

ADVIA Centaur® XP

ADVIA Centaur Rubella G and Rubella M Calibrator Assigned Value Cards

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)	Kit Build Date (YYYY-MM-DD)
ADVIA Centaur Rubella G (RUBG)	08666235	10310283	16975222 25881224 32323224	2020-11-21 2021-02-18 2021-02-18	2020-04-07 2020-05-02 2020-05-19
ADVIA Centaur Rubella M (RUBM)	02633319	10310285	07257190 15401190	2021-01-30	2020-03-13 2020-04-14

Reason for Correction

The purpose of this communication is to inform you that Siemens Healthcare Diagnostics Inc. has confirmed customer complaints stating calibrator value information for the ADVIA Centaur Rubella G and ADVIA Centaur Rubella M assays is not saved when the calibrator assigned value cards for the lots listed in Table 1 are scanned or manually entered onto the ADVIA Centaur XP system. This issue prevents customers from testing these assays. This communication also provides actions that must be taken should this issue occur in your laboratory.

The ADVIA Centaur XPT and ADVIA Centaur CP are not impacted.

Siemens is currently investigating the root cause of this issue. Preliminary root cause appears to be the addition of a character space in the name of the calibrator on the calibrator assigned value card. Siemens has identified that no other lots of these products are impacted.

Risk to Health

This issue prevents the scanning of calibrator assigned value cards, causing an apparent delay with no impact to health. Siemens is not recommending a lookback of previously generated results.

ADVIA Centaur Rubella G and Rubella M Assigned Value Cards

Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- If you use the ADVIA Centaur XP, do not use the calibrator assigned value cards provided in the kit lots listed in Table 1. Instead, use this communication by either:
 - Printing the Additional Information section of this communication and scanning the barcodes OR
 - Manually entering the information from the Additional Information section of this communication (Refer to ADVIA Centaur XP Immunoassay System Operator's Guide, Defining Calibrator Values Using the Keyboard section for instructions.).
- If you use the ADVIA Centaur XPT or ADVIA Centaur CP, you may continue to use the kit lots listed in Table 1 with the calibrator assigned value cards provided in the kits.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.

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 Rubella G and Rubella M Assigned Value Cards

Additional Information

- ADVIA Centaur Rubella G Kit Lot 16975222 / Calibrator Lot C722

ADVIA Centaur®

RubG

CAL
校正剤

Assigned Value Card
Carte des valeurs
Wertezuordnungskarte
Carta dei Valori Assegnati
Tarjeta de Valores Asignados
Cartão de Valores Definidos
Kort med tildelte værdier
Kort med angivna värden
表示値カード

添付文書参照

01915795 Rev. B

LOT Ch.-B 製造番号 C722 Exp./Verw. bis 使用期限 2020-11-21

RUBG

4d22ca08

CAL L 低濃度校正剤 **CAL H** 高濃度校正剤

Mass/IUPAC: SI Units: Mass/IUPAC: SI Units:

14.9 IU/mL 14.9 IU/mL

- ADVIA Centaur Rubella G Kit Lots 25881224 & 32323224 / Calibrator Lot C724

ADVIA Centaur®

RubG

CAL
校正剤

Assigned Value Card
Carte des valeurs
Wertezuordnungskarte
Carta dei Valori Assegnati
Tarjeta de Valores Asignados
Cartão de Valores Definidos
Kort med tildelte værdier
Kort med angivna värden
表示値カード

添付文書参照

01915795 Rev. B

LOT Ch.-B 製造番号 C724 Exp./Verw. bis 使用期限 2021-02-18

RUBG

f30a2dfd

CAL L 低濃度校正剤 **CAL H** 高濃度校正剤

Mass/IUPAC: SI Units: Mass/IUPAC: SI Units:

13.4 IU/mL 13.4 IU/mL

ADVIA Centaur Rubella G and Rubella M Assigned Value Cards

- ADVIA Centaur Rubella M Kit Lots 07257190 & 15401190 / Calibrator Lot C890

ADVIA Centaur®

RubM


CAL
校正剂

Assigned Value Card
Carte des valeurs
Wertzuordnungskarte
Carta dei Valori Assegnati
Tarjeta de Valores Asignados
Cartão de Valores Definidos
Kort med tildelte værdier
表示値カード

添付文書参照

01915795 Rev. B

LOT 製造番号 C890 Exp./ Verw. bis 使用期限 2021-01-30



0179248a

CAL **L** 低濃度校正剂 **CAL** **H** 高濃度校正剂

Mass/IUPAC: SI Units: Mass/IUPAC: SI Units:

RUBM

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ADVIA Centaur is a trademark of Siemens Healthcare Diagnostics Inc.

ADVIA Centaur Rubella G and Rubella M Assigned Value Cards

FIELD CORRECTION EFFECTIVENESS CHECK

ADVIA Centaur Rubella G and Rubella M Calibrator Assigned Value Cards

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice CC 20-06.A.OUS dated June 2020 regarding ADVIA Centaur Rubella G and Rubella M Calibrator Assigned Value Cards. 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

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@siemens-healthineers.com.
Or to fax this completed form to the Customer Care Center at (XXX) XXX-XXXX.

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