

Siemens Healthcare Diagnostics GmbH, SHS EMEA CEET QT, Siemensstrasse 90,
1210 Vienna

Name M.A. Roland Ertl
Department SHS EMEA CEET QT

Telephone +43 51707-38274
Mobile +43 (664) 8011738274
E-mail roland.re.ertl@siemens-healthineers.com

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Urgent Field Safety Notice:

**Atellica® Solution / ADVIA Centaur® XP / ADVIA Centaur® XPT / ADVIA Centaur® CP
Atellica IM and ADVIA Centaur Systems Urine Cortisol Negative Bias**

To whom it may concern,

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

Table 1. Atellica® Solution and ADVIA Centaur® Systems Affected Product(s)

Assay	Siemens Material Number (SMN)	Unique Device Identification (UDI)	Kit Lot #	Exp. Date (YYYY-MM-DD)	Mfg. Date (YYYY-MM-DD)
Atellica IM Cortisol 50T	10995538	(01)00630414598659(10)50732343(17)20230707 (01)00630414598659(10)50733343(17)20230707	50732343 50733343	2023/07/07	2022/04/07
		(01)00630414598659(10)88975345(17)20230930	88975345	2023/09/30	2022/06/30
		(01)00630414598659(10)29106347(17)20240103	29106347	2024/01/03	2022/10/03
		(01)00630414598659(10)29107347(17)20240103	29107347 and higher	2024/01/03	2022/10/03
Atellica IM Cortisol 250T	10995537	(01)00630414598642(10)50734343(17)20230707	50734343	2023/07/07	2022/04/07
		(01)00630414598642(10)88974345(17)20230930	88974345	2023/09/30	2022/06/30
		(01)00630414598642(10)29105347(17)20240103	29105347 and higher	2024/01/03	2022/10/03
ADVIA Centaur Cortisol 50T	10994924	(01)00630414602943(10)49741344(17)20230707	49741344	2023/07/07	2022/04/07
		(01)00630414602943(10)07241346(17)20230930	07241346	2023/09/30	2022/06/30
		(01)00630414602943(10)88318346(17)20230930	88318346	2023/09/30	2022/06/30
		(01)00630414602943(10)29109348(17)20240103	29109348 and higher	2024/01/03	2022/10/03
ADVIA Centaur Cortisol 250T	10994926	(01)00630414602950(10)49742344(17)20230930	49742344	2023/07/07	2022/04/07
		(01)00630414602950(10)88319346(17)20230930	88319346	2023/09/30	2022/06/30
		(01)00630414602950(10)29108348(17)20240103	29108348 and higher	2024/01/03	2022/10/03

This issue affects all current and future lots of the Atellica IM and ADVIA Centaur Systems Cortisol assays until the product issue is resolved

Reason for Correction

The purpose of this communication is to inform you of an issue with the product indicated in Table 1 above and provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics Inc. has confirmed customer observations of a negative bias with urine patient samples and urine cortisol Quality Control (QC) results intermittently out of range low. As indicated in the Instructions for Use, if QC results do not fall within with the assigned values, do not report results.

Lot-to-lot comparison studies between affected and unaffected kit lots showed a negative bias with urine samples (see Figure 1). Siemens is currently investigating the root cause of the negative bias and working to restore assay performance with urine samples.

Siemens requires that customers discontinue use of urine patient samples with kit lots listed in Table 1 and higher until further notice.

Serum and plasma samples are **NOT** affected, and customers can continue to use the Cortisol assay with these sample types.

Risk to Health

Worst case, there is a potential for erroneously depressed urine Cortisol patient results, which may lead to a delayed differential diagnosis of hypercortisolism, such as Cushing Syndrome. Mitigations include correlation of results to patient's clinical signs and symptoms, additional laboratory and repeat testing findings.

Actions to be Taken by the Customer

- Discontinue use of urine patient samples with the Atellica IM Cortisol and ADVIA Centaur Cortisol assays until further notice.
- Customers may continue to use serum and plasma sample types with the Atellica IM Cortisol and ADVIA Centaur Cortisol assays.
- Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- If you have received any complaints of illness or adverse events associated with the products listed in Table 1, immediately contact your local Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

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

Signature:

Electronically signed by: Roland Ertl
Reason: I am approving this document
Date: Mar 23, 2023 14:48 GMT+1

Email: roland.re.ertl@siemens-healthineers.com

Signature:

Electronically signed by: Gernot Osterer
Reason: I have reviewed this document
Date: Mar 23, 2023 15:41 GMT+1

Email: gernot.osterer@siemens-healthineers.com

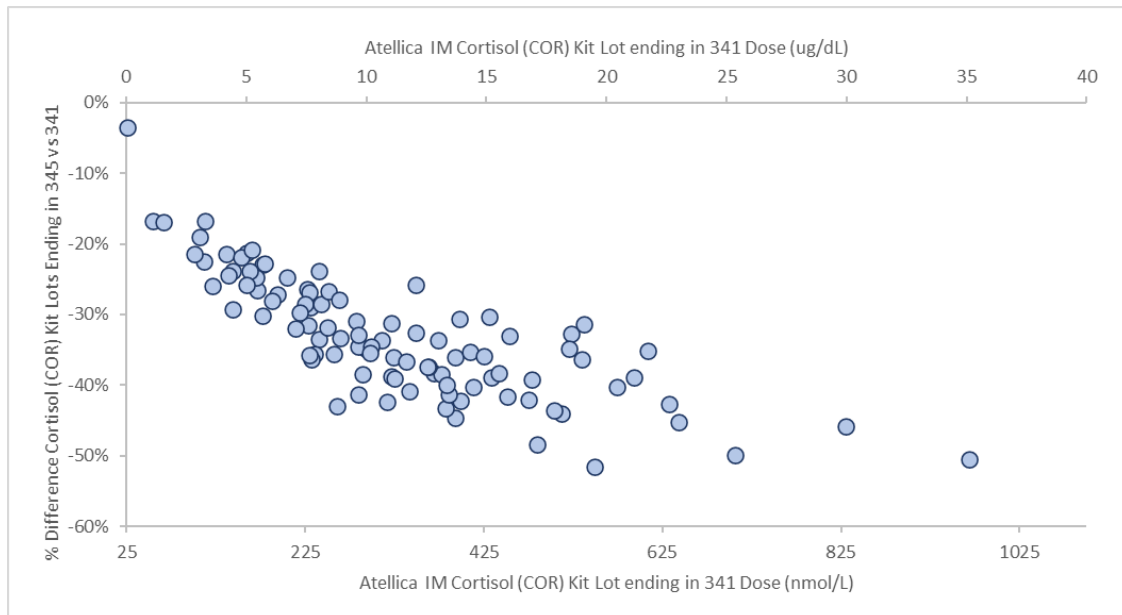
i.A. Roland Ertl, MA
Quality Management CEECA

i.A. Ing. Gernot Osterer
Product Manager CEECA

Annex I: Additional Information

One hundred urine samples were tested with Atellica IM Cortisol kit lots ending in 341 (unaffected) and 345 (affected) across the Assay Measuring Range. Figure 1 shows the observed % differences (bias). This data is representative of all in-date Atellica IM lots. While the investigation showed the ADVIA Centaur XP/XPT and ADVIA Centaur CP have a lesser degree % difference, these platforms are included in this Field Action because they are manufactured with the same materials.

Figure 1. % Difference Plot – Atellica IM Cortisol Kit Lots Ending in 345 vs Kit Lots Ending in 341



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Legal Manufacturer SRN: US-MF-000016560