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CONTRÔLES Hb A1c CAPILLAIRE MULTI-SYSTÈMES (10x2)
MULTI-SYSTEM Hb A1c CAPILLARY CONTROLS (10x2)

Ref. 4767

CONTRÔLES Hb A1c CAPILLAIRE MULTI-SYSTÈMES (2)
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2019/12

MULTI-SYSTEM Hb A1c CAPILLARY CONTROLS (2)

Intended use

The Multi-System Hb A1c CAPILLARY Controls (2) are designed for the migration control and quality 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.

The Hb A1c CAPILLARY Controls are designed for laboratory use. They should be used like human bloods. The values obtained must fall within the range determined for each batch.

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

For *In Vitro* Diagnostic Use.

Reagent and composition

Hb A1c CAPILLARY Controls 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 controls are in a stabilized lyophilized form.

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

Storage and stability

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

- Before reconstitution, store the lyophilized controls refrigerated (2 to 8 °C). They are stable until the expiration date indicated on the vial labels.
- After reconstitution, store the controls at 2 - 8 °C in a closed conical tube for control blood and use them within the day (for 24 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 6 months maximum between - 18 °C and - 30 °C.
- Before use, thaw completely the reconstituted controls at 2 - 8 °C for at least 45 minutes before the analysis and use them within the day (for 8 hours maximum). Before each use, check the controls are completely thawed (without any ice) and homogenize them. After use, store them between - 18 °C and - 30 °C without any delay. Do not freeze and thaw the reconstituted controls more than 30 times.
- Do not leave the reconstituted controls at room temperature.
- After hemolysis with the CAPILLARYS 2 FLEX-PIERCING instrument, store the dilution segments with controls at 2 - 8 °C and use them within the day (for 8 hours maximum). They may be stored, without any delay, between - 18 °C and - 30 °C for 1 month maximum. Do not freeze and thaw a dilution segment with hemolyzed control more than three times.
- Before use, ensure that the frozen dilution segments containing the hemolyzed controls are completely thawed by placing them at room temperature (15 – 30 °C) for 20 to 30 minutes. Once the control segments are completely thawed (without any ice), it is important to homogenize (mix) each well repeatedly using a pipette prior to the analysis.

NOTE : It is recommended to store dilution segments with hemolyzed Hb A1c CAPILLARY Controls 1 and 2 in boxes for controls storage (see § "EQUIPMENT AND ACCESSORIES REQUIRED" in the package insert of CAPILLARYS Hb A1c kit). In that case, use imperatively one box for controls storage for storage in freezer between - 18 °C and - 30 °C and one box for thawing.

CAPI 3 Hb A1c procedure with the CAPILLARYS 3 instrument and MINICAP Hb A1c procedure with the MINICAP FLEX-PIERCING instrument

- Before reconstitution, store the lyophilized controls refrigerated (2 to 8 °C). They are stable until the expiration date indicated on the vial labels.
- After reconstitution, store the controls at 2 - 8 °C in a closed conical tube for control blood and use them within the day (for 24 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 6 months maximum between - 18 °C and - 30 °C.
- Before use, thaw completely the reconstituted controls at 2 - 8 °C for at least 45 minutes before the analysis and use them within the day (for 8 hours maximum). Before each use, check the controls are completely thawed (without any ice) and homogenize them. After use, store them between - 18 °C and - 30 °C without any delay. Do not freeze and thaw the reconstituted controls more than 30 times.
- Do not leave the reconstituted controls at room temperature.

NOTE : During transportation, the lyophilized controls can be kept without refrigeration (15 to 30 °C maximum) for 15 days without any adverse effects on performance.

Procedure

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

- Reconstitute each lyophilized control vial with distilled or deionized water. Allow to stand for 30 minutes and mix gently (avoid formation of foam).

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

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

Determination of customized values for Hb A1c CAPILLARY Controls with the CAPILLARYS 2 FLEX-PIERCING instrument

Each laboratory must establish values for Hb A1c CAPILLARY Controls 1 and 2 that are specific for each CAPILLARYS 2 FLEX-PIERCING automated instrument according to the following procedure.

WARNING : The determination of controls values must always be performed after the first calibration of the CAPILLARYS 2 FLEX-PIERCING instrument, after having changed one or many capillaries and after having changed the lot number of calibrators and controls.

- Place each tube with the control (identified with its specific bar code label) on a wedge adapter for the blood control tubes, in position No. 1 on a CAPILLARYS 2 FLEX-PIERCING sample rack No. F0 intended for blood control samples, containing a new dilution segment.

  NOTE : In order to avoid any confusion, it is recommended to use a white dilution segment for Hb A1c CAPILLARY Control 1 and a grey dilution segment for Hb A1c CAPILLARY Control 2.

- Start the analysis : Slide the sample rack into the CAPILLARYS 2 FLEX-PIERCING instrument.
- The results are then automatically considered by the software for the data analysis.
- Calculate the mean values of HbA_{1c} percentages for both controls. Check that they fall within the ranges provided with each lot of control (see the table "HbA_{1c} percentages") and that the coefficients of variation are equal to or less than 2 % OR that the difference between the minimal value and the maximal value of HbA_{1c} percentage for each control is ≤ 0.3 point for control level 1 and ≤ 0.6 point for control level 2.
- If not, analyze again the dilution segment with the corresponding control, previously diluted during the first series : place an empty tube for control identified with the bar code label and slide again the rack with the dilution segment into the CAPILLARYS 2 FLEX-PIERCING instrument. In the window called "Hb A1c Control" which appears on the screen, select "Manual dilution" and validate.
- If the mean values of HbA_{1c} percentages do not still fall within the ranges provided with each lot and / or,

- if the coefficients of variation are higher than 2 % and / or,
- if the difference between the minimal value and the maximal value of HbA_{1c} percentage for each control is higher than 0.3 point for control level 1 AND / OR higher than 0.6 point for control level 2,
  calibrate again the instrument with the Hb A1c CAPILLARY Calibrators (See the package insert of CAPILLARYS Hb A1c kit). Call SEBIA Technical Service when the test fails to perform.
- To establish customized values of each control for each CAPILLARYS 2 FLEX-PIERCING automated instrument, calculate the mean HbA_{1c} percentages (%) and the mean HbA_{1c} concentrations (mmol/mol). The ranges to apply for quality controls are the following :
  For Hb A1c CAPILLARY Control 1 : mean HbA_{1c} % ± 0.3 or mean HbA_{1c} concentration (in mmol/mol) ± 3.
  For Hb A1c CAPILLARY Control 2 : mean HbA_{1c} % ± 0.4 or mean HbA_{1c} concentration (in mmol/mol) ± 4.

Determination of customized values for Hb A1c CAPILLARY Controls with the CAPILLARYS 3 instrument

Each laboratory must establish values for Hb A1c CAPILLARY Controls 1 and 2 that are specific for each CAPILLARYS 3 automated instrument according to the following procedure.

WARNING : The determination of controls values must always be performed after the first calibration of the CAPILLARYS 3 instrument, after having changed one or many capillaries and after having changed the lot number of calibrators and controls.

- Place each tube with the control (identified with its specific bar code label) in position No. 1 on a CAPILLARYS 3 sample rack No. 0 intended for blood control samples.
- Start the analysis : Slide the sample rack into the CAPILLARYS 3 instrument.
- The results are then automatically considered by the software for the data analysis.
- Calculate the mean values of HbA_{1c} percentages for both controls. Check that they fall within the ranges provided with each lot of control (see the table "HbA_{1c} percentages") and that the coefficients of variation are equal to or less than 2 % OR that the difference between the minimal value and the maximal value of HbA_{1c} percentage for each control is ≤ 0.3 point for control level 1 and ≤ 0.6 point for control level 2.
- If not, analyze again the concerned control : place the tube identified with the bar code label in position No. 1 on the sample rack No. 0 intended for blood control samples and slide again the rack into the CAPILLARYS 3 instrument.
- If the mean values of HbA_{1c} percentages do not still fall within the ranges provided with each lot and / or,
- if the coefficients of variation are higher than 2 % and / or,
- if the difference between the minimal value and the maximal value of HbA_{1c} percentage for each control is higher than 0.3 point for control level 1 AND / OR higher than 0.6 point for control level 2, calibrate again the instrument with the Hb A1c CAPILLARY Calibrators (See the package insert of CAPI 3 Hb A1c kit). Call SEBIA Technical Service when the test fails to perform.
- To establish customized values of each control for each CAPILLARYS 3 automated instrument, calculate the mean HbA_{1c} percentages (%) and the mean HbA_{1c} concentrations (mmol/mol). The ranges to apply for quality controls are the following :
  For Hb A1c CAPILLARY Control 1 : mean HbA_{1c} % ± 0.3 or mean HbA_{1c} concentration (in mmol/mol) ± 3.
  For Hb A1c CAPILLARY Control 2 : mean HbA_{1c} % ± 0.4 or mean HbA_{1c} concentration (in mmol/mol) ± 4.

Determination of customized values for Hb A1c CAPILLARY Controls with the MINICAP FLEX-PIERCING instrument

Each laboratory must establish values for Hb A1c CAPILLARY Controls 1 and 2 that are specific for each MINICAP FLEX-PIERCING automated instrument according to the following procedure.

WARNING : The determination of controls values must always be performed after the first calibration of the MINICAP FLEX-PIERCING instrument, after having changed one or both capillaries and after having changed the lot number of calibrators and controls.

- The analysis of each control must be performed according to the same procedure as described below. It is recommended to analyze both controls within the same working day.
- For each control, place the tube (identified with the corresponding bar code label), **in position No. 28** on a MINICAP FLEX-PIERCING rotating sampler ("Control" position with centering ring).
- **Do not place any sample tube in positions 1 to 26 of the rotating sampler.**
- Pour 5 mL of MINICAP Hb A1c hemolysing solution in a hemolysing tube (identified with the hemolysing solution bar code label) without introducing air bubbles and place it in position No. 27 on the rotating sampler ("Diluent / Solution" position without any centering ring) (A message will be displayed if the tube or the hemolysing solution is missing).

IMPORTANT : Ensure the absence of foam in the tube before placing it on the rotating sampler.

- Slide the rotating sampler into the MINICAP FLEX-PIERCING instrument.
- Close the doors of the MINICAP FLEX-PIERCING instrument, the analysis starts automatically.
- In the window which appears on the screen, select 3 analyses of the Hb A1c CAPILLARY Control to perform and validate.
- The results are then automatically considered by the software for the data analysis.
- Remove the tube with control from position 28 as soon as the window appears indicating to remove the tube.
- Perform the analysis of the second control according to the same procedure.

WARNING : After having closed the doors of the instrument, <u>when the analysis of the second control is performed within the same day than that of the first control,</u>

- ***Wait until the instrument has checked the absence of tube in position No. 1,***
- ***Click on the flashing button to open the "Information messages" window indicating the absence of tube in position No. 1,***
- ***Close the "Information messages" window,***
- ***Start the analysis using the "Click to run the control in position 28" button.***

- Calculate the mean values of HbA_{1c} percentages for both controls. Check that they fall within the ranges provided with each lot of control (see the table "HbA_{1c} percentages") and that the coefficients of variation are equal to or less than 2 % OR that the difference between the minimal value and the maximal value of HbA_{1c} percentage for each control is ≤ 0.3 point for control level 1 and ≤ 0.6 point for control level 2.
- If not, analyze again the concerned control.
- If the mean values of HbA_{1c} percentages do not still fall within the ranges provided with each lot and / or,
- if the coefficients of variation are higher than 2 % and / or,
- if the difference between the minimal value and the maximal value of HbA_{1c} percentage for each control is higher than 0.3 point for control level 1 AND / OR higher than 0.6 point for control level 2,
  calibrate again the instrument with the Hb A1c CAPILLARY Calibrators (See the package insert of MINICAP Hb A1c kit). Call SEBIA Technical Service when the test fails to perform.
- To establish customized values of each control for each MINICAP FLEX-PIERCING automated instrument, calculate the mean HbA_{1c} percentages (%) and the mean HbA_{1c} concentrations (mmol/mol). The ranges to apply for quality controls are the following :
  <u>For Hb A1c CAPILLARY Control 1</u> : mean HbA_{1c} % ± 0.3 or mean HbA_{1c} concentration (in mmol/mol) ± 3.
  <u>For Hb A1c CAPILLARY Control 2</u> : mean HbA_{1c} % ± 0.4 or mean HbA_{1c} concentration (in mmol/mol) ± 4.

<u>Quality control</u> :

See the package inserts of CAPILLARYS, CAPI 3 and MINICAP Hb A1c kits.

NOTE : Enter the customized values of controls in concentration (mmol/mol) AND in percentage (cal %) in the tables for control values for each new lot of control for quality controls management.

WARNING :

- Please check that the LOT NUMBERS of the controls (indicated on each vial) are identical as the ones currently used with the instrument.
  If not, determine customized values for the instrument with the new lots.
  The lots of control 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 controls 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.

NOTES :

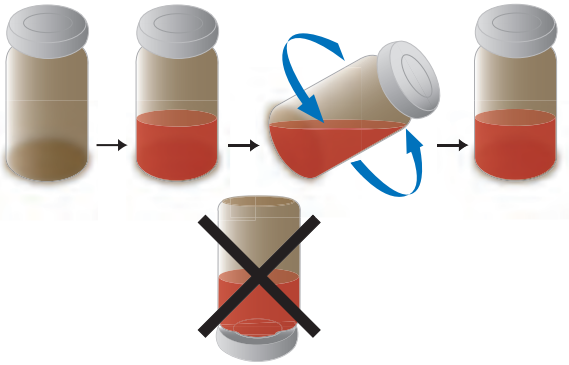
- *The expected values are indicated in the package insert provided with the control vials.*
- *The values and / or the electrophoretic patterns are applicable whatever the reagent lot or the concerned instrument.*

Volumes de reconstitution avec eau distillée ou déminéralisée
Volumes of reconstitution with distilled or deionized water

CAPILLARYS 2 FLEX-PIERCING instrument CAPILLARYS Hb A1c.....	0.6 mL
CAPILLARYS 3 OCTA & CAPILLARYS 3 TERA instruments CAPI 3 Hb A1c	0.75 mL
MINICAP FLEX-PIERCING instrument MINICAP Hb A1c.....	0.75 mL

NOTE : La précision du volume de reconstitution à respecter est de ± 1,0 %.
NOTE: The precision of the reconstitution volume to be maintained is ± 1.0 %.

Reconstitution des contrôles
Controls reconstitution



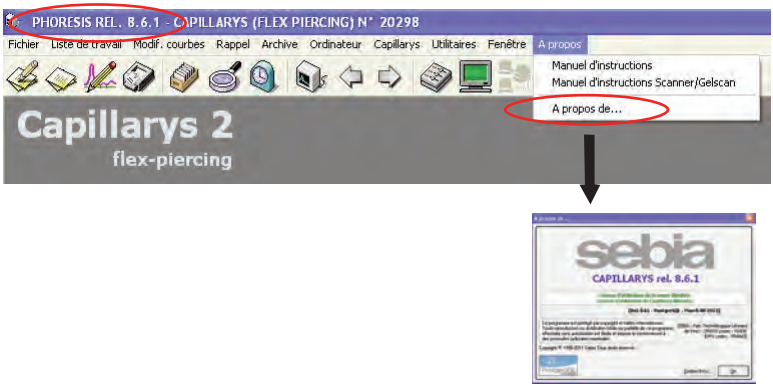
Étiquettes codes-barres : utilisation selon la version du logiciel PHORESIS*
Bar code labels : Utilization according to the PHORESIS version*

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).

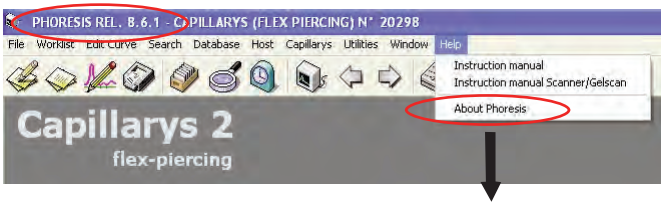
WARNING : 2 types of bar code labels are provided with the vial. Use the label that corresponds to the PHORESIS software version (versions 9.0 and higher or versions lower than 9.0).

	PHORESIS vs < 9.xx	PHORESIS vs ≥ 9.xx
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 correspondant :*



** 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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2018/09