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 Customer,

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

Reason for correction

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.

Predicted risk to patient

A false negative result for a heterozygous carrier of the -3.7 deletion or anti-3.7 gene triplication has no clinical consequence for the subject since these genotypes are supposed to be silent carriers without symptoms.

In the presence of the -3.7 del and a detectable point mutation, false interpretation of a patient's genotype as a homozygote instead of a compound heterozygote has no impact on the clinical diagnosis. In both cases the patient is expected to clearly present with alpha-thal trait.

Decisions based on a false negative result may be of concern in genetic counselling. In the event of pregnancy, in the worst case the offspring of falsely genotyped parents may suffer with an unforeseeable HbH disease. For high-risk couples, i.e., one partner presenting with heterozygous alpha^0-thal trait or with HbH disease and the other being an undetected carrier of the -3.7 del, there is a 25% risk of having a child with the severe clinical condition of HbH disease.

Particular considerations

The α-Globin StripAssay® is intended to be used as a confirmatory test for suspected alpha-thalassemia patients and to identify the carrier status in the patient's relatives. Its outcome shall always be interpreted in the context of the patient's overall clinical phenotype, and with regard to carrier screening the patient's family history should be considered as well.

When interpreting the results obtained from affected kits, we advise clinicians to consider other diagnostic tests and a patient's current clinical condition. If the results do not match the clinical presentation and discrepancies with previous or concurrent tests are observed, the patient should be retested. In the frame of genetic counselling, particular attention should be paid to a possibly false negative result for a high-risk couple.

Actions to be taken by the customer

- Please immediately stop usage of the α-Globin StripAssay® kits of the above identified lots if you have affected lots on stock. Discard the included HS-Taq DNA Polymerase as per local requirements. Note, only the HS-TAQ DNA Polymerase is to be disposed. Do not dispose of the other components within the kit.
- Please complete and return the attached Product Return Response Form (Customer) within 10 days of receipt of this letter.
- Your Supplier will provide replacement of HS-Taq DNA Polymerase for the affected kits based on quantities indicated on the Product Return Response Form (Customer).
- Upon receipt of the replacement HS-TAQ DNA Polymerase continue using the identified Lots and all other kit components along with the replacement HS-Taq DNA Polymerase.

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.

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

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
ViennaLab Diagnostics
GmbH
regulatory@viennalab.com

ViennaLab Diagnostics GmbH
Gaudenzdorfer Guertel 43-45
1120 Vienna
Phone: +43 1 812 0156

December 2, 2021

Product Correction Return Response Form (Customer)

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	10-TW-20-002	2022-01	10-VI-21-001	2022-06
	10-TW-20-010	2022-01	10-VI-21-028	2022-06
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	30-EI-21-013	2022-02	30-SE-21-019	2022-07
	30-EI-21-006	2022-02	30-SE-21-014	2022-07
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	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

Please check the appropriate boxes.

☐ I have read and followed the instructions provided in the Urgent Field Safety Notice dated December 2, 2021; I have the following α-Globin StripAssay® Lots and quantities in my possession:

α-Globin StripAssay® Lot	Quantity

☐ I have checked our stock and do not have this product on stock.

Response Form completed by:

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

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