

URGENT Field Safety Notice

G8 Elution Buffer HSi No.2 (S) Recall

Product: G8 Elution Buffer HSi No.2 (S)
Product Code: 0021801
Lot number: R8-203H
FA Reference: FA3
Type of action: Recall
Date: 18 July 2023

Dear Valued Tosoh Customer,

This letter contains important information regarding the G8 Elution Buffer HSi No.2 (S) (P/N.: 0021801), which is used in conjunction with the Tosoh Automated Glycohemoglobin Analyzer HLC-723G8 provided by Tosoh Europe to your facility. As part of this action, Tosoh is initiating a voluntary recall for lot R8-203H of the G8 Elution Buffer HSi No.2 (S).

Background

Auto-packing machines are used to pack Elution Buffer pouches into product boxes. An internal investigation revealed that during the assembly of the G8 Elution Buffer HSi No.2 (S) (P/N.: 0021801), a residual amount of G11 Elution Buffer No.1 (S) pouches were left in the auto-packing machine. Consequently, these G11 Elution Buffer No.1 (S) pouches were packed into G8 Elution Buffer HSi No.2 (S) boxes.



Figure 1: G11 Elution Buffer No.1 (S) pouch with G8 Elution Buffer HSi No.2 (S) box



Risk to health

In the event that G11 Elution Buffer No.1 (S) is used instead of G8 Elution Buffer HSi No.2 (S) on Tosoh Automated Glycohemoglobin Analyzer HLC-723G8, the obtained result will be "0.00 HbA1c%".

As the obtained result of "0.00 HbA1c%" clearly indicates an inaccurate measurement, the risk of incorrect patient treatment based on these results is minimal. Therefore, we concluded that the associated risk linked to this event is very low.

Corrective Action

The manufacturing team has taken measures to prevent this from occurring in the future, by implementing additional steps in the manufacturing and packaging processes.

Actions to be taken by the Customer/User

- 1) Ensure that all the contents of this Field Safety Notice are read and understood by those within your organization who need to be aware.
- 2) If you have further distributed the impacted product, please forward this notice and all the related documentation to those users(s).
- 3) Return the completed customer **Confirmation Form** on **Page 3** of this notification to **vigilance.emea@tosoh.com**

If your organization received the correct product (G8 Elution Buffer HSi No.2 (S)), you can use the products that have already been delivered with the correct buffer pouch (G8 Elution Buffer HSi No.2 (S)).

If your organization received G8 Elution Buffer HSi No.2 box with the G11 Elution Buffer No.1 pouch inside, we ask that you dispose of the product and complete the customer Confirmation Form on Page 3 of this notification, which should be sent to **vigilance.emea@tosoh.com**, **along with a picture of the affected box and pouch**. Tosoh will provide you with a new G8 Elution Buffer HSi No.2 free of charge.

Should you have any questions or require assistance relating to this notification, please contact your local Tosoh representative or the QA/RA department at **vigilance.emea@tosoh.com**.

On behalf of the manufacturer

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Tosoh Europe NV



TOSOH EUROPE N.V.

CONFIRMATION FORM

**PLEASE COMPLETE AND FAX BACK TO QA/RA department: +32 (0)13 66 47 49
or email to: Vigilance.EMEA@tosoh.com**

Our Reference: FA3

G8 Elution Buffer HSi No.2 (S) lot R8-203H Recall

This form is to confirm receipt of the enclosed Tosoh Europe NV Field Safety Corrective Action dated 3 May 2023, which provides information regarding **G8 Elution Buffer HSi No.2 (S) lot R8-203H Recall**. Please complete the below form.

1) Name of Facility:

2) Tosoh Customer Code (if known) :

3) Name of contact person:

4) Telephone number of contact person:

5) Email address of contact person:

(1): I confirm this notice has been read, understood and that all recommended actions have been implemented as required.

(2): I have not received an affected G8 Elution Buffer HSi No.2 box, lot R8-203H containing the G11 Elution Buffer No.1 (S) pouch

Customer Name

Date: (DD/MM/YY):

Customer Signature:

Thank you for your kind cooperation.