

**HORIBA ABX SAS**

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Montpellier, July 24th, 2017  
Ref: FSN\_2017\_24-07

**FIELD SAFETY NOTICE**  
**ABX PENTRA HbA1c WB Cal (ref: A11A01703) from lot no. 1704201**

Dear HORIBA Medical Customer,

Following internal investigations and for getting a better standardization, we have decided to change our calibration process for **HbA1c**, **A1c\_H** and **A1c\_WB** applications on the PC200, P400 and PC400.

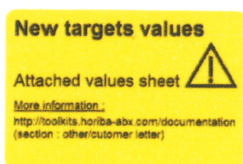
**IMPACT:**

From lot no. **1704201** of HbA1c WB Cal (ref: A11A01703) the target values of the six levels will not be fixed anymore but **will become dependent of the lot number** as others chemistry tests.

**ACTION/RESOLUTION:**

Calibrator target values will be linked to the lot number, a value sheet will be included in the box and will be available in our documentation website: <http://toolkits.horiba-abx.com/documentation>.

A sticker on the first lots of HbA1c WB Cal kit will inform about this change:



The calibrator notice is modified: no more fixed target values mentioned. This new version of the notice is available online: <http://toolkits.horiba-abx.com/documentation> (Section Clinical Chemistry/02 calibrator notices).

Please find hereunder an example of the screen where to register these targets values in the software:

**P400/PC400**  
**A1c-WB**

Calibration | Contrôle

Nom: HbA1c CAL      Lot n°: 123456      Date d'expiration: 01/01/2018

**Entrée des valeurs cibles**

Test	Numéro	Unité
A1c-WB	53	µmol/L

Standard principal: \_\_\_\_\_

Niveau 1: \_\_\_\_\_      Niveau 5: \_\_\_\_\_

Niveau 2: \_\_\_\_\_      Niveau 6: \_\_\_\_\_

Niveau 3: \_\_\_\_\_      Niveau 7: \_\_\_\_\_

Niveau 4: \_\_\_\_\_      Niveau 8: \_\_\_\_\_

Standard de correction: 1

**A1c-H**

Calibration | Contrôle

Nom: HbA1c CAL      Lot n°: 123456      Date d'expiration: 01/01/2018

**Entrée des valeurs cibles**

Test	Numéro	Unité
A1c-H	54	µmol/L

Standard principal: \_\_\_\_\_

Niveau 1: \_\_\_\_\_      Niveau 5: \_\_\_\_\_

Niveau 2: \_\_\_\_\_      Niveau 6: \_\_\_\_\_

Niveau 3: \_\_\_\_\_      Niveau 7: \_\_\_\_\_

Niveau 4: \_\_\_\_\_      Niveau 8: \_\_\_\_\_

Standard de correction: 1

**PC200  
HBA1**

The screenshot shows the 'START-UP' screen of the PC200 HBA1 software. At the top, there are navigation buttons for 'Calibration', 'QC Setting', 'QC Registration', 'Reg SerialDilut', and 'Cal Regist'. Below this, the 'Method' is set to '44' and 'Name' is 'HBA1'. The 'Sample' is 'Common' and 'Unit' is 'umol/l'. 'Replicate' is 'Single' and 'Stability' is '14 Days'. 'Mode' is 'Linear Interpolatio' and 'Lot' is 'New'. A table for 'Cal Name' has columns for 'Conc', 'ATUAL', 'MASTER', 'Lot #', and 'All', with rows S1 through S7. To the right, there is a graph area for 'DeltaOD' with 'Master' and 'Actual' lines. Below the graph are fields for 'Reagent blank', 'Blank', 'Type', and 'Absorbance'.

**RECOMMENDATIONS:**

Please share this information with your laboratory staff, and retain this notification as part of your Quality System documentation.

If you have any questions regarding this Field Information, please contact your local HORIBA's Medical representative.

This information has been transmitted to ANSM, French regulatory organization. Please check if the local regulatory entity needs to be informed as well.

Thank you for your continued support to HORIBA's Medical products.

Yours sincerely,

*Georges FERRANDI*  
Corporate Marketing Manager