

Urgent Field Corrective Action

BR-02416

December 2015

PFA-100 System / INNOVANCE PFA-200 System

Some lots of INNOVANCE PFA P2Y show wrong shelf life

Dear valued customer,

Our records indicate that your facility may have received the following product:

Table 1. Affected Product(s)

Assay	Catalog Number	Siemens Material Number (SMN)	Lot Number
INNOVANCE® PFA P2Y	B4170-22	10445700	5464024; 5464025; 5464026; 5464027

Reason for Correction

Siemens Healthcare Diagnostics has confirmed that the above mentioned INNOVANCE PFA P2Y cartridge lots show a false extended shelf life.

Risk to Health

Internal investigations have shown that INNOVANCE PFA P2Y cartridges used beyond the correct but within the displayed shelf life date showed a maximal deviation of down to -11% which is within the overall performance claims.

There is no risk to health.

Actions to be Taken by the Customer

Please do not use the INNOVANCE PFA P2Y cartridge lots beyond the correct shelf life dates as given in the following table 2.

Table 2. Corrected shelf life

Assay	Lot	correct shelf life
INNOVANCE® PFA P2Y	5464024	2015-10-15
	5464025	2015-12-17
	5464026	2016-01-27
	5464027	2016-04-28

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.

Original signature is on file

Dr. Norbert Dedner
Director
Quality Systems & Compliance

Original signature is on file

Marlen Suller
Senior Director
Global Marketing Hemostasis

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FIELD CORRECTION EFFECTIVENESS CHECK

PFA-100 / INNOVANCE PFA-200

Some lots of INNOVANCE PFA P2Y show wrong shelf life

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Corrective Action letter BR-02416 dated December 2015 regarding PFA-100 / INNOVANCE PFA-200 - Some lots of INNOVANCE PFA P2Y show wrong shelf life. 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 [Letter Type] instructions provided in this letter. Yes No

2. Do you now have any of the noted product on hand? Please check inventories before answering. Yes No

If the answer to the question above is yes, please complete the table below to indicate the quantity of affected product in your laboratory and replacement product required.

Product Description Product Catalog #/SMN #/Lot #	Quantity of Affected Product in inventory that has been discarded	Replacement Quantity Required
INNOVANCE PFA P2Y; please specify lot		

Name of person completing questionnaire: _____

Title: _____

Institution: _____

Instrument Serial Number: _____

Street: _____

City: _____

State: _____

Phone: _____

Country: _____

Customer Sold To #: _____

Customer Ship To #: _____

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