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Urgent Field Safety Notice:

ADVIA Centaur® XPT

ADVIA Centaur HBsAg Confirmatory Assay Cannot Calibrate with ADVIA Centaur HBsAgII Kit Lots Ending in 220 and 223

Dear Sirs,

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	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

Reason for Correction

Siemens Healthcare Diagnostics Inc. has confirmed customer complaints of 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 listed in Table 1. The inability to calibrate the ADVIA Centaur HBsAg Conf assay on the ADVIA Centaur XPT prevents the generation of HBsAg Conf results and could delay reporting of Conf results. This issue is observed only on the ADVIA Centaur XPT. Customers can continue to generate HBsAgII results with kit lots ending in 220 and 223 on ADVIA Centaur XPT.

Preliminary root cause investigation suggests there is an error in the two-dimensional (2D) barcode for the Conf Reagent B on the MCCs in the ADVIA Centaur HBsAgII kit lots listed in Table 1.

Siemens has determined no other lots of these products are affected.

The ADVIA Centaur XP platform is NOT impacted.

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, please complete the replacement request form in this communication. You may request replacement product for your current inventory of the kits listed in Table 1.
- • 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.

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.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH



i.V. Dipl. Ing. Franz Schwarz
Quality Management CEE



i.A. Ing. Gernot Osterer
Product Manager Austria & SEE