CONTRÔLES Hb A1c CAPILLAIRE
Hb A1c CAPILLARY CONTROLS

Ref. 4774
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Intended use
The Hb A1c CAPILLARY Controls are designed for the quality control of human glycated hemoglobin A\textsubscript{1c} quantification with CAPILLARYS Hb A1c electrophoresis procedure performed with the CAPILLARYS 2 FLEX-PIERCING automated instrument for capillary electrophoresis. The Hb A1c CAPILLARY Controls are designed for Professional Use Only.

\textbf{WARNING} : The controls are specific for the CAPILLARYS Hb A1c procedure. They must not be used in any way for procedures on agarose gels and vice versa.

For \textit{In Vitro} 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\textsubscript{1c} level and Hb A1c CAPILLARY Control 2 presents an elevated HbA\textsubscript{1c} level (see the "HbA\textsubscript{1c} percentages" table for further information).

Storage and stability
- 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 8 hours maximum). After use, they must be stored without any delay between - 18 °C and - 22 °C due to the risk of microbial contamination and denaturation. They are stable for 6 months maximum between - 18 °C and - 22 °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 - 22 °C without any delay. Do not freeze and thaw the reconstituted controls more than 30 times.
- 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 - 22 °C for 1 month maximum. Do not freeze and thaw a dilution segment with hemolyzed control more than three times.
- Do not leave neither reconstituted controls nor dilution segments with a hemolyzed control at room temperature.
- Before use, thaw completely the frozen dilution segments with the hemolyzed controls at 2 - 8 °C for at least 45 minutes before the analysis. Check the controls are completely thawed (without any ice) and homogenize each well of thawed dilution segments by repeated pipettings.

\textbf{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 - 22 °C and one box for thawing at 2 - 8 °C.

\textbf{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
\textbf{IMPORTANT} : For optimal use of each Hb A1c CAPILLARY Control, it is necessary to use one bar code label intended to identify the tube for control which contains the analyzed blood control (close the tube with its specific cap before using it).
Reconstitute each lyophilized control vial with 0.6 mL of distilled or deionized water. Allow to stand for 30 minutes and mix gently (avoid formation of foam).

\textbf{NOTE} : The precision of the reconstitution volume to be maintained is ± 1.0 %.
Apply each reconstituted control in a tube designed for blood control and close the tube with its cap.
**Determination of customized values for Hb A1c CAPILLARY Controls:**
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 HbA1c percentages for both controls. Check that they fall within the ranges provided with each lot of control (see the table "HbA1c percentages") and that the coefficients of variation are equal to or less than 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 HbA1c percentages do not fall yet within the range provided with each lot and/or if the coefficients of variation are higher than 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 HbA1c percentages (%) and the mean HbA1c concentrations (mmol/mol). The ranges to apply for quality controls are the following:
  
  **For Hb A1c CAPILLARY Control 1:** mean HbA1c % ± 0.3 or mean HbA1c concentration (in mmol/mol) ± 3.
  **For Hb A1c CAPILLARY Control 2:** mean HbA1c % ± 0.4 or mean HbA1c concentration (in mmol/mol) ± 4.

**Quality control:**
See the package insert of CAPILLARYS Hb A1c kit.

**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.

**NOTE:** The expected values are indicated in the package insert provided with the control vials.