



**Follow-up
Urgent Field Safety Notice
CC 20-09.B.OUS
December 2020**

ADVIA Centaur® XPT

**Follow-up: ADVIA Centaur HBsAg Confirmatory Assay Cannot Calibrate with
ADVIA Centaur HBsAgII – Additional Lots Added**

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

Table 1. ADVIA Centaur Affected Product(s)

| Assay | Catalog Number | Siemens Material Number (SMN) | Kit Lot Number | Expiration Date (YYYY-MM-DD) | Date of Manufacture (YYYY-MM-DD) |
|-------------------------------|----------------|-------------------------------|----------------|------------------------------|----------------------------------|
| ADVIA Centaur HBsAgII (HBsII) | 10492138 | 10492138 | 21869220 | 2021-03-10 | 2020-03-10 |
| | | | 34096220 | 2021-03-10 | 2020-03-10 |
| | | | 36114220 | 2021-03-10 | 2020-03-10 |
| | | | 57373220 | 2021-03-10 | 2020-03-10 |
| | | | 41157223 | 2021-03-18 | 2020-03-18 |
| | | | 47885223 | 2021-03-18 | 2020-03-18 |
| | | | 50607223 | 2021-03-18 | 2020-03-18 |
| | | | 54149223 | 2021-03-18 | 2020-03-18 |
| | | | 62951223 | 2021-03-18 | 2020-03-18 |
| | | | 59288226 | 2021-04-29 | 2020-04-20 |
| | | | 79159226 | 2021-04-29 | 2020-04-29 |
| | | | 80529226 | 2021-04-29 | 2020-04-29 |
| | | | 65646228 | 2021-06-10 | 2020-06-10 |
| | | | 84619228 | 2021-06-10 | 2020-06-10 |
| | | | 94676228 | 2021-06-10 | 2020-06-10 |
| | | | 98511228 | 2021-06-10 | 2020-06-10 |
| | | | 99187228 | 2021-06-10 | 2020-06-10 |
| | | | 03143229 | 2021-08-31 | 2020-08-31 |
| | | | 87253229 | 2021-08-31 | 2020-08-31 |

Reason for Follow-up Correction

Siemens Healthcare Diagnostics Inc. is issuing a revision to Urgent Field Safety Notice CC 20-09.A.OUS to inform customers of additional lots impacted by an inability to calibrate the ADVIA Centaur HBsAg Confirmatory assay on the ADVIA Centaur XPT under certain circumstances.

Follow-up: ADVIA Centaur HBsAg Confirmatory Assay Cannot Calibrate with ADVIA Centaur HBsAgII – Additional Lots Added

Urgent Field Safety Notice CC 20-09.A.OUS was issued in September 2020 to inform customers that the ADVIA Centaur HBsAg Confirmatory assay cannot calibrate with ADVIA Centaur HBsAgII kit lots ending in 220 and 223.

Investigation of new customer complaints has confirmed the inability to calibrate the ADVIA Centaur HBsAg Confirmatory (Conf) assay on the ADVIA Centaur XPT when using Master Curve Cards (MCCs) provided in the ADVIA Centaur HBsAgII kit lots ending in 226, 228 and 229 listed in Table 1, when the Conf assay is set up as a reflex test in the HBsII Test Definition (TDef). The inability to calibrate the ADVIA Centaur HBsAg Conf assay when the Conf assay is set up as a reflex test in the HBsII TDef on the ADVIA Centaur XPT prevents the generation of HBsAg Conf results.

This issue is observed only on the ADVIA Centaur XPT. The ADVIA Centaur XP platform is NOT impacted.

Customers can continue to generate **HBsAgII** results with **all** kit lots on both the ADVIA Centaur XP and the ADVIA Centaur XPT.

Risk to Health

When this issue occurs, a failed calibration will cause an apparent delay in testing with negligible potential for injury. The impact is mitigated by availability of unaffected lots and use of standard laboratory procedures to ensure uninterrupted testing.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- If you use the ADVIA Centaur XPT and the ADVIA Centaur HBsAg Confirmatory assay:
 - Kit lots ending in 220 and 223: You may request replacement product for your current inventory of kit lots ending in 220 and 223. Please complete and return the replacement request form in this communication.
 - Kit lots ending in 226, 228 and 229:
 - Review the HBsII Test Definition to determine if you have a reflex test on the HBsII Test Definition.
 - If you do not have a reflex test on the HBsII Test Definition, no further action is required, and you may continue to use the product as is.
 - If you have a reflex test, perform the following steps:
 1. From the Test Results Overview tab Select 'No Filter' and Move ALL HBsII and Confirmatory tests to Historical.
 2. From the Calibration Results Overview tab, Move all HBsII and Confirmatory calibration results to Historical.

Follow-up: ADVIA Centaur HBsAg Confirmatory Assay Cannot Calibrate with ADVIA Centaur HBsAgII – Additional Lots Added

3. Remove the Reflex to the Confirmatory assay in all of the tabs in the Ranges section of the HBsII Test Definition.

4. Scan the Master Curve Card for the Confirmatory assay from kit lots ending in 226, 228 or 229.

5. Set up the Reflex to the Confirmatory assay on the HBsII Test Definition. Please refer to the ADVIA Centaur XPT Online Help > Setup > Test Definitions > Setting HBs Reflex to Confirmatory for additional information

Once you have performed these steps, they do not have to be repeated when the MCC from other ADVIA Centaur HBsAgII kit lots are used.

- This workaround does not have to be performed with ADVIA Centaur HBsAgII kit lots ending in 232 and above.
- If you use only the HBsAgII assay on the ADVIA Centaur XPT and you do not use the Confirmatory assay, you may continue to use the kit lots listed in Table 1 with the Master Curve Cards provided in the kits.
- If you use the ADVIA Centaur XP, you may continue to use the kit lots listed in Table 1 with the Master Curve Cards provided in the kits without further actions.

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 Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

ADVIA Centaur is a trademark of Siemens Healthcare Diagnostics Inc.

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FIELD CORRECTION EFFECTIVENESS CHECK

Follow-up: ADVIA Centaur HBsAg Confirmatory Assay Cannot Calibrate with ADVIA Centaur HBsAgII – Additional Lots Added

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice CC 20-09.B.OUS dated December 2020 regarding Follow-up: ADVIA Centaur HBsAg Confirmatory Assay Cannot Calibrate with ADVIA Centaur HBsAgII – Additional Lots Added. 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 run the ADVIA Centaur HBsAg Confirmatory assay on the ADVIA Centaur XPT? Yes No
- 3. Do you now have any of the noted product(s) on hand? Please check inventories before answering. Yes No

If the answers to the questions 2 and 3 above are 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 Discarded/ Replacement Quantity Required |
|--|---|
| ADVIA Centaur HBsAgII SMN 10492138 Kit Lots Ending 220 and 223 | |

Name of person completing questionnaire: _____

Title: _____

Institution: _____ Instrument Serial Number: _____

Street: _____

City: _____ State: _____

Phone: _____ Country: _____

Customer Sold To #: _____ Customer Ship To #: _____

Please send a scanned copy of the completed form via email to XXXX@XXXX.

Or to fax this completed form to the Customer Care Center at XXXXXX.

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