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Urgent Field Safety Notice (ACHC 20-05):

Atellica® CH Analyzer

Resolution of the Potential for Inaccurate Test Results Associated with Reaction Cuvette Segments

Dear Sirs,

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

Table 1. Atellica CH 930 Affected Product

Assay	Siemens Material Number (SMN)
Atellica CH Reaction Cuvette Segment	11099326

Reason for Communication

In January 2020 and February 2020, Siemens Healthcare Diagnostics Inc. issued an Urgent Field Safety Notice (UFSN) ACHC20-05.A.OUS and ACHC20-05.B.OUS respectively, to inform all customers who purchased reaction cuvette segment lots ending in "17,"18" and "19" and above of a cuvette defect resulting in water from the water bath contaminating the interior of the cuvette. Customers were instructed to run the Atellica™ CH Carbon Dioxide, concentrated (CO2_c) assay in 300 replicates to determine if any of the cuvette positions were impacted.

In March 2020 Siemens issued ACHC20-05.C.OUS and ACHC20-05.D.OUS. Customers received ACHC20-05.C.OUS if they received ACHC20-05.B.OUS and received ONLY ACHC20-05.D.OUS if they DID NOT receive ACHC20-05.B.OUS. These letters provided customers with additional guidance on calculation of CO2_c results.

Siemens has now implemented additional pre-release screening for all reaction cuvette segments prior to shipment to customers. Beginning with reaction cuvette segment lot N1518920 (manufacturing date 2020-07-08) and for all subsequent lots that are manufactured thereafter, customers will no longer be required to follow the instructions provided in the UFSN's that have been issued previously.

Siemens is actively working towards replenishing inventory levels for this product. Full order quantities may not be immediately available in order to ensure that all customers have an adequate supply. This communication provides actions to be taken by your laboratory.

Actions to be Taken by the Customer

For the Atellica CH Cuvette Segment SMN 11099326, also listed in Table 1 above, please perform the following steps:

Review the lot numbers of reaction cuvette segments in your laboratory:

1. Lot N1518920 and any lots made after: This can be identified as follows: N15DDDYY- where DDD is ≥189 AND YY ≥ 20.
2. Any lots made before lot N1518920: This can be identified as follows: N15DDDYY- where DDD is <189 AND YY ≤20.

    - If your inventory ONLY has reaction cuvette segments as indicated in "1" you will no longer need to follow the instructions in the previously issued UFSN's.

    - If your inventory ONLY has reaction cuvette segments as indicated in "2" you will need to continue to follow the instructions in the previously issued UFSN's until your laboratory has ordered and received sufficient inventory of lots described in "1" above.

    - If your inventory has a combination of reaction cuvette segments as indicated in "1" and "2" above, follow the instructions below:

        - If you have sufficient inventory of lots described in "1" above, discontinue and discard category "2" cuvette segments.

        - If you do not have sufficient inventory described in "1" above and you plan to continue using lots described in "2" above, then continue to follow the instructions in the previously issued UFSN's.

        - Once your laboratory has received an adequate supply of the lots described in "1" above, discard all earlier lots from category "2" from your laboratory inventory.

- Please review this letter with your Medical Director.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- Review your inventory of these products to determine your laboratory's replacement needs and to provide information to Siemens Healthineers for reporting to the authorities.
- 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.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH

i.V. Dipl. Ing. Franz Schwarz
Quality Management CEE

i.A. Dr.in Brigitte Gassner
Product Manager Austria & SEE