



STATE OF WASHINGTON
WASHINGTON STATE PATROL
WASHINGTON STATE TOXICOLOGY LABORATORY

2203 Airport Way South, Suite 360 • Seattle, Washington 98134-2027 • (206) 262-6100 • FAX (206) 262-6145

January 6, 2023

Subject: SIEMENS Healthineers Customer Notification December 5, 2022

Washington State Patrol Toxicology Laboratory User Agencies:

On December 6, 2022 the Washington State Patrol Toxicology Division received notification from manufacturer SIEMENS regarding low absorbance rates or low optical density readings for Lot P5 of the Syva Emit II Plus Opiate Assay 115 mL Reagent (see attached). A SIEMENS internal investigation confirmed that only a small portion of the Opiate 115 mL Lot P5 kits were impacted and that an impacted kit would exhibit an error flag while processing in qualitative mode.

The Washington State Patrol Toxicology Division has confirmed receipt of two kits with Lot P5 for use in EMIT screening for opiates. A review of EMIT testing was completed. It was determined that one Opiates Lot P5 had been utilized by the Laboratory. Testing data where Lot P5 was used, was reviewed and no error flags were observed. Presumptive positive results from EMIT screening are confirmed by a separate, more specific method of testing, prior to reporting. The other kit has not been used and has been sent back to SIEMENS for replacement.

Please contact the Laboratory at 206-262-6100 or toxlab@wsp.wa.gov with any questions.

Sincerely,

Eric Lo
Toxicology Laboratory Division
Laboratory Manager

EL:el/eg
Attachment



Syva® Emit® II Plus Opiate Assay

Emit® II Plus Opiate 115 mL Reagent Lot P5 Low Absorbance Rates or Low Optical Density (OD) Readings on Calibrations for the Qualitative 300 ng/mL or 2000 ng/mL Cutoff

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

Table 1. Syva® Emit® II Plus Opiate Assay

Product	Siemens Material Number (SMN)/REF (Catalog Number)	Unique Device Identification (UDI)	Lot Number	1 st Distribution Date (YYYY-MM-DD)	Expiration Date (YYYY-MM-DD)
OPI	10445416/ 9B309UL	00842768001819P52023042110445416840	P5	2021-10-21	2023-04-21

Reason for Customer Notification

A Siemens internal investigation has confirmed low absorbance rates (Viva Systems) or low optical density (OD) readings (Beckman systems) on calibrations for the qualitative 300 ng/mL or 2000 ng/mL cutoff for the Emit® II Plus Opiate 115 mL assay. This only impacts a small portion of the Opiate 115 mL lot P5 kits distributed. An impacted kit would exhibit an error flag while processing in qualitative mode indicating that the absorbance rate separation between the cutoff calibrator and the control (Negative/Positive) is not meeting the expected separation. If you receive this type of error, you should follow your internal Laboratory Quality Control procedures since the results obtained are outside acceptable limits. When a valid qualitative OPI calibration and acceptable Quality Control results (without flags) are obtained, the assay performance is not affected.

Actions to be Taken by the Customer

For the product listed in Table 1, please perform the following steps

- If you experience this issue, you may request a no-charge replacement product from your local Siemens Healthineers or distributor office. Please review your inventory for these products and assess your laboratory's replacement needs.
- Complete and return the Product Replacement Form attached to this letter to request your no-charge replacement product(s).

Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

*Emit® II Plus Opiate 115 mL Reagent Lot P5 Low Absorbance Rates or Low Optical Density (OD)
Readings on Calibrations for the Qualitative 300 ng/mL and 2000 ng/mL Cutoff*

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers Technical Support Representative.

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PRODUCT REPLACEMENT FORM

Emit® II Plus Opiate 115 mL Reagent Lot P5 Low Absorbance Rates or Low Optical Density (OD)
Readings on Calibrations for the Qualitative 300 ng/mL or 2000 ng/mL Cutoff

This response form is to request no-charge product replacement and confirm receipt of the enclosed Siemens Healthineers Customer Notification SYC-23-01.A.US dated December 05, 2022, regarding Emit® II Plus Opiate 115 mL Reagent.

Please read the question below and indicate the appropriate answer.

Return this completed form to Siemens Healthineers as per the instructions provided at the bottom of this page.

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

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

Product Description REF #/SMN #/Lot #	Quantity of Cartons Discarded/ Replacement Quantity Required
Emit® II Plus Opiate 115 mL Reagent REF 9B309UL /SMN 10445416/Lot P5	

Name of person completing questionnaire: _____

Title: _____

Institution: _____

Instrument Serial Number: _____

Street: _____

City: _____

State: _____

Phone: _____

Country: _____

Please send a scanned copy of the completed form via email to uscctsfcaecfax.team@siemens-healthineers.com,
Or to fax this completed form to the Customer Care Center at (312) 275-7795.

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