CONTRÔLE Hb A2 NORMAL
NORMAL Hb A2 CONTROL

Ref. 4778
NORMAL Hb A2 CONTROL

Intended use
The Normal Hb A2 Control is designed:
- for the migration control of the human hemoglobin pattern and,
- for the quantitative quality control for human hemoglobins A and A2,
with the SEBIA electrophoresis procedures: HYDRAGEL HEMOGLOBIN(E) K20 used the K20 electrophoresis chamber, HYDRAGEL 7 & 15 HEMOGLOBIN(E) used with the HYDRASYS and HYDRASYS 2 instruments, CAPILLARYS HEMOGLOBIN(E) used with the CAPILLARYS 2 and CAPILLARYS 2 FLEX-PIERCING instruments and MINICAP HEMOGLOBIN(E) used with the MINICAP instrument.
The Normal Hb A2 Control is designed for laboratory use. It should be used (with its bar code label for the CAPILLARYS and MINICAP procedures) like a normal human blood.
The values obtained must fall within the range provided with each batch of Normal Hb A2 Control.

For In Vitro Diagnostic Use.

Reagent and composition
The Normal Hb A2 Control is obtained from a pool of normal human 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 Normal Hb A2 Control is in a stabilized lyophilized form.

Storage and stability
Before reconstitution, store the lyophilized Normal Hb A2 Control refrigerated (2 to 8 °C). It is stable until the expiration date indicated on the box or vial labels.
Store the reconstituted Normal Hb A2 Control at 2 - 8 °C. Due to the risk of microbial contamination and denaturation, use it within one week.
The reconstituted Control may also be frozen (in aliquots) and stored between - 18 °C and - 22 °C for 6 months maximum.
NOTE: It is recommended to split the Control into aliquots in microtubes before freezing it.
Before use, store the thawed Normal Hb A2 Control at 2 - 8 °C and use it within the day (for 8 hours maximum).
Do not freeze and thaw the Control more than 15 times.
IMPORTANT: After storage at 2 - 8 °C or between - 18 °C and - 22 °C, homogenize the reconstituted Normal Hb A2 Control before the analysis.
The hemolysed Normal Hb A2 Control should be stored at 2 - 8 °C and used within one day (for 8 hours maximum).

NOTE: During transportation, the lyophilized Normal Hb A2 Control can be kept without refrigeration (15 to 30 °C) for 15 days without any adverse effects on performance.

Procedure
HYDRAGEL HEMOGLOBIN(E) procedures used with the K20 electrophoresis chamber and the HYDRASYS and HYDRASYS 2 instruments
Reconstitute each Normal Hb A2 Control vial with distilled or deionized water. Allow to stand for 30 minutes and mix gently (avoid formation of foam).
After reconstitution, each Normal Hb A2 Control must be used as follows: Hemolyse 20 μL reconstituted Hb A2 Control with 60 μL hemolysing solution. Vortex for 10 seconds, incubate for 5 minutes at room temperature and use it immediately.
See the package inserts of HYDRAGEL HEMOGLOBIN(E) kits.
CAPILLARYS HEMOGLOBIN(E) procedure used with the CAPILLARYS 2 and CAPILLARYS 2 FLEX-PIERCING instruments and MINICAP HEMOGLOBIN(E) procedure used with the MINICAP instrument

Reconstitute each Normal Hb A2 Control vial with distilled or deionized water. Allow to stand for 30 minutes and mix gently (avoid formation of foam).
After reconstitution, use directly the Normal Hb A2 Control as a blood sample to analyze. It will be automatically diluted with hemolysing solution.

NOTE: For optimal use of the Normal Hb A2 Control with the CAPILLARYS 2, CAPILLARYS 2 FLEX-PIERCING and MINICAP instruments, it is recommended to split the Control into aliquots in microtubes before freezing (see paragraph “Storage and Stability”).

IMPORTANT: For optimal use of the Normal Hb A2 Control with the CAPILLARYS 2, CAPILLARYS 2 FLEX-PIERCING and MINICAP instruments, it is necessary to use one bar code label intended to identify the hemolysing tube holding the microtube which contains the Hb A2 Control aliquot (cut the cap of the microtube before using it).

See the package inserts of CAPILLARYS and MINICAP HEMOGLOBIN(E) kits.

It is recommended to include one track of Normal Hb A2 Control into each run on HYDRAGEL 7 & 15 HEMOGLOBIN(E) gels or one analysis with the CAPILLARYS & MINICAP HEMOGLOBIN(E) techniques.

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 Normal Hb A2 Control as a hazardous biological material.
This lot of control blood 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.

Expected values (percentages)
The levels have been determined using replicate analyses using SEBIA electrophoresis procedures listed in the following table and are specific for this lot of control.

IMPORTANT: In order to improve accuracy of densitometric quantitation on gels of poorly defined hemoglobin fractions (with smears), it is recommended to mark each peak at the feet of its sharply rising sides nearest to the peak.

NOTE : The expected values are indicated in the package insert provided with the control vials.
Volumes de reconstitution avec eau distillée ou déminéralisée
Volumes of reconstitution with distilled or deionized water

<table>
<thead>
<tr>
<th>Instrument/Chamber Type</th>
<th>Description</th>
<th>Volume (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HYDRASYS &amp; HYDRASYS 2 instruments</td>
<td>HYDRAFLUX 7 &amp; 15 HEMOGLOBIN(E)</td>
<td>2.0 mL</td>
</tr>
<tr>
<td>K20 electrophoresis chamber</td>
<td>HYDRAFLUX HEMOGLOBIN(E) K20</td>
<td>2.0 mL</td>
</tr>
<tr>
<td>CAPILLARYS 2 instrument</td>
<td>CAPILLARYS HEMOGLOBIN(E)</td>
<td>1.0 mL</td>
</tr>
<tr>
<td>MINICAP instrument</td>
<td>MINICAP HEMOGLOBIN(E)</td>
<td>1.0 mL</td>
</tr>
<tr>
<td>CAPILLARYS 2 FLEX-PIERCING instrument</td>
<td>CAPILLARYS HEMOGLOBIN(E)</td>
<td>1.6 mL</td>
</tr>
<tr>
<td>MINICAP FLEX-PIERCING instrument</td>
<td>MINICAP HEMOGLOBIN(E)</td>
<td>1.6 mL</td>
</tr>
</tbody>
</table>

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 %.