

**sebia**

**CONTRÔLE Hb AF  
Hb AF CONTROL**

Ref. 4777

IVD

CE

R<sub>x</sub>only

2020/07

## Hb AF CONTROL

### Intended use

The Hb AF Control is designed for the migration control before starting a new analysis sequence and for the qualitative quality control for human hemoglobins A and F, with the SEBIA electrophoresis procedures :

- CAPILLARYS NEONAT Hb used with the CAPILLARYS 2 and CAPILLARYS 2 NEONAT FAST instruments and,
- CAPILLARYS CORD BLOOD used with the CAPILLARYS 2 and CAPILLARYS 2 FLEX-PIERCING instruments.

The Hb AF Control is designed for laboratory use. It should be used, with its bar code label for the CAPILLARYS CORD BLOOD and NEONAT Hb procedures, like a normal human blood.

The values obtained must fall within the range provided with each batch of Hb AF Control (that are given as informative values only).

For *In Vitro* Diagnostic Use.

### Reagent and composition

The Hb AF Control is obtained from a pool of normal blood samples from human adults and from new-borns umbilical cord blood samples (see "Expected values" for further information). It contains stabilizers and preservatives (including chloramphenicol at a concentration no greater than 0.1 %) to maintain the stability of the hemoglobin fractions.

The Hb AF Control is in a stabilized lyophilized form.

### Storage and stability

Before reconstitution, store the lyophilized Hb AF Control refrigerated (2 to 8 °C). It is stable until the expiration date indicated on the box or vial labels.

After reconstitution, store the Hb AF Control at 2 – 8 °C and use it :

- within the day with the CORD BLOOD procedure,
- within 5 days maximum with the NEONAT Hb procedure.

For a prolonged storage, the reconstituted Hb AF Control must be frozen in aliquots and stored between - 18 °C and - 30 °C for 6 months maximum.

**IMPORTANT :** After storage at 2 - 8 °C or between - 18 °C and - 30 °C, homogenize the reconstituted Hb AF Control prior to use.

*NOTE : It is recommended to split the Control into aliquots in microtubes (for the analysis with CAPILLARYS 2) or in conical tubes for controls (for the analysis with CAPILLARYS 2 FLEX-PIERCING) before freezing it.*

Before use, store the thawed Hb AF Control at 2 - 8 °C and use it within the day, after homogenization. Do not freeze and thaw the Control more than 7 times.

The hemolyzed Hb AF Control should be stored at 2 - 8 °C and used within 1 hour after dilution with the instrument.

### IMPORTANT :

- Do not leave the dilution segment with the hemolyzed Control at room temperature.
- For the CAPILLARYS NEONAT Hb procedure, do not freeze the dilution segment with the hemolyzed Hb AF Control.
- For the CAPILLARYS CORD BLOOD procedure, the dilution segment containing the hemolysed Hb AF Control may be frozen and stored between - 18 °C and - 30 °C. Do not freeze and thaw the dilution segment with hemolysed Control more than three times. For optimal storage of the hemolyzed control at 2 - 8 °C or at - 18 / - 30 °C, it is recommended to protect the content of the dilution segment with an adhesive paper placed on the wells (remove the adhesive paper before using the dilution segment). Before use, thaw the frozen dilution segment with the hemolyzed control at 2 - 8 °C for at least 30 minutes before the analysis. Homogenize each well of the dilution segment, thawed or stored at 2 - 8 °C, by repeated pipettings, avoiding formation of air bubbles. Do not vortex the dilution segment.

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

## Procedure

### CAPILLARYS CORD BLOOD procedure used with the CAPILLARYS 2 and CAPILLARYS 2 FLEX-PIERCING instruments

Reconstitute the Hb AF 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  $\pm 1.0$  %.*

Collect the total amount of the reconstituted control.

After reconstitution, use directly the Hb AF Control as a blood sample to analyze or as a migration control. It will be automatically diluted with hemolysing solution.

*See the package insert of CAPILLARYS HEMOGLOBIN(E) kit, CAPILLARYS CORD BLOOD procedure.*

### CAPILLARYS NEONAT Hb procedure used with the CAPILLARYS 2 and CAPILLARYS 2 NEONAT FAST instruments

Reconstitute the Hb AF 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  $\pm 1.0$  %.*

Collect the total amount of the reconstituted control.

*See the package insert of CAPILLARYS NEONAT Hb kit.*

*NOTE : For optimal use of the Hb AF Control with the instrument, it is recommended to split the Control into aliquots in microtubes before freezing (see the paragraph "Storage and stability").*

**IMPORTANT :** For optimal use of the Hb AF Control, it is necessary to use one bar code label intended to identify the hemolysing tube holding the microtube which contains the Hb AF Control (cut the cap of the microtube before using it).

It is recommended to include one analysis of Hb AF Control into each run.

**WARNING :** No test method can provide an absolute assurance of the absence of HIV, hepatitis B and C or other infectious agents. Therefore, handle the Hb AF Control as a hazardous biological material.

This lot of control was 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.

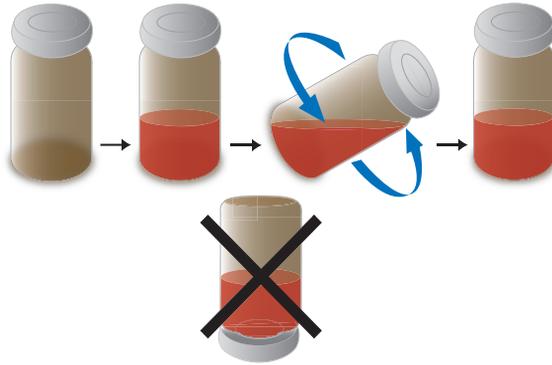
#### NOTES :

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

## Expected values (percentages)

The levels have been determined using replicate analyses using SEBIA electrophoresis procedures and are specific for this lot of control.

## CONTROL RECONSTITUTION



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

<b><u>CAPILLARYS 2 &amp; CAPILLARYS 2 NEONAT FAST instruments</u></b> CAPILLARYS NEONAT Hb .....	1.0 mL
<b><u>CAPILLARYS 2 instrument</u></b> CAPILLARYS SANGS DE CORDONS / CORD BLOOD* .....	0.4 mL
<b><u>CAPILLARYS 2 FLEX-PIERCING instrument</u></b> CAPILLARYS SANGS DE CORDONS / CORD BLOOD* .....	0.5 mL

(\*) Not yet FDA cleared for US market.

NOTE : La précision du volume de reconstitution à respecter est de  $\pm 1,0$  %.

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



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