

sebia

**CALIBRATEURS Hb A1c CAPILLAIRE
Hb A1c CAPILLARY CALIBRATORS**

Ref. 4755

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IVD

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Hb A1c CAPILLARY CALIBRATORS

Intended use

The Hb A1c CAPILLARY Calibrators are designed for the calibration and migration control of human glycated hemoglobin A_{1c} quantification with SEBIA capillary electrophoresis procedures :

- CAPILLARYS Hb A1c performed with the CAPILLARYS 2 FLEX-PIERCING automated instrument,
- CAPI 3 Hb A1c performed with the CAPILLARYS 3 automated instrument and,
- MINICAP Hb A1c performed with the MINICAP FLEX-PIERCING automated instrument.

They allow achieving results in patient blood samples that are comparable to the DCCT study (1, 2) and traceable to the IFCC reference system (3, 4).

The Hb A1c CAPILLARY Calibrators are designed for laboratory use. They should be used like human bloods.

WARNING : The calibrators are specific for the CAPILLARYS, CAPI 3 and MINICAP Hb A1c procedures.

For *In Vitro* Diagnostic Use.

Reagent and composition

Hb A1c CAPILLARY Calibrators 1 and 2 are obtained from pools of human blood samples. They contain stabilizers and preservatives to maintain the stability of the hemoglobin fractions. The calibrators are in a stabilized lyophilized form.

Hb A1c CAPILLARY Calibrator 1 presents a normal HbA_{1c} level and Hb A1c CAPILLARY Calibrator 2 presents an elevated HbA_{1c} level (see the "HbA_{1c} concentrations" table for further information).

Hb A1c calibrators values are traceable to the international IFCC reference procedure (which corresponds to the highest order in the hierarchy of metrological traceability).

Storage and stability

CAPILLARYS Hb A1c procedure with the CAPILLARYS 2 FLEX-PIERCING instrument

- Before reconstitution, store the lyophilized calibrators between - 18 °C and - 30 °C. They are stable until the expiration date indicated on the vial labels.

WARNING : Do not store lyophilized calibrators refrigerated (2 - 8 °C).

- After reconstitution, store the calibrators at 2 - 8 °C in a closed conical tube for control blood and use them within the day (for 8 hours maximum). After use, they must be stored without any delay between - 18 °C and - 30 °C due to the risk of microbial contamination and denaturation. They are stable for 22 months maximum between - 18 °C and - 30 °C.
- After storage between - 18 °C and - 30 °C and before use, thaw the reconstituted calibrators at 2 - 8 °C for at least 30 minutes before the analysis with the CAPILLARYS 2 FLEX-PIERCING instrument. Homogenize calibrators before each use. Store the thawed calibrators at 2 - 8 °C and use them within the day (for 8 hours maximum). After use, store them between - 18 °C and - 30 °C without any delay. Do not freeze and thaw the reconstituted calibrators more than 3 times (due to the reconstitution volume of each calibrator, one vial allows the preparation of 4 dilution segments).
- A dilution segment with hemolyzed calibrator is stable for 10 minutes maximum at 2 - 8 °C or at room temperature (15 - 30 °C) : when calibrating the instrument, this dilution segment can be re-used only once and must immediately be re-analyzed just after it is ejected from CAPILLARYS 2 FLEX-PIERCING. Do not store the dilution segment for more than 10 minutes [neither at room temperature (15 - 30 °C), nor at 2 - 8 °C].

CAPI 3 Hb A1c procedure with the CAPILLARYS 3 instrument

- Before reconstitution, store the lyophilized calibrators between - 18 °C and - 30 °C. They are stable until the expiration date indicated on the vial labels.

WARNING : Do not store lyophilized calibrators refrigerated (2 - 8 °C).

- After reconstitution, store the aliquoted calibrators at 2 - 8 °C in a closed conical tube for control blood and use them within the day (for 8 hours maximum). After use, they must be stored without any delay between - 18 °C and - 30 °C due to the risk of microbial contamination and denaturation. They are stable for 22 months maximum between - 18 °C and - 30 °C.

- After storage between - 18 °C and - 30 °C and before use, thaw the reconstituted calibrators at 2 - 8 °C for at least 30 minutes before the analysis with the CAPILLARYS 3 instrument. Homogenize calibrators before each use. Store the thawed calibrators at 2 - 8 °C and use them within the day (for 8 hours maximum). After use, store them between - 18 °C and - 30 °C without any delay. Do not freeze and thaw the reconstituted calibrators more than twice (due to the reconstitution volume of each calibrator, one vial allows the preparation of 3 reagent cups, each cup allows to perform 3 analysis sequences).

MINICAP Hb A1c procedure with the MINICAP FLEX-PIERCING instrument

- Before reconstitution, store the lyophilized calibrators between - 18 °C and - 30 °C. They are stable until the expiration date indicated on the vial labels.

WARNING : Do not store lyophilized calibrators refrigerated (2 - 8 °C).

- After reconstitution, prepare 2 aliquots with equivalent volumes (\approx 0.4 mL) of the whole amount of each calibrator in conical tubes for control blood, for use and / or storage. Store the aliquoted calibrators at 2 - 8 °C in a closed conical tube for control blood and use them within the day (for 8 hours maximum). After use, they must be stored without any delay between - 18 °C and - 30 °C due to the risk of microbial contamination and denaturation. They are stable for 22 months maximum between - 18 °C and - 30 °C.
- After storage between - 18 °C and - 30 °C and before use, thaw the reconstituted calibrators at 2 - 8 °C for at least 30 minutes before the analysis with the MINICAP FLEX-PIERCING instrument. Homogenize calibrators before each use. Store the thawed calibrators at 2 - 8 °C and use them within the day (for 8 hours maximum). After use, store them between - 18 °C and - 30 °C without any delay. Do not freeze and thaw the reconstituted calibrators more than 5 times (due to the reconstitution volume of each calibrator, one aliquot allows the preparation of 6 reagent cups, each cup allows to perform 3 analysis sequences).

NOTE : During transportation, the lyophilized calibrators can be kept refrigerated (between 2 to 8 °C maximum) for 1 month without any adverse effects on performance.

Procedure

Reconstitute each lyophilized calibrator vial with 0.6 mL of distilled or deionized water. Mix gently the calibrator vial to dissolve the whole lyophilized blood, ensure that no liquid contacts the cap (do not turn the vial upside down, see figure "Calibrators reconstitution"). Allow to stand for 30 minutes at 2 - 8 °C and mix gently (avoid formation of foam).

NOTE : The precision of the reconstitution volume to be maintained is \pm 1.0 %.

IMPORTANT : It is necessary to identify each conical tube for control with the specific bar code label provided with the calibrator to analyze (close the tube with its cap before using it). To ensure a proper readability of the bar code, the label must be stuck on the capped tube.

For CAPILLARYS Hb A1c and CAPI 3 Hb A1c :

For each calibrator :

- take a new conical tube for control and close it with its cap,
- stick the bar code label of the calibrator on the capped tube,
- remove the cap by holding it in the axis of the tube,
- place the entire reconstituted calibrator into the tube,
- reclose the tube with its cap.

For MINICAP Hb A1c :

For each calibrator :

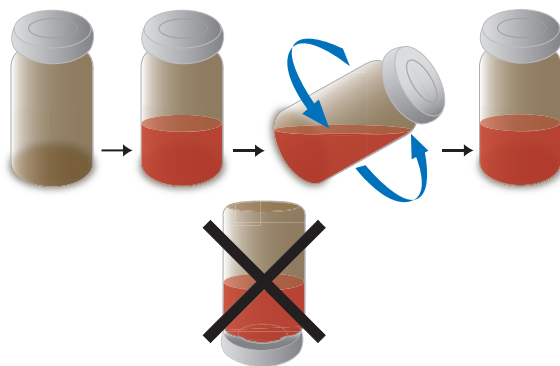
- take 2 new conical tubes for control and close them with their caps,
- stick a bar code label of the calibrator on each capped tube,
- remove the caps by holding them in the axis of the tube,
- prepare 2 aliquots with equivalent volumes (\approx 0.4 mL) of the entire reconstituted calibrator and place each aliquot into one tube,
- reclose each tube with its cap.

See the instructions for use of the CAPILLARYS, CAPI 3 and MINICAP Hb A1c kits. Before the analysis, enter or check in the window which appears on the screen, the parameters of both analyzed calibrators, indicated in the instructions for use of the Hb A1c CAPILLARY CALIBRATORS : HbA_{1c} concentration in mmol/mol, lot number and expiration date.

WARNING :

- Please check that the LOT NUMBERS of the calibrators (indicated on each vial) are identical as the ones currently used with the instrument.
If not, perform 3 successive calibrations with the new lots and re-determine customized values for controls with the instrument.
The lots of calibrator vials must never be separated.
- No test method can provide an absolute assurance of the absence of HIV, hepatitis B and C or other infectious agents. Therefore, handle the calibrators as a hazardous biological material.
These lots of bloods were found negative on assays approved by FDA or EU equivalent regulatory agency:
 - against hepatitis B surface antigen ;
 - for antibody to HCV ;
 - for antibody to HIV1 and HIV2.

CALIBRATORS RECONSTITUTION



HbA_{1c} CONCENTRATIONS

Assigned values have been established with the DCCT Reference Method and the IFCC Reference System for HbA_{1c}.

HbA_{1c} concentration is indicated in IFCC unit (mmol/mol).

NOTE :

- The HbA_{1c} concentrations are indicated in the package insert provided with the calibrator vials.
- The values and / or the electrophoretic patterns are applicable whatever the reagent lot or the concerned instrument.

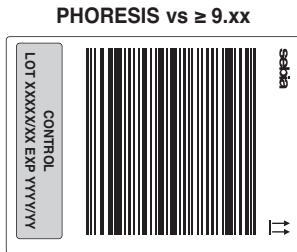
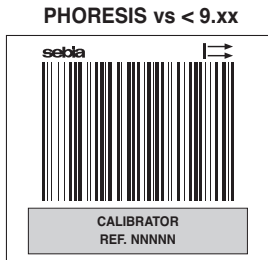
Étiquettes codes-barres : utilisation selon la version du logiciel PHORESIS*

Bar code labels : Utilization according to the PHORESIS version*

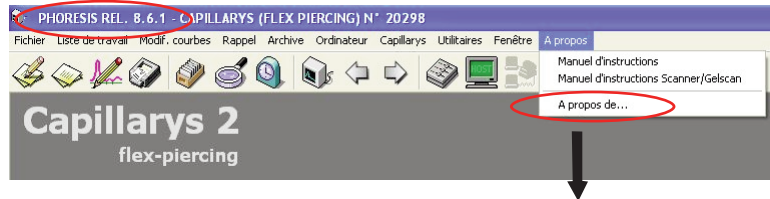
ATTENTION : 2 types d'étiquettes codes-barres sont fournis avec le flacon. Utiliser l'étiquette qui correspond à la version du logiciel PHORESIS (versions 9.0 et supérieures ou versions inférieures à 9.0).

WARNING : 2 types of bar code labels are provided with the vial. Use the label that corresponds to the PHORESIS software version (versions 9.0 and higher or versions lower than 9.0).

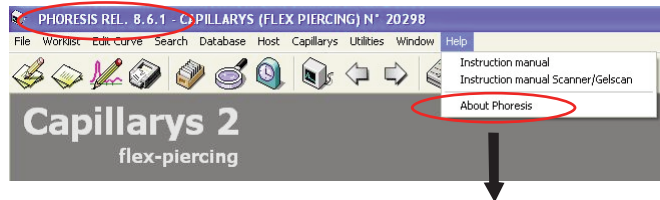
Étiquette code-barres
Bar code label



* La version du logiciel PHORESIS est indiquée dans la partie supérieure gauche de l'écran ou dans la fenêtre "A propos de..." du menu logiciel :



* The PHORESIS version is provided in the left upper part of the screen or in the window "About Phoresis" from the Help menu :



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