Updated Follow up Urgent Field Safety Notice

ACHC20-05.D.OUS

March 2020

Atellica® CH Analyzer

Atellica® CH 930 Analyzer – Potential for Inaccurate Test Results Associated with Reaction Cuvette Segments

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

Table 1. Atellica CH 930 Affected Product(s)

Product	Siemens Material Number (SMN)	Kit lots
Atellica CH Reaction Cuvette Segment	11099326	Kit lots ending in "19" and above

Reason for Correction

Siemens Healthcare Diagnostics Inc. issued an Urgent Field Safety Notice ACHC 20-05.A.OUS in January 2020, to inform all customers who had purchased cuvette segment lots "17" and/or "18" of an issue associated with this product.

Investigation of new customer complaints has determined that a cuvette defect allowing water from the water bath to contaminate the interior of the cuvette can occur with cuvette segment kit lots ending in "19" and above. The probability of a defective cuvette segment is estimated to be <0.5%. Not all cuvette positions within an affected cuvette segment are impacted.

There is a potential that sample results obtained at the impacted cuvette positions can be falsely elevated or depressed to varying degrees depending on the assay and the amount of water bath contamination.

This communication expands on the actions to be taken by the laboratory.

Siemens understands the urgency of this situation and is actively working to determine the root cause.

Risk to Health

When an affected cuvette is used for testing, the potential exists to report erroneous patient results depending on the analyte. Mitigations include correlation to clinical history and presentation as well as to other diagnostic laboratory testing and/or serial testing. As the likelihood of an affected cuvette and a subsequent clinically significant effect is unlikely, Siemens Healthineers is not recommending a lookback.

511 Benedict Avenue
Tarrytown, NY 10591

Actions to be Taken by the Customer

- Customers should run Atellica™ CH Carbon Dioxide, concentrated (CO2_c) assay in 300 replicates to determine if any of the cuvette positions are impacted.
    - If you **DO** have CO2_c in your inventory, proceed to Appendix 1
    - If you **DO NOT** have CO2_c in your inventory, proceed to Appendix 2.
- This action should be repeated each time cuvette segments are replaced (4 months).
- Please review this letter with your Medical Director.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 14 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 Healthineers Customer Care Center or your local Siemens Healthineers 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 Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

511 Benedict Avenue
Tarrytown, NY 10591

Appendix 1: Required of all customers who have CO2_c (reagent SMN 11097521, calibrator SMN 11099401) in their inventory.

1. Ensure that your Atellica CH 930 analyzer is in standby or ready mode.
2. If your Laboratory utilizes comma "," separators (rather than period ".") then it will be necessary to change the Display Language to English, by following the steps in the Atellica Solution Online Help, **"About Regional Settings in General Setup"**. Note: The language change is only required to complete the instructions provided in this letter. Restart is required when changing languages. In addition, refer to Appendix 4 last bullet.
3. Run 300 replicates of CO2_c calibrator as indicated in Appendix 3. This may take approximately 15 minutes of processing time on the analyzer.
4. Determine the mean value of the 300 calibrator replicates. Details provided in Appendix 4.
5. If all individual calibrator results are ≤12% of the mean calibrator value, no further action is required, and you can continue to process patient samples.
6. If any individual calibrator result is >12% of the mean calibrator value, please contact Siemens Customer Care Center to determine additional action to be taken prior to processing patient samples.
7. Ensure that steps 1-5 are followed each time cuvette segments are replaced on the analyzer.

Appendix 2: Required of all customers who do not have CO2_c (reagent SMN 11097521, calibrator SMN 11099401) in their inventory.

1. Run all patient samples in duplicate for every assay except for Sodium, Potassium, and Chloride.
2. Follow your established internal procedures to determine if additional testing is needed to identify samples with suspected discordance and to determine if the patient sample result is accurate.
3. If discordance is identified, please contact your Siemens Customer Care Center to determine additional action to be taken prior to processing patient samples.

Note: Siemens Customer Service is working to proactively provide CO2_c reagent and calibrator to customers who do not routinely run CO2_c in their laboratory. If you have not received this shipment, please contact your customer service representative. Once CO2_c is received by your laboratory follow steps 1-5 in Appendix 1.

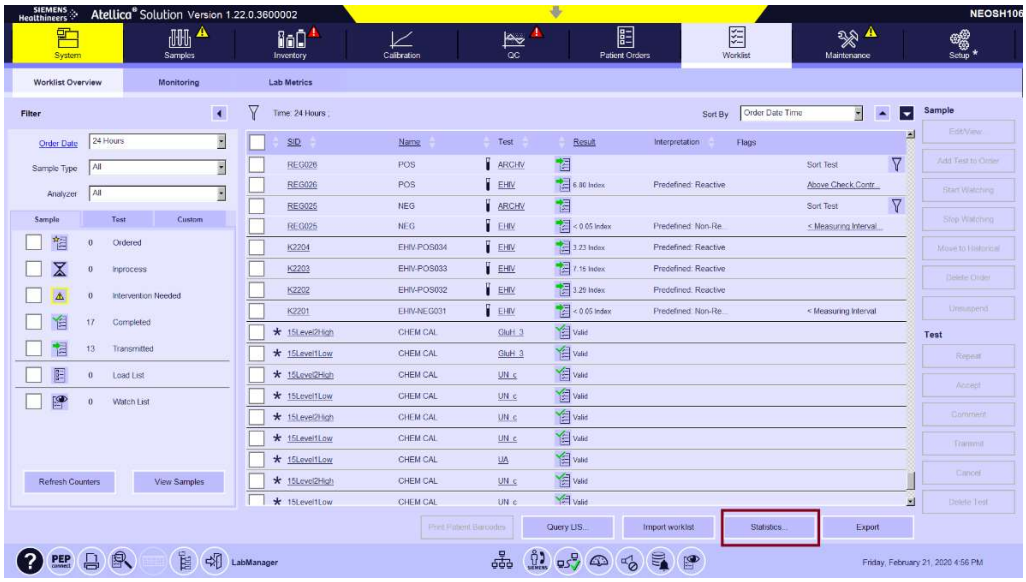
511 Benedict Avenue
Tarrytown, NY 10591

Appendix 3: Detailed instruction for setting up 300 replicates of CO2_c calibrator on your analyzer

1. Move all results to historical on the worklist overview screen.
2. Order 300 replicates of CO2_c on the patient order screen. The number of replicates ordered can be viewed at the top right-hand corner of the worklist overview screen.

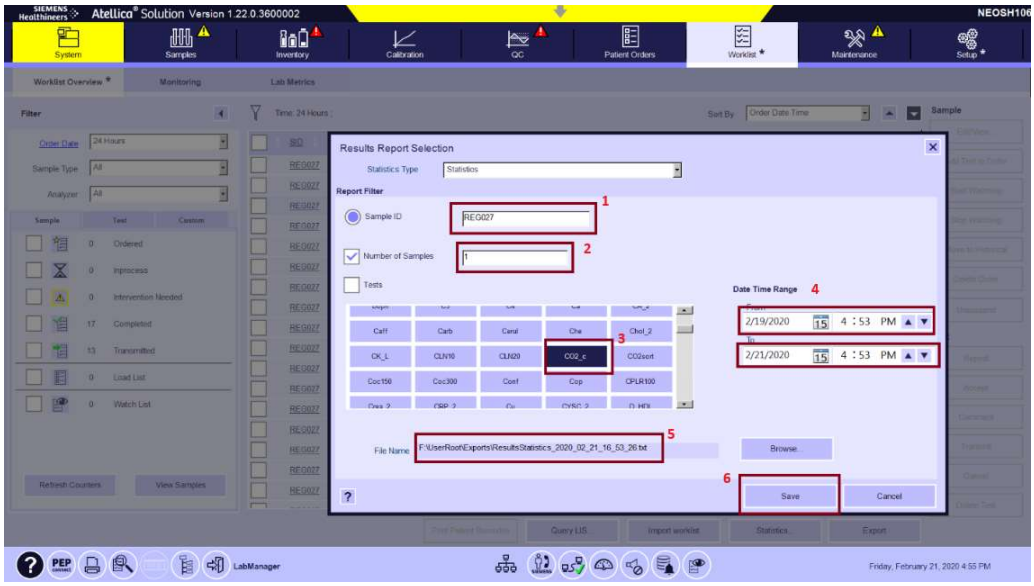
Appendix 4: Detailed instructions on calculating the mean calibrator value of 300 replicates

- **Go to Worklist>Worklist Overview>Statistics**



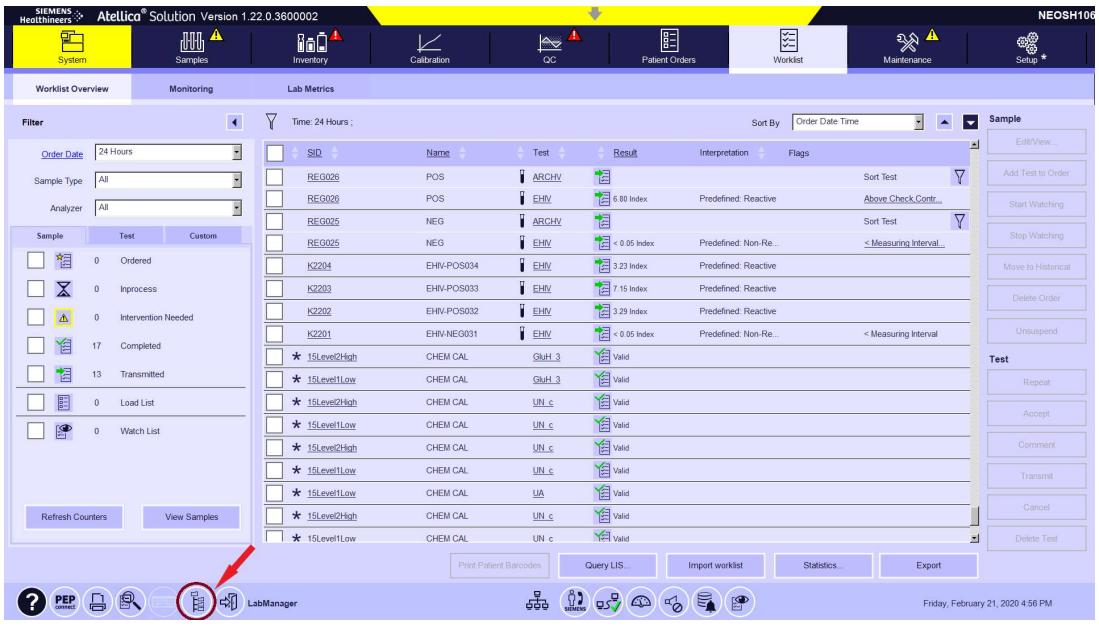
Results Report Selection window is displayed. The numbers on the screenshot correspond with the steps provided below.

511 Benedict Avenue
Tarrytown, NY 10591

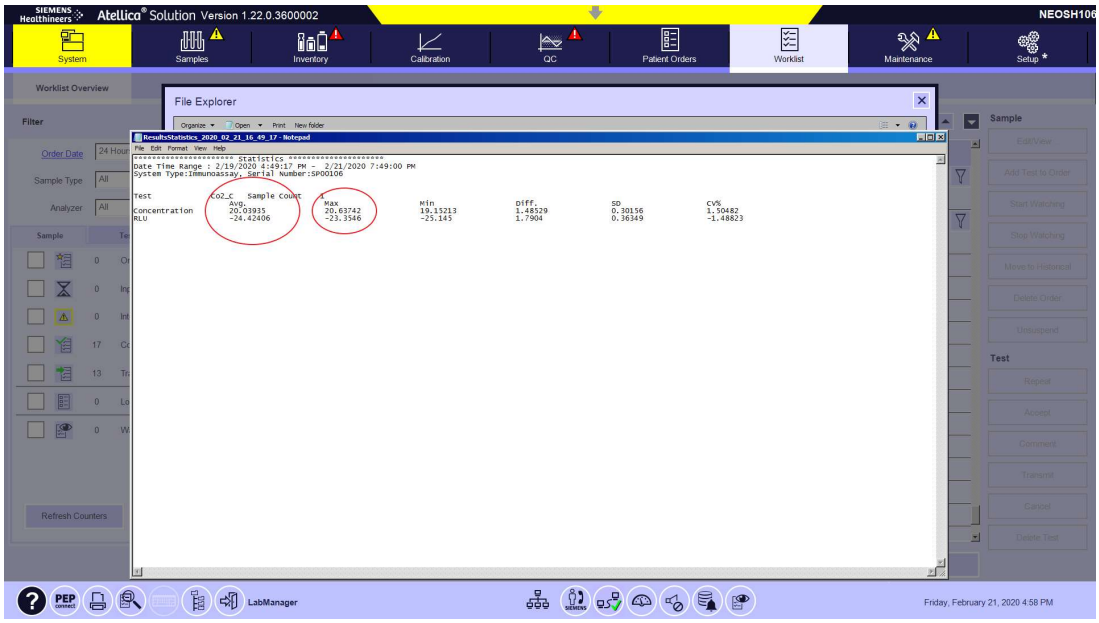


1. Enter sample ID (e.g. CO2_c1)
2. Enter Number of Samples as 1.
3. Select Test CO2_c
4. Enter Date and Time Range when the CO2_c sample was run.
5. Provide File Name (By default, it goes to F:\UserRoot\Exports)
6. Press Save Button.

- To access the statistics file, press Filed Explorer in status bar (indicated by red arrow below)



- Navigate to the folder where the statistics file is located (e.g. F:\UserRoot\Exports) then double click on the file name to open.



- The Average, Max, and Min values are displayed as indicated in the screenshot above.
- Locate the Max and Avg. (mean) values in the data. Divide the Max value by the Avg. value.
  - If this result is less than or equal to 1.12, none of the cuvette segments are impacted and you can continue to process patient samples
  - If this result is greater than 1.12 please contact your Customer Care Center for further assistance as indicated in Appendix 1.
  - **Once evaluation is complete please ensure that you revert to your original language setting**.

511 Benedict Avenue
Tarrytown, NY 10591

Siemens Healthcare SA,Freilagerstrasse 40, 8047 Zurich, Suisse

Nom Lydia Krüger
Département Application Manager Labordiagnostic

Téléphone +41 (0)58 199 11 22
Telefax
E-mail Qt.ch@siemens-healthineers.com

Notre référence RS / UI FSCA ACHC 20-05 D
Date 04.08.2020

Avis de produit (Field Safety Corrective Action FSCA ACHC 20-05 D)

Atellica CH® Analyzer

Chère cliente, cher client,

Nous vous prions de bien vouloir prendre connaissance de l`avis de produit ci-joint et d'informer vos utilisateurs.

Bien que, dans une perspective globale, seuls des cas isolés soient connus, en tant qu'entreprise de qualité certifiée nous prenons très au sérieux notre responsabilité et notre devoir d'informer nos clients. La loi fédérale sur les médicaments et les dispositifs médicaux (loi sur les produits thérapeutiques LPTh) et l'ordonnance sur les dispositifs médicaux (ODim) régissent entre autres les devoirs d'information et l'obligation d'agir des fabricants, des distributeurs ainsi que des utilisateurs et utilisatrices professionnels de dispositifs médicaux.

L'art. 15c al. 1 et Art. 15d ODim, exigent que les utilisatrices et utilisateurs soient informés du risque potentiel que vos dispositifs pourraient présenter pour la sécurité.

Les risques potentiels en matière de sécurité sont identifiés entre autres par des vérifications internes réalisées au titre de l'assurance de la qualité et par des retours de clients à l'international. La reproductibilité de propriétés défectueuses de dispositifs est entre autres déterminée dans le cadre de recherches. Si besoin est, des mesures destinées à éviter provisoirement ou durablement des défauts potentiels sont définies, initialisées et communiquées. Les circonstances et les conditions de chaque étude diffèrent, ce qui a un impact également sur la durée de ces études ainsi que sur le temps écoulé entre la constatation d'un défaut éventuel du dispositif et la communication des mesures.

Nous vous demandons de bien vouloir **confirmer la réception et la prise** de connaissance de la présente information en retournant le formulaire ci-joint dans **un délai de 7 jours**.

Si vous avez des questions ou si vous souhaitez obtenir des informations complémentaires, veuillez-vous adresser à notre **Customer Care Center** au n° de tél. **058 199 11 22**. Après instruction des utilisateurs, veuillez classer la fiche de sécurité ci-jointe dans le registre 1 de la notice d'utilisation des installations

Nous vous remercions de votre compréhension et de votre collaboration – au service de la sécurité des patients et des utilisateurs. Nous vous prions d'agréer, chère cliente, cher client, l'expression de nos salutations distinguées

Siemens Healthcare SA

Formulaire sans signature

Confirmation de l`avis de produit

Atellica CH® Analyzer

UI Ref. FSCA ACHC 20-05 D du 04.08.2020

→S` il vous plaît dans les 7 jours des réceptions adressée à:

Par E-Mail: qt.ch@siemens-healthineers.com

Par courrier : Siemens Healthcare SA
Quality
Freilagerstrasse 40
CH-8047 Zürich

		Interlocuteur:

Date d'entrée de l'information :

E-mail[#] :

☐ Je confirme / nous confirmons avoir reçu la consigne de sécurité relative aux dispositifs susmentionnée.

☐ Nous ne sommes pas concernés par cette mesure parce que _____.

☐ Nous aimerions commander l'avis de sécurité en français.

L'entreprise Siemens a-t-elle communiqué toutes les informations nécessaires de manière efficace et compréhensible ? ☐ Oui ☐ Non

Date signature du responsable cachet de l'établissement