Urgent Field Safety Notice

ACHC-20-02.A.OUS

February 2020

Atellica CH® Analyzer

Eltrombopag Interference with Atellica CH® Direct Bilirubin (DBil_2) and Total Bilirubin (TBil_2) Assays

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

Table 1. Atellica® Chemistry Systems Affected Product(s)

Assay	Test Code	Siemens Material Number (SMN)	Lot Number
Direct Bilirubin	DBil_2	11097532	ALL
Total Bilirubin	TBil_2	11097531	ALL

Reason for Correction

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

Siemens Healthcare Diagnostics has become aware that the United Kingdom Medicines and Healthcare Products Regulatory Agency published an alert to healthcare professionals informing them that laboratory tests for bilirubin should be monitored for patients who take the drug eltrombopag due to the potential for discordant results. Eltrombopag may be used in the treatment of thrombocytopenia and/or aplastic anemia. Siemens spiking studies have shown a positive bias in Total Bilirubin (TBil_2) results of 13.9% at a therapeutic eltrombopag concentration of 25 µg/mL. Bias of <10% was observed for Direct Bilirubin (DBil_2) at therapeutic eltrombopag concentration of 25 µg/mL.

Table 2 below reflects eltrombopag interference with Atellica CH® Total Bilirubin (TBil_2) and Direct Bilirubin (DBil_2) assays based on Siemens preliminary internal testing. The Instructions For Use for the ADVIA Chemistry DBIL_2 and TBIL_2 assays will be updated as appropriate, when the investigation is completed. Siemens will communicate once the IFUs have been updated.

511 Benedict Avenue
Tarrytown, N.Y. 10591
www.siemens.com/diagnostics

Table 2. Eltrombopag Preliminary Interference Data for Atellica CH Total Bilirubin and Direct Bilirubin assays.

Analyte	Analyte Concentration mg/dL [µmol/L]	Eltrombopag Concentration µg/mL [µmol/L]	Bias (%)
Direct Bilirubin	1.03 [17.6]	25 [56.5]	3.9
Direct Bilirubin	5.0 [85.5]	25 [56.5]	*less than or equal to 10%
Total Bilirubin	1.01 [17.3]	25 [56.5]	13.9
Total Bilirubin	22.8 [390]	25 [56.5]	*less than or equal to 10%

*Note: At supraphysiological concentrations of 75 µg/mL [170 µmol/L] of eltrombopag, the observed bias was less than 10%, therefore therapeutic concentrations at 25 µg/mL [56.5 µmol/L] of eltrombopag were not tested.

Risk to Health

The risk to health for the issue described above is negligible. The observed biases for total bilirubin and direct bilirubin at therapeutic concentrations of eltrombopag would not lead to a clinically significant change in patient management. Direct and total bilirubin results are not used in isolation but are correlated with clinical history and presentation as well as with other markers of liver function (e.g. alanine aminotransferase, aspartate aminotransferase, alkaline phosphatase, and/or lactate dehydrogenase). Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer:

- Review the information in Table 2.
- Please review this letter with your Medical Director.
- 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 Customer Care Center or your local Siemens 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 Customer Care Center or your local Siemens Technical Support representative.

Atellica is a trademark of Siemens Healthcare Diagnostics.

511 Benedict Avenue
Tarrytown, N.Y. 10591
www.siemens.com/diagnostics

FIELD CORRECTION EFFECTIVENESS CHECK

Eltrombopag Interference with the Atellica CH® Direct Bilirubin (DBil_2) and Total Bilirubin (TBil_2) Assays.

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice ACHC-20-02.A.OUS dated February 2020 regarding eltrombopag Interference with the Atellica CH® Direct Bilirubin (DBil_2) and Total Bilirubin (TBil_2) Assays. Please read the question and indicate the appropriate answer.

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

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

Name of person completing questionnaire:

Date:

Title:

Institution: Instrument Serial Number:

Street:

City: State:

Phone: Country:

Please return this completed form to the Customer Care Center by fax at (01) 6297401 or by email at CruinnFSNGroup@cruinn.ie. If you have any questions, contact your local Siemens technical support representative.

511 Benedict Avenue
Tarrytown, N.Y. 10591
www.siemens.com/diagnostics