

Urgent Field Safety Notice

StripAssays® with distortions of the size ratios in the schematic representation of the strips on the collector sheets

FSCA Ref: FSCA 2024/001

FSN Ref: FSN 2024/001

April, 3rd 2024

Dear Valued Customer,

ViennaLab Diagnostics GmbH is bringing to your immediate attention the product correction for collector sheet printouts of StripAssay® lots, listed below.

REF#	ASSAY LOT#	Expiry Date	Collector-sheet Version
4-160	10-ZW-24-004	2025-04	Av2Bv4 03/2010
4-160-A	30-EI-24-012	2025-03	Av2Bv4 03/2010
4-160-A	30-EI-24-015	2025-03	Av2Bv4 03/2010
4-160-A	30-EI-24-022	2025-03	Av2Bv4 03/2010
4-750	20-EI-24-012	2025-03	v2 03/2012

Background

Due to a distributor's feedback, it was drawn to our attention, that in the above-mentioned kits there may be distortions of the proportions in the schematic representation of the strips in the included collector sheet printouts.

Immediately after the incident became known, all customers were made aware of the possible problem by the distributor, with the request to check the collector sheets contained in the kit.

Reason for correction

The deviations of the schematic representation on the collector sheet from the actual dimensions of the strips of the StripAssays® caused by the distortion are clearly visible. This makes it difficult to visually evaluate the strips.

All other components of the StripAssay® lots are not affected.

Potential risk for patients

The deviations of the schematic representation on the collector sheet from the actual dimensions of the strips of the StripAssays® caused by the distortion make visual evaluation of the strips and interpretation of the results more difficult. This can lead to a delayed diagnosis.

The results of StripAssays® should always be interpreted in the context of all clinical and laboratory information available to the physician. Therefore, delaying the results does not pose an immediate risk to the patient.

Important note

When interpreting the results from the affected kits, other diagnostic tests and the patient's current clinical condition should also be taken into account. If the results are not consistent with the clinical picture and discrepancies are found with previous or concurrent tests, the patient should be retested.

Actions to be taken by the customer

- Please check your stock for the StripAssays® listed.
- Your distributor (supplier) will provide replacements for the collector sheets of the affected kits.
- Please, dispose the collector included in the kit and replace it with the separately supplied replacement collector after you have opened the kit.

Communication of this Field Safety Notice

This notification needs to be passed on to all those who need to be aware within your organization.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action.

Actions to be taken by ViennaLab Diagnostics

As part of our Quality Assurance process, we are investigating this incident and are implementing corrective actions.

If you have questions or concerns, please contact techhelp@viennalab.com.

The undersigned confirms that this notice has been submitted to the appropriate regulatory agencies.

We apologize for any inconvenience this may cause and appreciate your attention and cooperation in this matter.

Sincerely,

