

**ADVIA Centaur® XP
ADVIA Centaur® XPT**

Resolution - Herpes-2 IgG (HSV2) Onboard Stability and Calibration Frequency (Interval)

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

Table 1. ADVIA Centaur Systems Affected Product(s)

Assay	Siemens Material Number (SMN)	Unique Device Identification (UDI)	Lot Number	Date of Manufacture (YYYY-MM-DD)	Expiration Date (YYYY-MM-DD)
Herpes-2 IgG(100 Test)	10720849	(01)00630414016726(10)B35470(17)20231115	B35470	2022-11-15	2023-11-15

Reason for Communication

Siemens Healthcare Diagnostics Inc. is communicating the resolution to Urgent Field Safety Notice CC 21-02.A.OUS regarding the Onboard Stability and Calibration Frequency (Interval) of Herpes-2 IgG (HSV2) on ADVIA Centaur® XP and ADVIA Centaur® XPT.

Siemens has implemented improvements to the buffer system that restores the onboard stability to 60 days and the calibration frequency (interval) to 28 days as stated in the Instruction For Use. Beginning with kit lots B35470, the master curve card will restore the onboard stability to 60 days.

Actions to be Taken by the Customer

Beginning with kit lots B35470, the calibration interval can be increased to 28 days by following the guidance in the Operator’s Guide.

- If you use the ADVIA Centaur HSV2 assay on the ADVIA Centaur XP, change the calibration frequency to 28 days by following the instructions in the ADVIA Centaur® XP Immunoassay System Operator’s Guide 078D1064-01 in the Defining Calibration Options section.
- If you use the ADVIA Centaur HSV2 assay on the ADVIA Centaur XPT, change the calibration frequency to 28 days by following in instructions in the ADVIA Centaur® XPT Immunoassay System Operator’s Guide 10815932 in the About Test Definition Calibration Tab section.

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- 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 local Siemens Healthineers technical support representative.

ADVIA Centaur is a trademark of Siemens Healthcare Diagnostics Inc.