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Urgent Field Safety Notice:

Atellica CH Analyzer
Atellica CI Analyzer
Atellica CH Diazo Total Bilirubin (D_TBil) Inaccuracy in Quality Control (QC) and Patient Results

To whom it may concern,

Our records indicate that you have received:

Assay	Test Code	Siemens Material Number/Unique Device Identification	Lot Number
Atellica CH Diazo Total Bilirubin (D_TBil)	D_TBil	11537220/00630414614922	All lots

Issue Description

Siemens Healthineers has confirmed, through complaint investigation, that the lot calibration claim of 90 days per the Instructions for Use may not be met when using the Atellica CH D_TBil assay due to insufficient reagent 2 (P2) light protection. Siemens investigation indicated that light exposure of the reagent could potentially lead to falsely elevated or depressed results upon switching reagent wells or packs, and a potential for differing performance between reagent wells of the same pack. The direction of result bias depends on the pack used for lot calibration and the relative light exposure of subsequent packs to which the lot calibration is applied. All in-date Atellica CH D_TBil lots used on the Atellica CH and Atellica CI analyzers are impacted by this issue.
Note: Once the reagent pack is loaded onto the analyzer, the light-shielded compartment prevents any further light exposure. A design change will be performed to change to opaque, black packs to address light sensitivity.

Impact to Results

Erroneously elevated or depressed D_TBil patient results or invalid quality control may occur due to this issue if light-exposed packs are utilized. Internal investigation revealed biases that range from -2.40 to +2.51 mg/dL (-41.04 to +42.92 µmol/L). The absolute bias is consistent within a given reagent well and dependent on the length and intensity of light exposure. Results of this assay would be interpreted in conjunction with the patient's medical history, clinical presentation, and other findings.

Customer Actions

Perform the instructions provided below:

1) All D_TBil reagents must be stored in their outer kit box and out of direct light.
   - If stored in a walk-in cold room, it is important to keep lighting off when not in use.
   - Consider storing kit boxes on lower shelving and away from direct lighting.
   - If possible, store kit boxes in a refrigerator with an opaque door or within a secondary opaque container. If stored in a refrigerator with a glass door, measures to block light from coming through the glass door should be implemented.
2) Update the following QC settings of the Atellica software (See appendix for instruction):
   a) Enable QC on Pack Change By Assay Type for CH in order for QC to be processed when switching between wells.
   Note: This setting enables QC on Pack Change for all CH assays. All QC Levels for CH assays for which QC on Pack Change is not required should be deselected in the QC Master List.
   b) Enable Patient QC Flagging in order for impacted patient results to be identified after a QC failure.
   Note: All impacted patient results will have a "QC Fail" flag. Ensure that a result with a flag of "QC Fail" is held for review so that it can be rerun after passing QC.
3) Upon QC failure, perform a Pack Calibration on the impacted well.
   Note: Ensure that Pack Calibration is performed on the intended well that failed QC. Alternatively, a user may perform a Pack Calibration for each reagent well proactively. Refer to Atellica Solution and Atellica CI Analyzer Online Help for instructions.
4) Run QC.
5) Once acceptable QC has been obtained, repeat all D_TBil testing for all patient results flagged with "QC Fail".

- Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

Resolution

A follow-up communication will be provided when "Customer Actions" are no longer required.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.
Sincerely yours,

Siemens Healthcare Diagnostics GmbH

Electronically signed by: Martina Schreiber
Reason: I am approving this document
Date: Jul 11, 2025 14:21 GMT+2

ppa. Mag. Martina Schreiber

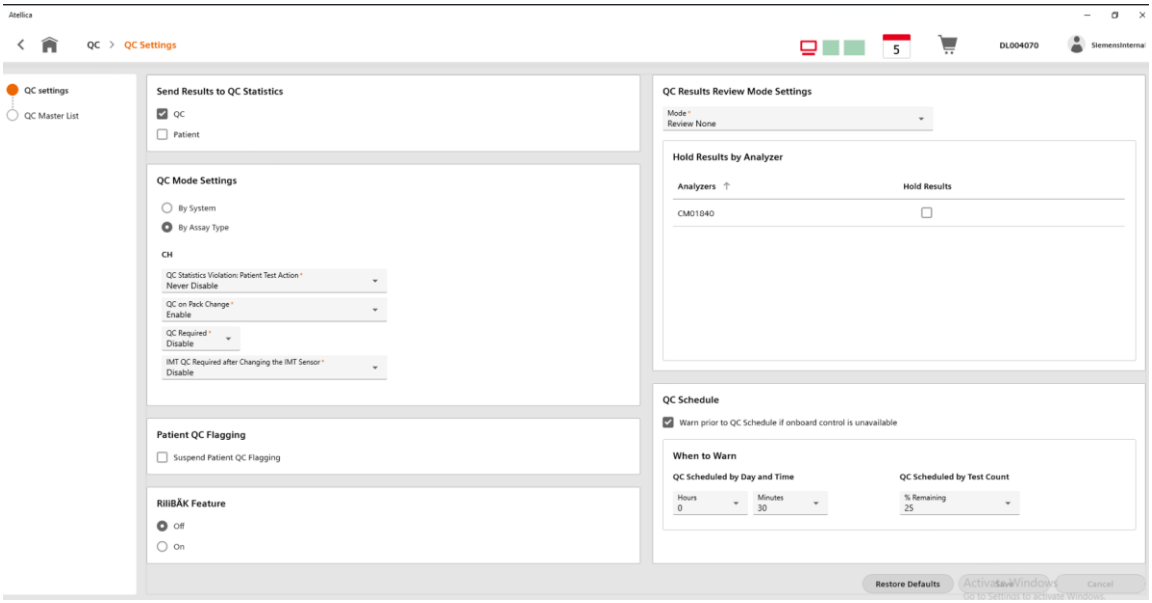
Electronically signed by: Carina Marie Viehboeck
Reason: I have reviewed this document
Date: Jul 11. 2025 12:55 GMT+2

i.A. Dipl.-Ing. Carina Viehböck

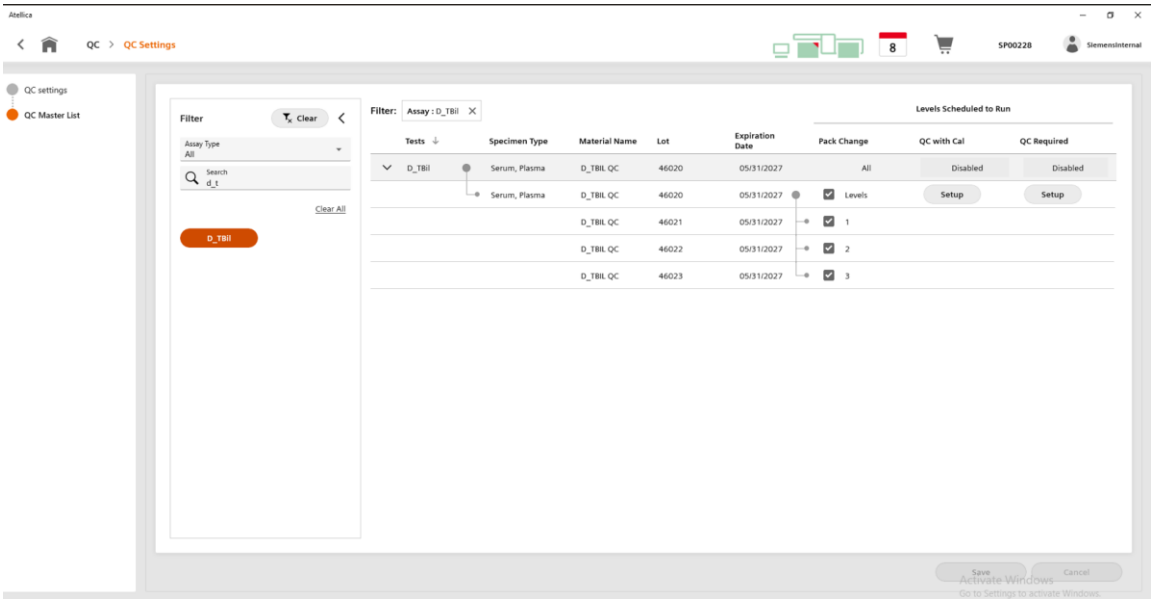
Appendix

Customer instructions to enable QC on Pack Change and QC Flagging. Refer to Atellica Solutions and Atellica CI Analyzer Online Help Guide for more detailed information on these settings.

1. From the System Navigator icon under QC, select **QC Settings**.
2. Under QC Mode Settings, select **By Assay Type**.
3. For CH, click the drop-down menu for QC on Pack Change and choose **Enable**.



4. Under QC settings, click on **QC Master List** and search for D_TBil.
5. If pack change isn't set to All, click **Set Up** and select all QC levels.
6. For all CH assays for which QC on Pack Change is *not* required, expand the QC list and deselect all levels of QC.



7. From the System Navigator icon under QC, select **Patient QC Flagging.**

8. Select **D_TBil, Edit/View**, select **Automatic** and click **Save**.