

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.

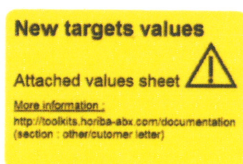
IMPACT:

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

READY

Calibration | Contrôle

Nom: H8a1c 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

READY

Calibration | Contrôle

Nom: H8a1c 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

Cal Name: _____

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

R Lot # (R1) _____ Last _____

(R2) _____

DeltaOD

Master Actual

Reagent blank: DeltaOD Last _____

Blank: DeltaOD Last _____

Type: _____ Conc: _____

Absorbance: DeltaOD Recalculation

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