

# **Urgent Field Corrective Action**

CHI 19-01

February 2019

Cc to Chairman Medical Board and relevant Head of Departments

# ADVIA Chemistry XPT Sample Probe Cover for Aptio by Siemens, Aptio by Inpeco and FlexLab Automation Interfaces

Our records indicate that your facility may have an ADVIA Chemistry XPT connected to Aptio by Siemens, Aptio by Inpeco or FlexLab Automation system, with an incorrect sample probe cover noted in Table 1.

Table 1. ADVIA Chemistry XPT Affected Product(s)

Product	Siemens Material Number (SMN)
HVN Mech Automation Kit - Aptio	11241418

## Reason for Field Action

Siemens Healthcare Diagnostics is informing customers that when an ADVIA Chemistry XPT instrument, SMN 10723034, is connected to Aptio by Siemens, Aptio by Inpeco or FlexLab Automation system, the required external sample probe cover, SMN 11241418, may need replacing due to a design defect.

#### Risk to Health

There is no risk of user injury or impact on results due to this defect.

## Actions to be Taken by the Customer

No action is required on your part.

A Siemens Customer Service Engineer will contact you to schedule an inspection of the cover and, if necessary, order and install a re-designed cover.

Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.

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 Chemistry XPT is a trademark of Siemens Healthcare Diagnostics.

# FIELD CORRECTION EFFECTIVENESS CHECK

ADVIA Chemistry XPT Sample Probe Cover for Aptio by Siemens, Aptio by Inpeco and FlexLab Automation Interfaces.

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Corrective Action, CHI 19-01, February 2019, regarding the ADVIA Chemistry XPT Sample Probe Cover for Aptio by Siemens, Aptio by Inpeco and FlexLab Automation Interfaces. Please read the question and indicate the appropriate answer.

Return this completed form to Siemens Healthcare Diagnostics as per the instructions provided at the bottom of this page.			
1. I have read and understood the Urgent Field Corrective Ac February 2019 instructions provided in this letter.	tion, CHI 19-01,	Yes □	No 🗆
Name of person completing questionnaire:			
Title:			
Institution:	Instrument Serial Numl	per:	
Street:			
City:	State:		
Phone:	Country:		

If you have any questions, contact your local Siemens technical support representative.