

## Customer Notification

BR-02716

February 2016

### Berichrom Antithrombin III

#### Different substrate reagent lot in limited number of kit lot packages

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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
Berichrom® Antithrombin III	OWWR15	10446672	45029
	OWWR17	10446673	45027

#### Reason for Customer Notification

Siemens Healthcare Diagnostics has confirmed that some packages of the Berichrom Antithrombin III kit lot mentioned in table 1 may contain a different substrate reagent lot as given in the package labeling. Dependent on the instrument used, some instruments with automatic reagent identification may request a new calibration.

The correct substrate reagent lot number is 520294.

#### Risk to Health

This issue has no impact on patient results. Therefore there is no Health Risk.

#### Actions to be Taken by the Customer

If you have received packages that contain the substrate reagent lot 520292, please request a free of charge replacement of Berichrom Antithrombin III.

In this case please complete and return the Product Replacement Form attached to this letter to request your no-charge replacement product.

*Berichrom Antithrombin III*

*Different substrate reagent lot in limited number of kit lot packages*

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

*Berichrom is a trademark of Siemens Healthcare Diagnostics.*

## PRODUCT REPLACEMENT FORM

### Berichrom Antithrombin III

#### Different substrate reagent lot in limited number of kit lot packages

This form is to be used to request no-charge replacement product for the enclosed Siemens Healthcare Diagnostics Customer Notification BR-02716 dated February 2016 regarding Berichrom AT III Substrate. Fax this completed form to Siemens Healthcare Diagnostics at the fax number provided at the bottom of this page.

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
Berichrom Antithrombin III, Product Code OWWR15; Lot 45029		
Berichrom Antithrombin III, Product Code OWWR17; Lot 45027		

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.