

Urgent Field Safety Notice

10819709, Rev. A

September 2014

ADVIA Centaur®
ADVIA Centaur® XP
ADVIA Centaur® CP

Cleaning Solution Degradation Issue

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

Table 1. ADVIA Centaur Systems Affected Product(s)

Production	Catalog Number	Siemens Material Number (SMN)	Lot Numbers	Expiration Date
ADVIA Centaur Cleaning Solution	112748	10310041	459356 443105	November 2014 November 2014

Reason for Recall

Siemens Healthcare Diagnostics has confirmed the ADVIA Centaur® Systems Cleaning Solution, lots 459356 and 443105, has degraded at a higher than expected rate. As a precaution, Siemens is requiring customers to discontinue use of the affected lots.

Testing has confirmed that the ADVIA Centaur Systems Cleaning Solution, lots 459356 and 443105, contains sufficient sodium hypochlorite concentrations to ensure effective instrument cleaning.

This issue is isolated to the lots listed in Table 1; there are no other lots impacted.

Risk to Health

There is no risk of instrument contamination. Recent studies have confirmed the concentration of sodium hypochlorite in the cleaning solution is still effective in its performance at this time. Therefore, there is no risk to health.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- Discontinue use of and discard the kit lots listed in Table 1. Dispose of the material according to local regulations or procedures.
- Review your inventory of these products to determine your laboratory's replacement needs and to provide information to Siemens.

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

ADVIA Centaur is a trademark of Siemens Healthcare Diagnostics.