Urgent Field Safety Notice

α-Globin StripAssay® (REF 4-160), impaired component HS-Taq DNA Polymerase

FSCA Ref: FSCA 2021/001
FSN Ref: FSN 2021/001

December 2, 2021

Product Name	Lots	Exp.date	Lots	Exp.date
α-Globin StripAssay® REF 4-160	30-EL-20-017	2021-12	10-DR-21-011	2022-05
	30-EL-20-001	2021-12	10-DR-21-035	2022-05
	10-TW-20-002	2022-01	10-VI-21-001	2022-06
	10-TW-20-010	2022-01	10-VI-21-028	2022-06
	30-TW-20-010	2022-01	10-VI-21-042	2022-06
	10-EI-21-023	2022-02	10-SE-21-001	2022-07
	10-EI-21-026	2022-02	10-SE-21-008	2022-07
	30-EI-21-015	2022-02	10-SE-21-038	2022-07
	30-EI-21-013	2022-02	30-SE-21-019	2022-07
	30-EI-21-006	2022-02	30-SE-21-014	2022-07
	30-EI-21-002	2022-02	30-SE-21-002	2022-07
	10-ZW-21-009	2022-03	10-SI-21-012	2022-08
	10-ZW-21-031	2022-03	10-SI-21-017	2022-08
	10-DR-21-005	2022-05	10-AC-21-001	2022-10

Dear Valued Distributor,

ViennaLab Diagnostics GmbH is bringing to your immediate attention the product correction α-Globin StripAssay® (REF 4-160) listed above.

Reason for correction

Our records show that you have received α-Globin StripAssay® (REF 4-160) of one or more Lot(s) mentioned above.

Internal stability testing has revealed an impaired performance of the HS-Taq DNA polymerase, a stand-alone component of the α-Globin StripAssay®. Loss of amplification of long gene fragments like the -3.7 kb deletion (1783 bp) and the anti-3.7 gene triplication (1772 bp) was observed with HS-Taq DNA Polymerase stored for 16 months at 2 to 8 °C. Furthermore, two customers reported inconclusive results due to missing or poorly stained bands.

Hazard giving rise to the Field Safety Corrective Action (FSCA)

Hence, full activity of the enzyme cannot be guaranteed until the end of the kit shelf-life. As a consequence of the potentially reduced polymerase activity, α-Globin StripAssay® kits including affected HS-Taq DNA Polymerase may produce an inconclusive result or a false negative result for the -3.7 kb deletion and anti-3.7 gene triplication.

All other α-Globin StripAssay® components are not affected by this recall.
All other α-Globin StripAssay® Lots are not affected by this recall.

Actions to be taken by the distributor

- Please immediately stop the distribution of the α-Globin StripAssay® kits of the above identified lots which you have on stock.
- Please complete and return the attached Product Correction Return Response Form (Distributor) within **5 (five)** days of receipt of this notice (and Certificate of Destruction, if applicable).
    - ViennaLab Diagnostics will provide you with immediate replacement kits for quantities indicated on the returned response form.
    - ViennaLab will provide you with the Urgent Field Safety Notice for distribution to customers who have received the affected kits.
    - ViennaLab Diagnostics will provide replacement of HS-Taq DNA Polymerase for the affected kits based on quantities indicated on the Product Correction Return Response Form (Customer).
- Upon receipt of the replacement HS-TAQ DNA Polymerase immediately notify your customers and provide them with the replacement HS-Taq DNA Polymerase.
- Maintain returned response forms from your customers for your records.

Communication of this Field Safety Notice

This notice 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.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

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

Sincerely,

xxx
regulatory@viennalab.com

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1120 Vienna
Phone: +43 1 812 0156

December 2, 2021

Product Correction Return Response Form (Distributor)

Product Name	Lots	Exp.date	Lots	Exp.date
α-Globin StripAssay® REF 4-160	30-EL-20-017	2021-12	10-DR-21-011	2022-05
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	10-ZW-21-031	2022-03	10-SI-21-017	2022-08
	10-DR-21-005	2022-05	10-AC-21-001	2022-10

Please check ALL appropriate boxes.

☐ I have read the instructions provided in the Urgent Field Safety Notice dated December 2, 2021 and have the following α-Globin StripAssay® Lots and quantities in my possession:
(If checked, complete the attached Certificate of Destruction.)

α-Globin StripAssay® Lot	Quantity

☐ The following α-Globin StripAssay® Lots and quantities were distributed to customers:

α-Globin StripAssay® Lot	Quantity	Country	Zip Code	City

Response Form completed by:

Name:

Title:
Telephone Number:
Email Address:
Organization Name:
Street:
City:
Zip code:
Country:

Please email the completed response form to: regulatory@viennalab.com

December 2, 2021

Certificate of Destruction

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	10-DR-21-005	2022-05	10-AC-21-001	2022-10

I have read the instructions provided in the Urgent Field Safety Notice dated December 2, 2021 and have disposed of the following α-Globin StripAssay® Lots and quantities per local requirements:

α-Globin StripAssay® Lot(s)	Quantity

Signature/Date:_____

Response Form completed by:

Name:
Title:
Telephone Number:
Email Address:
Organization Name:
Street:
City:
Zip code:
Country:

Please email this certificate together with the response form (distributor) to:
regulatory@viennalab.com