

CLINITEK Novus[®] Analyzer

Protein to Creatinine (P:C) Ratios Reporting Higher than Expected

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 V1.0/V1.1	10494134 10697937 10844545	All

Reason for Urgent Field Safety Notice

Due to a transcription error in the CLINITEK Novus Software, there is a potential for Protein to Creatinine (P:C) ratios of ≥ 300 mg/g to be reported higher than expected. In particular:

1. A P:C ratio of 300 mg/g may be reported as 500 mg/g.
2. A P:C ratio of 500 mg/g may be reported as >1500 mg/g.

This error can potentially occur when a CLINITEK Novus Pro12 Urinalysis Cassette is used on the CLINITEK Novus Analyzer.

Please note: P:C Ratios reported as Normal or 300 mg/g are not affected.

Risk to Health

The potential exists for additional testing due to an erroneous result caused by the issue described above. 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

- Complete and return the Field Correction Effectiveness Check Form attached to this letter.
- Please retain this letter with your laboratory records, and forward it 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.

Additional Information

A new software version for CLINITEK Novus Analyzer, V1.2, is being developed to address this issue and will be provided by Siemens as soon as it is available.

Trademarks

CLINITEK Novus is a trademark of Siemens Healthcare Diagnostics.

FIELD CORRECTION EFFECTIVENESS CHECK

Protein to Creatinine (P:C) Ratios Reporting Higher than Expected

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice 32329 Rev. A dated January 2015, regarding Protein to Creatinine (P:C) Ratios Reporting Higher than Expected. 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.

Urgent Field Safety Notice

32330 Rev. A

January 2015

CLINITEK Novus[®] Analyzer

Protein to Creatinine (P:C) and/or Albumin to Creatinine (A:C) Reporting Error

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 V1.0/V1.1	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 when using the Novus Pro 12 Urinalysis Cassette.

When albumin, creatinine, or protein displays an “ERR” message when a CLNITEK Novus Pro12 Urinalysis Cassette is used, the CLINITEK Novus Analyzer may still report a P:C or A:C value.

Risk to Health

The potential exists for a delay in obtaining results due to the issue described above. 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

- When protein, albumin, or creatinine displays an “ERR” message, and a P:C or A:C ratio is generated on the analyzer, the P:C or A:C ratio value should not be reported.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter
- 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.

Additional Information

A new software version for the CLINITEK Novus Analyzer, V1.2, is being developed to address this issue and will be provided by Siemens as soon as it is available.

Trademarks

CLINITEK Novus is a trademark of Siemens Healthcare Diagnostics.

FIELD CORRECTION EFFECTIVENESS CHECK

Protein to Creatinine (P:C) and/or Albumin to Creatinine (A:C) Reporting Error

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice 32330 Rev. A dated January 2015, regarding Protein to Creatinine (P:C) and/or Albumin to Creatinine (A:C) Reporting Error. 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.