



Customer Notification

Hemoglobin F and A2 Control re-assignment of values

Product: Hemoglobin F and A2 Control
 Product Code: 0997050
 Lot number: 1087
 FA Reference: FA1
 Type of action: Device modification
 Date: 09 November 2021

Dear Valued Tosoh Customer

This letter contains important information about the "Hemoglobin F&A2 Control" material used with the G11 instrument that is supplied by Tosoh Bioscience to your facility. Tosoh Bioscience has reassigned the values for this device.

Background

In the interest of proactively informing our customers, Tosoh Europe NV has decided to re-assign the value of HbA2 in "Hemoglobin F&A2 Control Lot 1087". This reflects the appropriate long-term stability of the control material.

Results

The values for "G11 Hemoglobin F&A2 Calibrator and F&A2 Calibrator Set 2" remain unchanged. All values are published on the Tosoh website under the respective "EXTRA INFO".

The values for "Hemoglobin F&A2 Control" for HbF and HbS remain unchanged. Only the values for the HbA2 will change, for both level 1 and 2.

The new values for HbA2 for "Hemoglobin F and A2 Control" related to Lot 1087, from this date onwards are:

Lot	HbF		HbA2		HbS
	Level 1	Level 2	Level 1	Level 2	Level 2
1087-range L:	2.20	5.98	1.7	4.7	19.9
1087-Mean:	2.62	7.38	2.1	5.8	24.9
1087-range H:	3.18	8.92	2.4	7.0	29.9



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Risk to health

Patient sample results are not affected by the reassignment of the reference values.

Actions to be taken by the Customer/User

- 1) Ensure that all the contents of this Customer Notification are read and understood by those within your organisation 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 user(s).
- 3) Return the completed Customer Response Form on Page 3 to info.raqa@tosoh.com as soon as possible.

Should you have any questions or require assistance relating to this Customer Notification, please contact your local Tosoh representative or the QA/RA department at info.raqa@tosoh.com

Yours sincerely

On behalf of the manufacturer

Ioannis Bekatoros

Quality Assurance and Regulatory Affairs Manager EMEA

Tosoh Europe NV



CONFIRMATION FORM

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

Our Reference: FA1

Field Safety Notice for Hemoglobin F and A2 Control change of reference values

This response form is to confirm receipt of the enclosed Tosoh Europe NV Customer Notification dated 09 November 2021, which provides information regarding Hemoglobin F and A2 Control change of reference values. 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 do not have any of the Tosoh products identified in this notification.

Customer Name

Date: (DD/MM/YY):

Customer Signature:

Thank you for your kind cooperation.