

Chek-Stix® Liquid QC Kit + Sediment

Chek-Stix Liquid QC + Sediment Incorrect Value Assignment for RBC and WBC

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

Table 1. Affected Product

Product	Siemens Material Number (SMN)	Unique Device Identification (UDI-DI)	Kit Lot Number	Vial Lot Number
Chek-Stix Liquid QC Kit + Sediment	11561696	00630414622910	S202216	S202211

Reason for Customer Notification

Siemens Healthineers received a Field Action Notice from Kova International regarding incorrect value assignment for RBC and WBC on Quality Control (QC) level 2 for Chek-Stix Liquid QC + Sediment. The purpose of this communication is to inform you of the issue and provide you with instructions on actions that your facility should take. The affected product is listed in Table 1.

The affected value assignment ranges have been revised. QC Level 1 is not affected. For more details, please refer to the attached Field Action Notice provided by Kova International.

Actions to be Taken by the Customer

- If you are a distributor, please ensure your customers receive this customer notification letter.
- Review attached Field Action Notice from Kova International.
- Use the attached revised Value Assignment Sheet (VAS) for the lot listed in Table 1. Note the revised VAS shows the vial lot number as S202211-R.
- Please review this letter with your Medical Director.

Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

The revised VAS for the affected vial lot will be available in Siemens Document Library. We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center 1800-815-508.

Additional Information

Chek-Stix® is a trademark of Siemens Healthcare Diagnostics Inc. Kova International is the legal manufacturer of the affected product, Chek-Stix Liquid QC Kit + Sediment.

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