

**Enzygnost Syphilis lot 48188 & 48312:  
 Anti-T. pallidum Reference N found low**

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	Expiration Date (YYYY-MM-DD)	Manufacturing Date (YYYY-MM-DD)
Enzygnost® Syphilis	OWVO115	10446663	48312	2019-11-29	2018-07-05
	OWVO215	10446665	48188	2019-11-29	2018-07-06

**Reason for Urgent Field Safety Notice**

Siemens Healthcare Diagnostics Products GmbH has confirmed customer complaints that the average OD for the Anti-T. pallidum Reference N can be lower than expected compared to the average OD of negative samples for the affected lots of Enzygnost Syphilis. This may lead to invalid test runs.

As the cut-off value is calculated by the Anti-T. pallidum Reference N, this effect could result in rare cases to a lower cut-off value which may lead to slightly delayed detection of fresh seroconversions during the primary infection phase.

**Risk to Health**

In summary the risk for a potential patient impact has been estimated to be extremely unlikely, leading to a negligible health risk. Therefore, a potential health risk is not reasonably to be expected to commensurate with the product issue.

With respect to previously obtained results based on our assessment taking the frequency of occurrence and all circumstances into consideration, a look back is not recommended.

However, we recommend discussing the content of this letter with your laboratory director with respect to the need to review previous test results, conduct patient follow-up, and/or repeat testing.

## **Actions to be Taken by the Customer**

Please discontinue use and discard any remaining inventory of the affected product lots. Review your inventory of these product lots to determine your laboratory's replacement needs.

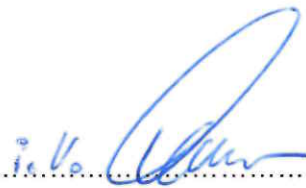
Please complete and return the Field Correction Effectiveness Check Form attached to this letter within 7 days.

Please distribute this information to all appropriate personnel in your laboratory, retain a copy in your files and forward this information to all parties that may use these product lots including others to whom you may have transferred these lots.

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

We apologize for any inconvenience that this situation has caused. Thank you for your patience and continued support.

Sincerely yours,



Dr. Norbert Dedner  
Director Quality System & Compliance



Frank Lübben  
Marketing Manager  
Global Marketing  
Infectious Disease Diagnostics

Enzygnost is a trademark of Siemens Healthcare Diagnostics.

## FIELD CORRECTION EFFECTIVENESS CHECK

### Enzygnost Syphilis lot 48188 & 48312: Anti-T. pallidum Reference N found low

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice PI-19-003\_A dated January 2019 regarding Enzygnost Syphilis lot 48188 & 48312: Anti-T. pallidum Reference N found low. Please read each 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 Safety Notice instructions provided in this letter. Yes  No
2. Do you now have any of the noted product(s) 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 Discarded/ Replacement Quantity Required
Enzygnost Syphilis; SMN 10446663; Lot 48312	
Enzygnost Syphilis; SMN 10446665; Lot 48188	

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