ViennaLab®

Urgent Field Safety Notice

FSCA Ref: FSCA 2025/002
FSN Ref: FSN 2025/002

September 24th 2025

Dear Valued Customer,

ViennaLab Diagnostics GmbH is bringing to your immediate attention the serious incident about the product **BRAF 600/601 StripAssay®** (REF 5-560) with the following details:

REF#	Kit Lot#	Teststrips LOT#	Kit Expiry Date	Country
5-560	10-VI-24-020	09-DR-24	2025-05	Romania
5-560	10-VI-24-020	09-DR-24	2025-05	Romania
5-560	10-SE-24-004	09-DR-24	2025-07	Romania
5-560	10-AC-24-011	09-DR-24	2025-10	Romania
5-560	10-AC-24-066	09-DR-24	2025-10	Romania
5-560	10-EL-24-003	09-DR-24	2026-01	Romania
5-560	10-DR-25-008	09-DR-24	2026-05	Romania

Background

Following a single customer complaint, we identified that one Teststrip from Lot #: 09-DR-24 may produce an unclear band pattern at lines 1 to 4 after test completion when the sample is positive for one of the corresponding mutations. It is important to note that this lot has been on the market for over a year, during which 7144 Teststrips have been distributed, and we have received only one report of this issue. This indicates that the occurrence is extremely rare and isolated, and there is currently no evidence of a systematic problem affecting the lot.

Unclear bands do not lead to false positive or false negative results, but they may prevent proper interpretation of that individual Teststrip. In such cases, a repeat test may be required, which could cause a delay in obtaining the result. Users are reminded that Section VI of the IFU provides guidance for identifying unclear bands using the Collector Sheet, and Figure 3 illustrates examples of such bands. We are continuing our investigation to fully understand the root cause, and we will take any necessary actions should further complaints be received. In the meantime, the overall risk to test performance and patient safety remains extremely low, and the vast majority of tests from this lot perform as intended.

Below, on the left side (Figure 1A), is an example of unclear bands on the Teststrip after completing the test.

Below, on the right side (Figure. 1B) is the right band pattern on the Teststrip according to the IFU.

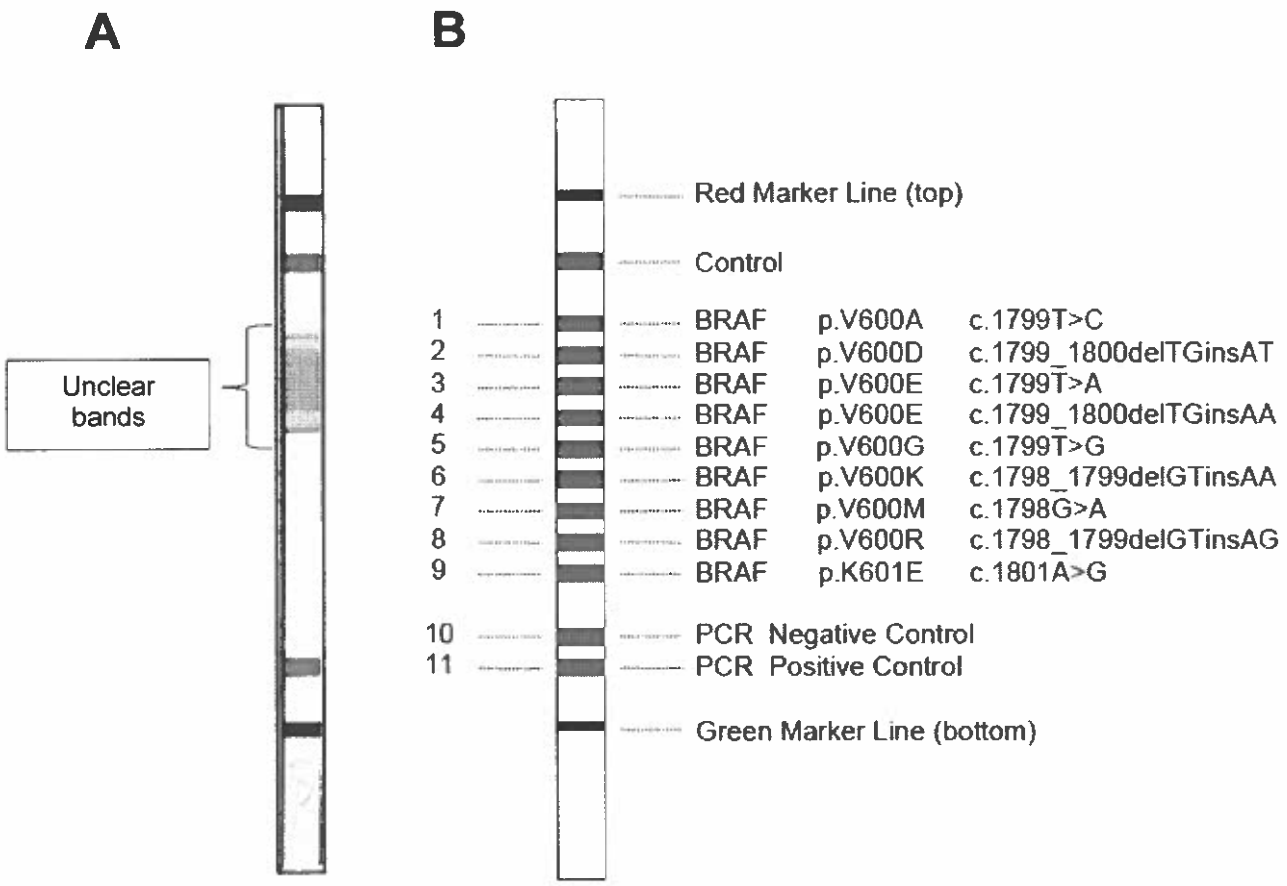

Figure 1: (A) An example of unclear bands after hybridization. (B) The Teststrip design from the current version of the IFU and the current version of the Collector Sheet.

Impact

Unclear bands do not cause false positive or negative results but may prevent proper interpretation, requiring a repeat test therefore possibly causing a slight delay. Investigations are ongoing, and any new reports will prompt appropriate action. Given the extremely low incidence (1 out of 7,144 Teststrips) and the isolated nature of the issue, a recall is not considered necessary at this time. Continuous monitoring remains in place, and any information suggesting a broader risk will trigger immediate review and, if needed, corrective actions, including a potential recall.

No other components of the BRAF 600/601 StripAssay® (REF 5-560) have been affected.

No other kit lots or Teststrip lots of BRAF 600/601 StripAssay® (REF 5-560) have been impacted.

Actions to be taken by the customer

You may continue to use the lots containing the potentially affected Teststrip Lot (Lot #: 09-DR-24).

Always follow the instructions provided in the IFU. According to Section VI (Interpretation of Results), results can be assessed using the Collector Sheet. By following the instructions and reviewing the example results in Figure 3, end users can recognize any "unclear bands" that may appear.

It is assumed the issue is extremely rare, having occurred only once; if you notice unclear bands or missing separation of bands, please repeat the test and inform your distributor with the proof of Teststrips with "unclear bands" or ViennaLab at techhelp@viennalab.com.

Communication of this Field Safety Notice

The affected customer from this initial complaint was informed directly.

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,

Dr. Ceren Karacay-Steinwender

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