

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.

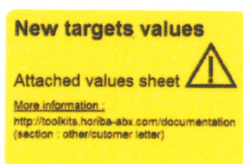
IMPACT:

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**

START-UP

Calibration | QC Setting | QC Registration | Reg SerialDilut | Cal Regist

Method	44	Name	HBA1
Sample	Common	Unit	umol/l
Replicate	Single		
Stability	14 Days		
Mode	Linear Interpolatio	Lot	New

R Lot # (R1) _____ Last _____
 (R2) _____

DeltaOD

Master Actual

Cal Name	Conc	ATUAL	MASTER	Lot #	All
S1					
S2					
S3					
S4					
S5					
S6					
S7					

Reagent blank DeltaOD Last _____
 Blank DeltaOD Last _____
 Type Conc _____
 Absorbance DeltaOD Recalculation _____

Save Cancel **Print**

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