

Customer Notification

POC 25-015.A.OUS

Chek-Stix Liquid QC Kit Chek-Stix Liquid QC Kit + Sediment

Title Foreign Material Identified in Quality Control Product

Date Issued August 2025

Product	Siemens Material Number	GTIN	Unique Device Identification	Kit lot #	Expiry date (YYYY-MM-DD)
Chek-Stix Liquid QC Kit	11561695	00850015517204	00630414622910	S202532	2026-04-30
				S202583	2026-09-30
Chek-Stix Liquid QC Kit + Sediment	11561696	00850015517198	00630414622927	S202529	2026-08-31
				S202540	2026-09-30
				S202584	2026-09-30
				S202597	2026-11-30

Issue Description The purpose of this communication is to inform you of a potential issue with the products indicated in the table above and provide instructions on actions that your facility must take.

Siemens Healthineers received a Product Correction and Removal Notification from Kova International regarding Foreign Material Identified in Quality Control Product. The affected products/lots are listed in the table above. These products are for use on the CLINITEK Novus, and/or Atellica UAS 800 and the Atellica 1500. For more details about the issue and the actions to be taken, please refer to the attached Product Correction and Removal Notification from Kova International.

- Customer Actions**
- Review Kova’s Product Correction and Removal Notification attached.
 - Review this letter with your Medical Director and/or Point of Care Supervisor to determine the appropriate course of action.
 - If you are a distributor, ensure your customers receive this customer notification letter.
 - Retain this letter with your laboratory records and forward this letter to those who may have received this product in your facility.
 - If you have any of unused kit lots listed above, you may contact the local Siemens/distributor office for suitable QC alternatives or to request reimbursement. Complete and return the Product Replacement Form attached to this letter.

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.

PRODUCT REPLACEMENT FORM

This response form is to request no charge replacement product for the enclosed Siemens Healthineers Customer Notification POC 25-015.A.OUS dated August 2025. Please read each question and indicate the appropriate answer.

Return this completed form as per the instructions provided at the bottom of this page.

- 1. Do you have the affected product(s) on hand? Please check inventories before answering? Yes No
- 2. Have all affected Site Personnel been notified? Yes No
- 3. Has a copy of the letter retained and posted with the current product labeling? Yes No

If the answer to the question #1 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 #	Kit Quantity of Affected Product/lot in inventory Discarded/Replacement Quantity Required		
Chek-Stix Liquid QC Kit, SMN# 11561695 Lot # S202532, S202583			
Chek-Stix Liquid QC Kit + Sediment, SMN# 11561696 Lot # S202529, S202540, S202584, S202597			
Name of person completing questionnaire:			
Title:			
Institution:			
Street:			
City / Zip Code:		State:	
Phone:		Country:	

Please send a scanned copy of the completed form via email to fscareportingunit.my@siemens-healthineers.com.

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.



Product Correction and Removal Notification
For attention of: Healthcare Professionals

Date Issued: July, 2025

**Chek-Stix Liquid QC Kit / Chek-Stix Liquid QC Kit + Sediment
Foreign Material Identified in Quality Control Product**

Type of Action: Product Correction and Removal Notification

Products:

Product	Part Code	Kit Lot No.	Level 1 Lot No.	Level 2 Lot No.	Expiry Date	UDI from Kit Label
Chek-Stix Liquid QC Kit, 120mL	SMN 11561695	S202532	S202472	S202530	04-30-2026	00630414622910
		S202542	S202531	S202572	09-30-2026	
		S202583	S202531	S202582	09-30-2026	
		S202601	S202541	S202572	11-30-2026	
Chek-Stix Liquid QC Kit + Sediment, 120mL	SMN 11561696	S202529	S202515	S202469	08-31-2026	00630414622927
		S202540	S202553	S202469	09-30-2026	
		S202584	S202553	S202538	09-30-2026	
		S202597	S202554	S202555	11-30-2026	
		S202598	S202580	S202555	11-30-2026	

Dear Valued Customer,

KOVA International is initiating a Product Correction and Removal Notification for the products listed above. This letter contains important information that needs your immediate attention.

ISSUE:	<p>Customers have reported the presence of foreign material when using Chek-Stix Liquid QC Kit, 120mL and Chek-Stix Liquid QC Kit + Sediment, 120mL.</p> <p>An internal investigation conducted by KOVA International confirmed the presence of foreign material due to microbial contamination. There is no impact to QC performance; therefore, patient results would not be affected.</p> <p>We are providing this notice to raise awareness of the issue and to mitigate any unforeseen instrument or performance challenges.</p>
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NECESSARY ACTIONS TO BE TAKEN BY CUSTOMER:	<p>Please share this information with your laboratory staff who need to be aware of this notification as part of your laboratory Quality System documentation, including Laboratory Director and/or POC supervisor. If you have forwarded any of the impacted product(s) listed above to another laboratory, please provide them a copy of this letter.</p> <p>If you have any of the kit lots listed above, please contact your Siemens Healthineers Technical Solution Center, your local Siemens Healthineers representative, or your distributor for suitable QC alternatives or reimbursement.</p>
CONTACT	<p>If you or any of the health care providers you serve have questions regarding this notice, please contact your local SIEMENS Customer Service representative.</p>

We sincerely apologize for any inconvenience this may cause your laboratory and hope for your understanding and cooperation.

Yours Sincerely,

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Yours Sincerely,

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