SIEMENS Healthineers

Customer Notification

PP-22-001-A-C OUS

March 2022

Atellica® CH 930 Analyzer

N Latex FLC Lambda – falsely elevated results with flags

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

Table 1. N Latex FLC Lambda (A) Affected Product(s)

Reagent	Siemens Material Number (SMN)	Unique Device Identification (UDI)	Kit Lot Number	Expiration Date	Manufacturing / 1st Distribution Date
N Latex FLC Lambda	10873447	0405686900185VA	All lots in shelf life and future lots until further notice.		
	10482438	0405686900185VA			

Reason for Customer Notification

The purpose of this communication is to inform you of an issue with the product indicated in Table1 above and provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics Products GmbH has confirmed that customers may experience an increased rate (average flagging rate: 6%) of flagged FLC LAMBDA Quality Control (QC) and patient sample results when using this assay on the Atellica CH 930 Analyzer. The flag message on the analyzer is >70 mg/L which indicates *"> Measuring Interval"* on the respective QC or patient results. Typically, the error massage appears when the results obtained are found to be above the defined upper measuring limit.

Siemens investigation has concluded that the increased rate of flagged results is caused by a changed behavior of the pre-defined antigen excess check. The antigen excess check uses specified kinetic data of QC and patient samples to assess the slope of the reaction kinetic. Empirically an increased slope in area of this kinetic might be an indicator for an antigen excess / high dose hook effect, which is then flagged if a certain slope threshold is exceeded. As QC samples are flagged in the same manner as patient samples, this is an indication of a temporarily limited robustness of the check algorithm with the assay indicated in Table 1 above.

Therefore, results might be displayed as >70 mg/L, when the real result is <70mg/L.

There is no evidence to indicate that unflagged QC and patient results are affected by this issue.

The root cause investigation is currently ongoing.

Siemens Healthcare Sdn Bhd [201501001338 (1126670-U)]
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Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- For the product listed in Table 1, please perform the following steps:
- Do not report QC and patient samples that are flagged >70mg/L.
- If "> Measuring Interval" range flagged results are obtained for patient samples, please use the automated re-dilution function of the Atellica CH 930 Analyzer to re-measure the samples. If you obtain a flagged result >70 mg/L, please do not report this result.
- If "> Measuring Interval" range flagged results are obtained for QC samples, please re-run the QC samples until a quantitative and unflagged result is obtained.

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 at 1800-888-872 or your local Siemens Healthineers technical support representative.

Sincerely yours,

This letter was created electronically and is valid without signature

i. V. Nils Neumann
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Quality Systems & Compliance

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FIELD ACTION EFFECTIVENESS CHECK

N Latex FLC Lambda – falsely elevated results obtained

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Customer Notification PP-22-001-A-C dated March 2022 regarding N Latex FLC Lambda – falsely elevated results obtained. Please read each question and indicate the appropriate answer.

Return this completed form to Siemens Healthcare Sdn Bhd as per the instructions provided at the bottom of this page.

1. I have read and understood the instructions provided in this letter. Yes ☐ No ☐

Name of person completing questionnaire:

Title:

Institution: Instrument Serial Number:

Street:

City: State:

Phone: Country:

Please send a scanned copy of the completed form via email to: fscareportingunit.my@siemens-healthineers.com

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

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