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Urgent Field Safety Notice:

Atellica CH Analyzer

Atellica CI Analyzer

Atellica CH Creatine Kinase (CK_L): Potential for Falsely Elevated Results with Lot Numbers 252591, 252602 and 252612

To whom it may concern,

Our records indicate that you have received:

Assay	Test Code	Siemens Material Number/Unique Device Identification	Lot Number	Manufacturing Date	Expiration Date
Atellica CH Creatine Kinase	CK_L	11097640/ 00630414006642	252591	01-Jul-2025	01-Aug-2026
			252602	01-Jul-2025	01-Aug-2026
			252612	01-Aug-2025	01-Sep-2026

Siemens Healthineers has confirmed, through investigation of customer complaints, the potential for falsely elevated patient, quality control (QC), and/or calibrator results when using Atellica CH Creatine Kinase (CK_L) lot numbers 252591, 252602 and 252612 on the Atellica CH and Atellica CI Analyzers. This issue may be observed with both serum and plasma sample types. QC results may or may not detect the issue. Siemens Healthineers is actively investigating the root cause of this issue.

Impact to Results

Customers have reported initial results above the measuring interval (>1300 U/L) or above the extended measuring interval (>39,000 U/L) where the true result is lower. True results may be below, within or above the measuring interval.

Customer Actions

- Immediately discontinue use of and discard the kit lots listed in the Products Section above.
- Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.
- Review your inventory of these products to determine your laboratory's replacement needs and to provide information to Siemens Healthineers for regulatory reporting.
- 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 a copy to any personnel who may have received or used this product.

— Resolution

Alternate, unaffected Atellica CH CK_L kit lots are available.

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



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