

**sebia**

**A1c/EC – KIT DE PRÉLÈVEMENT  
POUR SANG CAPILLAIRE (A)**

***A1c/CE – CAPILLARY BLOOD  
SAMPLE KIT (A)***

Ref. 9212

IVD

CE

2019/12

## INTENDED USE

The "A1c/CE – Capillary blood sample kit (A)" device is designed for collection, hemolysis and transportation of blood samples for their analysis with the SEBIA capillary electrophoresis procedures :

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

For *In Vitro* Diagnostic Use.

## PRINCIPLE OF THE TEST

See the instructions for use of the SEBIA CAPILLARYS Hb A1c or CAPI 3 Hb A1c kits.

## REAGENTS AND MATERIALS SUPPLIED IN THE "A1c/CE – CAPILLARY BLOOD SAMPLE KIT (A)"

**WARNING : See the safety data sheets.**

ITEMS	PN 9212
Capillary tubes (ready to use)	2 packs of 100 each
Transport tubes (microtubes with hemolyzing solution and adapters, ready to use)	2 packs of 100 each (100 µL hemolyzing solution per tube)

FOR OPTIMAL MANAGEMENT OF TRACEABILITY : All reagents from the same kit must be used together.

TO OBTAIN THE EXPECTED PERFORMANCES : The package insert instructions must be observed.

### 1. CAPILLARY TUBES

#### Presentation

Single use glass capillary tubes are ready to use. Their inner side is coated with anticoagulant (potassium-EDTA).

#### Use

For blood sample collection at the puncture site for the quantitative determination of HbA<sub>1c</sub> by capillary electrophoresis.

**WARNING : The glass capillary tubes are fragile and may be easily broken. Handle with care.**

#### Storage

Before use, store capillary tubes in the closed original protective packaging in a dry place at room temperature (15 – 30 °C) or refrigerated (2 and 8 °C). They are stable until the expiration date indicated on the kit package or capillary tubes box label.

### 2. TRANSPORT TUBES

#### Presentation

Single use tubes are ready to use. Each transport tube is composed of a microtube with hemolyzing solution locked into an adapter. Hemolyzing solution contains : components, nonhazardous at the concentration used, necessary for optimum performance.

#### Use

For hemolysis and transportation of blood samples collected in capillary tubes.

The adapter is intended to protect the microtube with hemolyzed blood sample during transportation and to maintain it for the analysis in the sample rack "Cxxx" of the CAPILLARYS 2 FLEX-PIERCING instrument or in the sample rack "MC Cxxx" of the CAPILLARYS 3 instrument.

For the identification of the sample, place the sample identification label on the adapter of the transport tube.

**WARNING : Do not use the transport tube in the absence of hemolyzing solution.**

#### Storage, stability and signs of deterioration

Before use, store transport tubes in the closed original protective packaging refrigerated (between 2 and 8 °C). Under these conditions, they are stable until the expiration date indicated on the kit package or transport tubes pack label. DO NOT FREEZE.

**NOTE : Transport tubes may also be stored at room temperature (15 – 30 °C) for 6 months maximum.**

Discard tubes if hemolyzing solution changes its appearance, e.g., becomes cloudy due to microbial contamination.

See "Sample collection and storage" paragraph for storage of transport tubes with hemolyzed blood sample.

## **UTILIZATION WITH THE CAPILLARYS 2 FLEX-PIERCING INSTRUMENT**

### **REAGENTS REQUIRED BUT NOT SUPPLIED**

#### **CAPILLARYS Hb A1c KIT (SEBIA, PN 2015)**

##### **Presentation, use, storage, stability and signs of deterioration**

See the package insert of the kit.

**IMPORTANT** : Samples collected with the "A1c/CE – Capillary blood sample kit (A)" device must be analyzed only with CAPILLARYS Hb A1c procedure and the Capillary sample racks (see "EQUIPMENT AND ACCESSORIES REQUIRED") using,

- green dilution segments (from the CAPILLARYS Hb A1c kit) with PHORESIS releases < 8.63 (and  $\geq 8.61$  p4) or,
- yellow dilution segments with PHORESIS releases  $\geq 8.63$ .

### **EQUIPMENT AND ACCESSORIES REQUIRED**

1. See the package insert of SEBIA CAPILLARYS Hb A1c kit.

#### **2. YELLOW DILUTION SEGMENTS (SEBIA, PN 2079, 70 UNITS)**

##### **Use**

Colored single use segments, required for the analysis of blood samples collected using this device. To place on the sample rack No. Cxxx from the CAPILLARYS 2 FLEX-PIERCING instrument.

The dilution segments are shaped to fit on the sample racks.

**WARNING** : Dilution segments with biological samples have to be handled with care.

#### **3. CAPILLARY SAMPLE RACKS (5) (SEBIA, PN 1361, 5 UNITS)**

##### **Use**

Sample racks identified with a specific bar code "Cxxx", intended for the analysis of blood samples collected with the "A1c/CE – Capillary blood sample kit (A)" device.

#### **4. CLAMP FOR CAPILLARY BLOOD COLLECTION TUBE (SEBIA, PN 9213, 5 UNITS)**

##### **Use**

To hold the capillary tube when collecting the blood sample at the puncture site.

### **SAMPLES FOR ANALYSIS**

#### **Sample collection and storage**

The analysis must be performed on blood samples collected using this device.

Blood samples must be collected according to the procedure described in the instructions for capillary blood collection (these instructions can be forwarded to the patient by the laboratory when he has to collect the sample). The blood drop is collected from a puncture site performed with an appropriate medical device.

1. Take a transport tube out of the pack.

**WARNING** : Do not let the uncapped tube standing on the bench (tipping hazard).

2. Perform a puncture site according to the procedure corresponding to the used medical device.

3. Take a capillary tube out of the pack and hold it using the capillary tube clamp.

4. Apply the capillary tube, held by the clamp, on the blood drop at the puncture site and collect the blood sample until the capillary tube is **completely** filled.

5. Uncap the transport tube and place the capillary tube filled with collected blood sample into the microtube with hemolyzing solution. The lower part of the capillary tube must plunge into the hemolyzing solution.

6. Close tightly the transport tube with its cap.

7. If the capillary tube does not immerse into the hemolyzing solution, bring it down by shaking the transport tube down or lightly tap the tube on the bench.

8. Shake the tube to ensure a good transfer of the blood into the hemolyzing solution without turning it upside down.

9. Add the sample identification label.

10. Send immediately the collected sample to the laboratory.

Between collection and analysis, the blood samples may be stored in transport tubes for :

- 8 days maximum between 2 and 8 °C or,
- 8 days maximum between 15 and 25 °C or,
- 3 days maximum at 30 °C or,
- 8 days maximum at - 18 / - 30 °C.

For results analysis, it is recommended to consider transportation conditions of samples between patient's home and laboratory.

**IMPORTANT** : Upon receipt at the laboratory, store the samples in the device between 2 and 8 °C, and analyze them **within 8 hours maximum**.

## Sample preparation

The analysis must be performed on whole blood samples that are hemolyzed within the device.

- Check the feature of the transport tube after the receipt by the laboratory (do not analyze the sample when the tube has been damaged during transportation).
- Check each sample is correctly identified with its identification label.
- When a part of the hemolyzed sample is present close to the cap in the upper part of the tube, shake it down into the bulk liquid.
- Vortex the blood sample for 5 seconds.
- Let the capillary tube inside the microtube of the transport tube.
- For the analysis on the CAPILLARYS 2 FLEX-PIERCING instrument, use only a sample rack No. Cxxx.
- The sample rack No. Cxxx contains 8 positions for tubes. Place up to 8 transport tubes with hemolyzed sample on each sample rack (positions 1 to 8) ; the bar code of each tube must be visible in the openings of the sample rack.

### Utilization of transport tubes with PHORESIS releases < 8.63 (and ≥ 8.61 p4)

- Uncap the tube.
- Let the capillary tube inside the microtube.
- Place a new **green dilution segment** on the sample rack No. Cxxx, the central pin of the segment must face the operator.
- Take 100 µL of each hemolyzed sample and apply it into wells No. 1 to 8 of the dilution segment from the right side to the left side (well No. 1 on the right side and well No. 8 on the left side). Follow these side indications while manipulating the segment.
- **Cap tightly the tube and let it on the sample rack.**
- Start the analysis without any delay.

### Utilization of transport tubes with PHORESIS releases ≥ 8.63

- **Check each tube is tightly capped.**
- Place a new **yellow dilution segment** on the sample rack No. Cxxx, the central pin of the segment must face the operator. The sample rack will be ejected if the segment is missing.
- Start the analysis without any delay.

*NOTE : If necessary, a second analysis of the sample may be performed within one hour following the first analysis.*

## Samples to avoid

- Avoid blood samples that have coagulated in the capillary tube.
- Avoid aged, improperly stored blood samples. Hemoglobin degradation products may affect the electrophoretic pattern : an additional fraction (artefact) may migrate particularly to Hb A2 position or more anodically than Hb A0 (in the "other Hb A" position).

*See "Electrophoretic patterns", examples of samples showing consistant and inconsistant patterns for HbA<sub>1c</sub> fraction quantitative determination with degradation products that appear according to the sample storage conditions.*

## PROCEDURE

### I. ELECTROPHORETIC MIGRATION

*See the package insert of CAPILLARYS Hb A1c kit.*

1. Slide the sample rack No. Cxxx into the CAPILLARYS 2 FLEX-PIERCING instrument.  
The results are then automatically considered by the software for the data analysis.
2. After the analysis, discard the transport tubes containing the leftover hemolyzed sample with the capillary tube, and the dilution segments with biological waste products.

**WARNING : Transport tubes and dilution segments with biological samples have to be handled with care.**

**WARNING : For the analysis, samples collected using the device must be placed only on a CAPILLARYS 2 FLEX-PIERCING sample rack No. Cxxx. Do not place directly the transport tube on a sample rack within a series of samples.**

### II. RESULT ANALYSIS

*See the package insert of CAPILLARYS Hb A1c kit.*

### III. END OF ANALYSIS SEQUENCE

*See the package insert of CAPILLARYS Hb A1c kit.*

### IV. FILLING OF REAGENT CONTAINERS

*See the package insert of CAPILLARYS Hb A1c kit.*

## RESULTS

*Quality control, Values, Interpretation, Interferences and Limitations and Troubleshooting : See the package insert of CAPILLARYS Hb A1c kit, SEBIA.*

**PERFORMANCE DATA**

**Accuracy – External correlation**

The external concordance study between the venous blood samples analysis and the capillary blood samples analysis with the CAPILLARYS Hb A1c procedure performed with the CAPILLARYS 2 FLEX-PIERCING instrument was evaluated in a study based on the Clinical Laboratory Standards Institute (CLSI - USA) EP09-A2 guideline "Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Second Edition (Interim Revision)".

The results for HbA<sub>1c</sub> concentrations (mmol/mol) and percentages (%) were analyzed using statistical tools recommended by CLSI.

*NOTE : The results presented below have been obtained from 1 external accuracy study performed in a hospital laboratory located in France.*

The levels of HbA<sub>1c</sub> were measured in 60 pairs of blood samples (venous blood sample on collection tube / capillary blood sample collected with the "A1c/CE – Capillary blood sample kit (A)" device), including 29 samples with normal HbA<sub>1c</sub> levels and 31 samples with elevated HbA<sub>1c</sub> levels, both by electrophoretic separations obtained with CAPILLARYS Hb A1c procedure with the CAPILLARYS 2 FLEX-PIERCING instrument.

The measured values of HbA<sub>1c</sub> concentrations and percentages from both procedures were analyzed by a linear regression statistical procedure. The obtained results have demonstrated a perfect correlation for HbA<sub>1c</sub> quantification between venous blood samples and capillary blood samples analyzed with the CAPILLARYS Hb A1c procedure.

The results of linear regression analysis between both collection modes are tabulated below (y = capillary blood samples), the sensibility and specificity for analyses using both collection modes with the CAPILLARYS Hb A1c procedure have been calculated using the recommended method (Wendling, 1986).

HbA <sub>1c</sub>	Correlation coefficient	y-Intercept	Slope	Range of values CAPILLARYS Hb A1c & "A1c/CE – Capillary blood sample kit (A)"	Sensibility (%)	Specificity (%)
Concentration (mmol/mol)	0.999	0.176	0.990	27 - 130	100.0	96.6
Percentage (%)	0.999	0.020	0.993	4.6 - 14.0	100.0	100.0

## **UTILIZATION WITH THE CAPILLARYS 3 INSTRUMENT**

**NOTE** : In this instruction sheet, the name "CAPILLARYS 3" is used for the SEBIA CAPILLARYS 3 OCTA, CAPILLARYS 3 TERA and CAPILLARYS 3 TERA TLA automated instruments.

### **REAGENTS REQUIRED BUT NOT SUPPLIED**

#### **CAPI 3 Hb A1c KIT (SEBIA, PN 2515)**

##### **Presentation, use, storage, stability and signs of deterioration**

See the instructions for use of the kit.

**IMPORTANT** : Samples collected with the "A1c/CE – Capillary blood sample kit (A)" device must be analyzed with CAPI 3 Hb A1c procedure using only the CAPILLARYS 3 & MC Capillary blood racks (see "EQUIPMENT AND ACCESSORIES REQUIRED") and PHORESIS releases  $\geq 9.04$ .

### **EQUIPMENT AND ACCESSORIES REQUIRED**

1. See the instructions for use of the SEBIA CAPI 3 Hb A1c kit.
2. **CAPILLARYS 3 & MC CAPILLARY BLOOD RACKS (5) (SEBIA, PN 1363, 5 UNITS)**

#### **Use**

Sample racks identified with a "MC Cxxx" label, intended for the analysis of blood samples collected with the "A1c/CE – Capillary blood sample kit (A)" device used with the CAPILLARYS 3 instrument.

3. **CLAMP FOR CAPILLARY BLOOD COLLECTION TUBE (SEBIA, PN 9213, 5 UNITS)**

#### **Use**

To hold the capillary tube when collecting the blood sample at the puncture site.

### **SAMPLES FOR ANALYSIS**

#### **Sample collection and storage**

The analysis must be performed on blood samples collected using this device.

Blood samples must be collected according to the procedure described in the instructions for capillary blood collection (these instructions can be forwarded to the patient by the laboratory when he has to collect the sample). The blood drop is collected from a puncture site performed with an appropriate medical device.

1. Take a transport tube out of the pack.  
**WARNING** : Do not let the uncapped tube standing on the bench (tipping hazard)
2. Perform a puncture site according to the procedure corresponding to the used medical device.
3. Take a capillary tube out of the pack and hold it using the capillary tube clamp.
4. Apply the capillary tube, held by the clamp, on the blood drop at the puncture site and collect the blood sample until the capillary tube is **completely** filled.
5. Uncap the transport tube and place the capillary tube filled with collected blood sample into the microtube with hemolyzing solution. The lower part of the capillary tube must plunge into the hemolyzing solution.
6. Close tightly the transport tube with its cap.
7. If the capillary tube does not immerse into the hemolyzing solution, bring it down by shaking the transport tube down or lightly tap the tube on the bench.
8. Shake the tube to ensure a good transfer of the blood into the hemolyzing solution without turning it upside down.
9. Add the sample identification label.
10. Send immediately the collected sample to the laboratory.

Between collection and analysis, the blood samples may be stored in transport tubes for :

- 8 days maximum between 2 and 8 °C or,
- 8 days maximum between 15 and 25 °C or,
- 3 days maximum at 30 °C or,
- 8 days maximum at - 18 / - 30 °C.

For results analysis, it is recommended to consider transportation conditions of samples between patient's home and laboratory.

**IMPORTANT** : Upon receipt at the laboratory, store the samples in the device between 2 and 8 °C, and analyze them **within 8 hours maximum**.

#### **Sample preparation**

The analysis must be performed on whole blood samples that are hemolyzed within the device.

- Check the feature of the transport tube after the receipt by the laboratory (do not analyze the sample when the tube has been damaged during transportation).
- Check each sample is correctly identified with its identification label and each tube is tightly capped.
- When a part of the hemolyzed sample is present close to the cap in the upper part of the tube, shake it down into the bulk liquid.
- Vortex the blood sample for 5 seconds.

- Let the capillary tube inside the microtube of the transport tube.
- For the analysis with the CAPILLARYS 3 instrument, use only a CAPILLARYS 3 & MC Capillary blood rack, identified "MC Cxxx". Do not use any standard sample rack (important risk of instrument and tube damage).
- The sample rack "MC Cxxx" contains 8 positions for tubes. Place up to 8 transport tubes with hemolyzed sample on each sample rack (positions 1 to 8) ; the bar code of each tube must be visible in the openings of the sample rack.
- Start the analysis without any delay.

*NOTE : A sample rack "MC Cxxx" may be inserted into the instrument among a series of standard sample racks.*

#### **Special case : Second analysis of the sample**

If necessary, a second analysis of the sample can be performed.

- For that, add to the microtube which contains the sample, 50 µL of Hemolysing solution pipetted from a new transport tube.
- Vortex the blood sample for 5 seconds.
- Place the tube on a sample rack "MC Cxxx" and start the analysis without any delay.
- Discard the transport tube from which the 50 µL of hemolyzing solution have been pipetted.
- **Do not analyze the sample more than twice.**
- After the second analysis, due to the additional dilution of the sample, a warning message "Too low OD" and the purple warning symbol may be displayed on the pattern (when OD < 0.06). If the pattern is consistent, the HbA<sub>1c</sub> value can be considered (see "Electrophoretic patterns" with examples of samples showing consistent and inconsistent patterns for HbA<sub>1c</sub> fraction quantitative determination).

#### **Samples to avoid**

- Avoid blood samples that have coagulated in the capillary tube.
- Avoid aged, improperly stored blood samples. Hemoglobin degradation products may affect the electrophoretic pattern : an additional fraction (artefact) may migrate particularly to Hb A2 position or more anodically than Hb A0 (in the "other Hb A" position).

*See "Electrophoretic patterns", examples of samples showing consistent and inconsistent patterns for HbA<sub>1c</sub> fraction quantitative determination with degradation products that appear according to the sample storage conditions.*

## **PROCEDURE**

### **I. ELECTROPHORETIC MIGRATION**

*See the instructions for use of the CAPI 3 Hb A1c kit.*

1. Slide the sample rack "MC Cxxx" into the CAPILLARYS 3 instrument.  
The results are then automatically considered by the software for the data analysis.
2. After the analysis, discard the transport tubes containing the leftover hemolyzed sample with the capillary tube, with biological waste products.  
**WARNING : Transport tubes and reagent cups with biological samples have to be handled with care.**

**WARNING : For the analysis, samples collected using the device must be placed only on a CAPILLARYS 3 sample rack "MC Cxxx". Do not place directly the transport tube on a standard sample rack within a series of samples.**

### **II. RESULT ANALYSIS**

*See the instructions for use of the CAPI 3 Hb A1c kit.*

### **III. END OF ANALYSIS SEQUENCE**

*See the instructions for use of the CAPI 3 Hb A1c kit.*

### **IV. FILLING OF REAGENT CONTAINERS**

*See the instructions for use of the CAPI 3 Hb A1c kit.*

## **RESULTS**

*Quality control, Values, Interpretation, Interferences and Limitations and Troubleshooting : See the instructions for use of the SEBIA CAPI 3 Hb A1c kit.*

## **PERFORMANCE DATA**

### **Accuracy – External correlation**

The external concordance study between the analysis of blood samples in collection tubes and the analysis of blood samples in the "A1c/CE – Capillary blood sample kit (A)" device with the CAPI 3 Hb A1c procedure performed with the CAPILLARYS 3 instrument was evaluated in a study based on the Clinical and Laboratory Standards Institute (CLSI - USA) EP09-A2 guideline "Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Second Edition (Interim Revision)".

The results for HbA<sub>1c</sub> concentrations (mmol/mol) and percentages (%) were analyzed using statistical tools recommended by CLSI.

*NOTE : The results presented below have been obtained from 1 external accuracy study performed in a hospital laboratory located in France.*

The levels of HbA<sub>1c</sub> were measured in 140 pairs of blood samples (blood sample in collection tube / blood sample in the "A1c/CE – Capillary blood sample kit (A)" device), including 23 samples with normal HbA<sub>1c</sub> levels and 117 samples with elevated HbA<sub>1c</sub> levels, both by electrophoretic separations obtained with CAPI 3 Hb A1c procedure performed with the CAPILLARYS 3 instrument.

The measured values of HbA<sub>1c</sub> concentrations and percentages were analyzed by a linear regression statistical procedure. The obtained results have demonstrated a perfect correlation for HbA<sub>1c</sub> quantification between blood samples in collection tubes and blood samples in the "A1c/CE – Capillary blood sample kit (A)" device analyzed with the CAPI 3 Hb A1c procedure.

The results of linear regression analysis are tabulated below ( $y$  = blood samples in the "A1c/CE – Capillary blood sample kit (A)" device), the sensibility and specificity have been calculated using the recommended method (Wendling, 1986).

HbA <sub>1c</sub>	Correlation coefficient	y-Intercept	Slope	Range of values CAPI 3 Hb A1c & "A1c/CE – Capillary blood sample kit (A)"	Sensibility (%)	Specificity (%)
Concentration (mmol/mol)	0.998	0.025	0.995	24 - 150	96.6	95.7
Percentage (%)	0.999	-0.019	0.998	4.3 - 15.9	96.6	95.7



**BIBLIOGRAPHIE / BIBLIOGRAPHY**

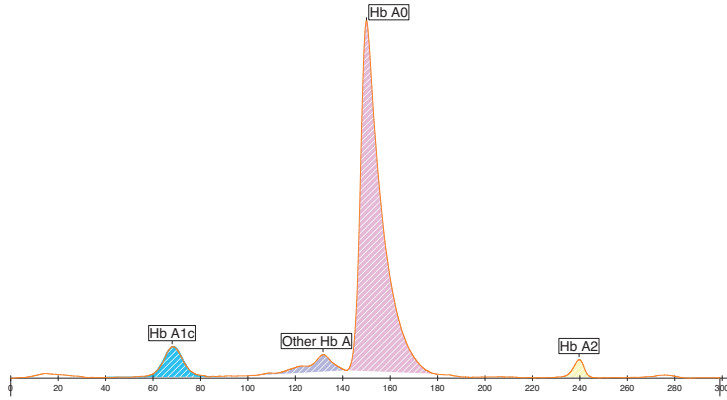
**BIBLIOGRAFIE - BIBLIOGRAFIA - BIBLIOGRAFÍA - BIBLIOGRAFI - ΒΙΒΛΙΟΓΡΑΦΙΑ - BIBLIOGRAFIJU - BIBLIOGRAFIJA - KAYNAҚÇA - БИБЛИОГРАФИЯ - 参考书目 - БИБЛИОГРАФИЮ - 参考文献 - IZMANTOTĀ LĪTERATŪRA - BIBLIOGRAFIU - KIRJANDUS**

FR : Voir la notice d'utilisation du kit CAPILLARYS Hb A1c & CAPI 3 Hb A1c.  
GB : See instructions for use of the CAPILLARYS Hb A1c & CAPI 3 Hb A1c kit.  
DE : Siehe Gebrauchsanleitungen für das CAPILLARYS Hb A1c & CAPI 3 Hb A1c-Kit.  
NL : Raadpleeg de gebruiksvorschriften van de CAPILLARYS Hb A1c & CAPI 3 Hb A1c kit.  
IT : Vedere le istruzioni per l'uso del kit CAPILLARYS Hb A1c & CAPI 3 Hb A1c.  
ES : Ver las instrucciones del kit CAPILLARYS Hb A1c & CAPI 3 Hb A1c.  
PT : Consulte as instruções de utilização do kit CAPILLARYS Hb A1c & CAPI 3 Hb A1c.  
SV : Se bruksanvisningen för användning av CAPILLARYS Hb A1c & CAPI 3 Hb A1c kitet.  
GR : Βλ. τις οδηγίες χρήσης του κιτ CAPILLARYS Hb A1c & CAPI 3 Hb A1c.  
HR : Pogledajte upute za upotrebu kompleta CAPILLARYS Hb A1c & CAPI 3 Hb A1c.  
LT : Žr. "CAPILLARYS Hb A1c & CAPI 3 Hb A1c" rinkinio naudojimo instrukcijas.  
PL : Patrz instrukcja użytkowania zestawu CAPILLARYS Hb A1c & CAPI 3 Hb A1c.  
RO : Consultați instrucțiunile de utilizare pentru trusa CAPILLARYS Hb A1c & CAPI 3 Hb A1c.  
CS : Uputstvo za upotrebu potražite u kompletu CAPILLARYS Hb A1c & CAPI 3 Hb A1c.  
HU : Lásd a CAPILLARYS Hb A1c & CAPI 3 Hb A1c készlet használati útmutatóját.  
TR : CAPILLARYS Hb A1c & CAPI 3 Hb A1c kitinin kullanma kılavuzuna bakınız.  
CZ : Viz pokyny k použití sady CAPILLARYS Hb A1c & CAPI 3 Hb A1c.  
BG : Вижте инструкциите за употреба на комплекта CAPILLARYS Hb A1c & CAPI 3 Hb A1c.  
NO : Se instruksjonene for bruk av CAPILLARYS Hb A1c & CAPI 3 Hb A1c-SETT.  
DK : Se brugsanvisningen for CAPILLARYS Hb A1c & CAPI 3 Hb A1c-kit.  
CN : 参见 CAPILLARYS Hb A1c & CAPI 3 Hb A1c 试剂盒的使用说明。  
RU : См. инструкции по применению набора CAPILLARYS Hb A1c & CAPI 3 Hb A1c.  
JP : セビア社CAPILLARYS Hb A1c & CAPI 3 Hb A1cキットの使用説明書を参照してください。  
LV : Lai iegūtu informāciju par CAPILLARYS Hb A1c & CAPI 3 Hb A1c komplekta lietojumu, skatīt instrukcijas.  
SK : Pozrite si pokyny na použitie súpravy CAPILLARYS Hb A1c & CAPI 3 Hb A1c.  
EE : Vt komplekti CAPILLARYS Hb A1c & CAPI 3 Hb A1c kasutusjuhiseid.

## SCHÉMAS / FIGURES

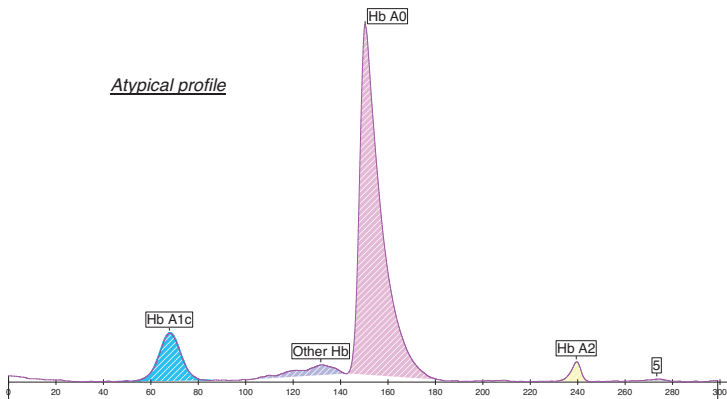
### PROFILS ÉLECTROPHORÉTIQUES - ELECTROPHORETIC PATTERNS

Figure 1



Profil conforme (prélèvement de sang capillaire conservé 8 jours à 2 – 8 °C)  
*Consistent pattern (capillary blood sample stored for 8 days at 2 – 8 °C)*

Figure 2

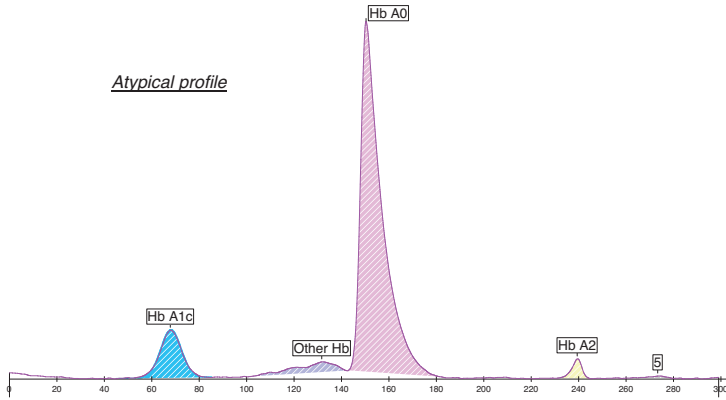


Profil conforme (prélèvement de sang capillaire conservé 8 jours à - 18 / - 30 °C)  
*Consistent pattern (capillary blood sample stored for 8 days at - 18 / - 30 °C)*

SCHÉMAS / FIGURES

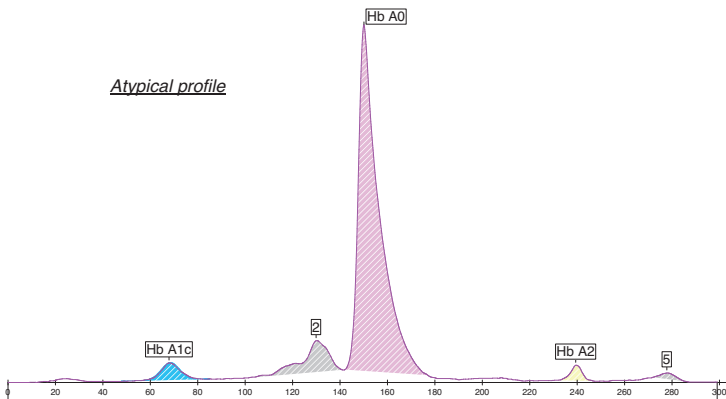
PROFILS ÉLECTROPHORÉTIQUES - ELECTROPHORETIC PATTERNS

Figure 3



Profil conforme (prélèvement de sang capillaire conservé 5 jours à 15 – 25 °C)  
Consistent pattern (capillary blood sample stored for 5 days at 15 – 25 °C)

Figure 3 bis

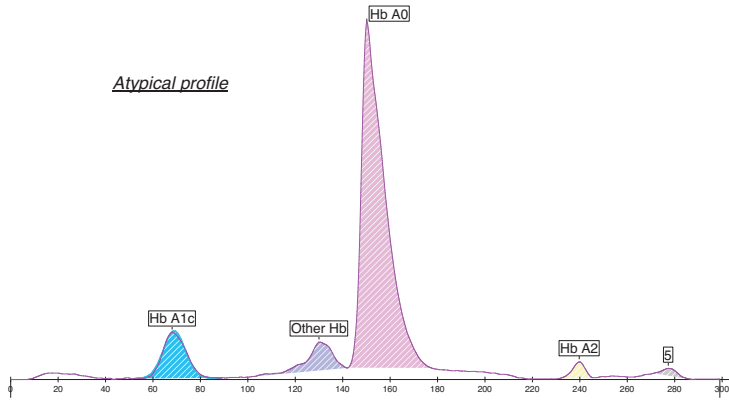


Profil conforme (prélèvement de sang capillaire conservé 8 jours à 15 – 25 °C)  
Consistent pattern (capillary blood sample stored for 8 days at 15 – 25 °C)

SCHÉMAS / FIGURES

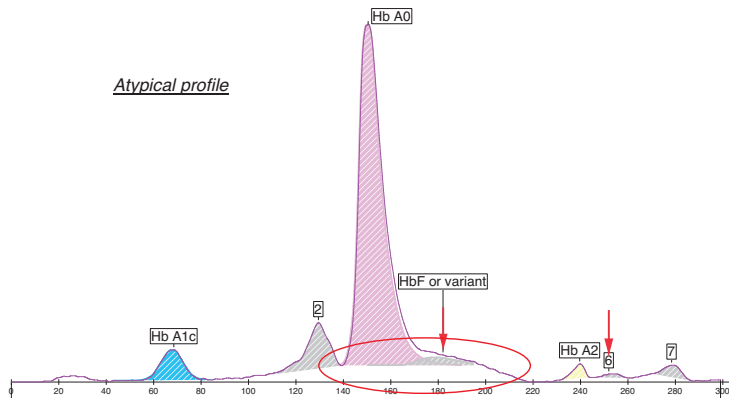
PROFILS ÉLECTROPHORÉTIQUES - ELECTROPHORETIC PATTERNS

Figure 4



Profil conforme (prélèvement de sang capillaire conservé 3 jours à 30 °C)  
Consistent pattern (capillary blood sample stored for 3 days at 30 °C)

Figure 5

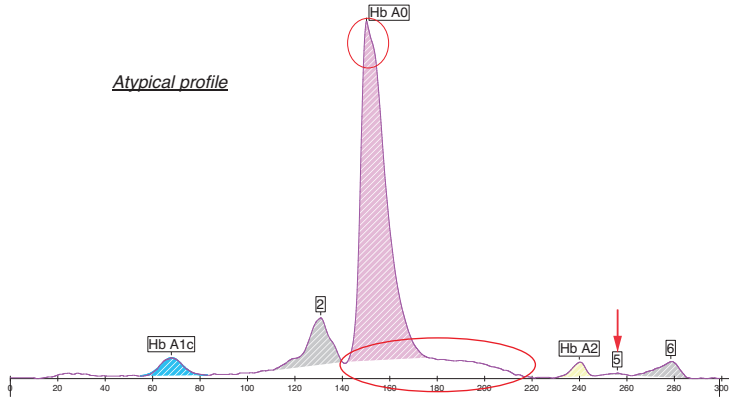


Profil non conforme  
Inconsistent pattern

SCHÉMAS / FIGURES

PROFILS ÉLECTROPHORÉTIQUES - ELECTROPHORETIC PATTERNS

Figure 6



Profil non conforme  
Inconsistent pattern



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