated.

View of Gasket Properly Seated

View of Gasket Not Properly Seated



1. If the gasket is positioned correctly, please follow the troubleshooting steps outlined in the On-line Help on the system for - Error code 600 13 24 - to troubleshoot other possible causes of Vacuum Low Errors.
2. If the gasket is not positioned correctly, call your Siemens Technical support center to schedule a replacement.

- Service engineers will inspect the Glass Rod Sensor on the next service visit and replace the Glass Rod Sensor if necessary.
- Complete and return the Field Correction Effectiveness Check attached to this letter within 30 days.

Please review this letter with your Medical Director.

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 may cause. If you have any questions, please contact your Siemens Customer Care Center or your local Siemens technical support representative.

ADVIA Centaur® / ADVIA Centaur® XP are trademarks of Siemens Healthcare Diagnostics.

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FIELD CORRECTION EFFECTIVENESS CHECK

Potential Vacuum Leaks at the Glass Rod Sensor on the Waste Reservoir

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Corrective Action CI-16-01.A.OUS dated November 2015 regarding Potential Vacuum Leaks at the Glass Rod Sensor on the Waste Reservoir. Please read each question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax number provided at the bottom of this page.

1. I have read and understood the Urgent Field Corrective Action instructions provided in this letter. Yes ☐ No ☐

Name of person completing questionnaire:

Title:

Institution: Instrument Serial Number:

Street:

City: State:

Phone: Country:

Please fax this completed form to the Customer Care Center at (###) ###-####. If you have any questions, contact your local Siemens technical support representative.

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