

CLINITEK Novus[®] Analyzer

Potential Reporting Errors When the Report Clarity Setting is Disabled

Our records indicate that your facility may have received one of the following products:

Table 1. CLINITEK Novus[®] Affected Products

Instrument	SW Version	Siemens Material Number (SMN)	Serial Number
CLINITEK Novus Analyzer	SW V1.1/V1.2	10494134 10697937 10844545	All

Reason for the Urgent Field Safety Notice

Siemens Healthcare Diagnostics has identified a potential reporting error with the CLINITEK Novus Analyzer.

If the Report Clarity setting is disabled, there is a potential for the Specific Gravity (SG), Leukocytes, Albumin, P:C ratio, and/or the A:C ratio to be misreported.

NOTE: Albumin, P:C ratio and A:C ratio parameters are not available in the US.

Risk to Health

The potential risk is limited to possible additional laboratory testing due to falsely elevated results, or a delay in follow-up testing due to a false negative result, which may occur with Leukocytes, SG, and Albumin. The overall risk to health is negligible, and Siemens is not recommending a review of previously generated results or repeat testing due to this issue.

Actions to be Taken by the Customer

- Keep the Report Clarity setting on your analyzer turned On.
Note: By default the Report Clarity setting is enabled on instruments when they are shipped from Siemens.
- If you have disabled the Report Clarity setting, please enable it. To enable the Report Clarity setting, navigate to **Setup** → **Configuration** → **Sample** → **Report Clarity**, and select **Enable** under “Report Clarity.”
- Complete and return the Field Correction Effectiveness Check form attached to this letter

Potential Reporting Errors When the Report Clarity Setting is Disabled

- 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 at (###) ###-#### or your local Siemens technical support representative.

CLINITEK Novus is a trademark of Siemens Healthcare Diagnostics.

FIELD CORRECTION EFFECTIVENESS CHECK

Potential reporting errors when the Report Clarity Setting is disabled.

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice 32997 Rev. A dated July 2015, regarding Potential Reporting Errors When the Report Clarity Setting is Disabled. Please read the question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax number provided at the bottom of this page.

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 fax this completed form to the Customer Care Center at (###) ###-####. If you have any questions, contact your local Siemens technical support representative.