

Atellica CH[®] Analyzer**Sentinel Diagnostics Zinc Lot 90227 with Standard Lot H0207 resulting in Downward Drift in Patient Samples**

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

Table 1. Atellica CH[®] Affected Product

Assay	Sentinel List Number (LN)	Siemens Material Number (SMN)	Lot Number	Expiration Date (YYYY-MM)
Zinc	17640H	10317329	90227	2021/08

Reason for Correction

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

Siemens Healthcare Diagnostics Inc. has received the attached Urgent Field Safety Notice (UFSN), reference number N.07/2020 dated October 29, 2020 for the above noted product from Sentinel Diagnostics, the product manufacturer. As the distributor of the product, Siemens is informing our customers that the Sentinel investigation has highlighted an issue with the standard (component lot H0207), included in the Zinc product, that can induce a drift down of lot 90227 results versus other lots, resulting in an underestimation up to approximately 15%.

Risk to Health

Per Sentinel Diagnostics UFSN – The use of the affected lot could generate falsely low zinc results (-15%) in patient samples that can incorrectly lead to a suspected zinc deficiency. This incorrect evaluation could lead to an unnecessary zinc supplementation. This medical treatment can be considered as low risk for the patient's health.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- Discontinue the use of the impacted lot immediately and destroy any remaining inventory of impacted lot.
- If you have an alternate reagent lot available in inventory, switch to this alternate lot according to your laboratory procedures.
- Complete and return the Siemens Healthineers Field Correction Effectiveness Check Form attached to this letter within 30 days.

Sentinel Diagnostics Zinc Lot 90227 with Standard Lot H0207 resulting in Downward Drift in Patient Samples

- 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.

Sentinel Diagnostics Zinc Lot 90227 with Standard Lot H0207 resulting in Downward Drift in Patient Samples

FIELD CORRECTION EFFECTIVENESS CHECK

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This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice, ACHC21-03.A.OUS dated November 2020 regarding Sentinel Diagnostics Zinc Lot 90227 with Standard Lot H0207 resulting in Downward Drift in Patient Samples Please read each 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 UFSN instructions provided in this letter. Yes ☐ No ☐
2. Do you now have any of the noted product(s) on hand? Please check inventories before answering. Yes ☐ No ☐

If the answer to the question above is yes, please complete the table below to indicate the quantity of affected product in your laboratory and replacement product required.

Product Description Product Catalog #/SMN #/Lot #	Quantity of Affected Product in inventory Discarded/ Replacement Quantity Required
Zinc, SMN 10317329, Lot 90227	

Name of person completing questionnaire: _____

Title: _____

Institution: _____ Instrument Serial Number: _____

Street: _____

City: _____ State: _____

Phone: _____ Country: _____

Customer Sold To #: _____ Customer Ship To #: _____

Please send a scanned copy of the completed form via email to XXXX@XXXX

Or to fax this completed form to the Customer Care Center at XXXXXX

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



Urgent Field Safety Notice N. 07/2020

Product Name	List Number (LN)	Lot Number	Expiration Date
Zinc	17640H	90227	2021/08

Date: October 29th, 2020

Details on affected devices:

This letter contains important information regarding the ZINC product REF 17640H lot 90227. Please review the information carefully and follow the necessary actions.

Description of the problem:

Internal investigations performed have highlighted an issue with the standard (component lot H0207), included in the Zinc product, that can induce a drift down of lot 90227 results versus other lots, resulting in an underestimation up to approximately 15%.

Patient Impact:

The use of the affected lot could generate falsely low zinc results (-15%) in patient samples that can incorrectly lead to a suspected zinc deficiency. This incorrect evaluation could lead to an unnecessary zinc supplementation. This medical treatment can be considered however as low risk for the patient's health.

Actions to be taken:

1. Discontinue the use of the impacted lot immediately and destroy any remaining inventory of impacted lot;
2. If you have an alternate reagent lot available in inventory, switch to this alternate lot according to your laboratory procedures;

4. Review the content of this communication with your Medical Director and retain this letter for any future reference.

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organization or to any organization/individuals where the potentially affected devices have been transferred.