

sebia

CAPILLARYS HEMOGLOBIN(E)

Ref. 2007

*Composition du kit
Kit composition*

IVD

CE

2017/01

REAGENTS AND MATERIALS SUPPLIED IN THE CAPILLARYS HEMOGLOBIN(E) KIT**WARNING :** See the safety data sheets.

ITEMS	PN. 2007
Buffer (ready to use)	2 vials, 700 mL each
Hemolyzing solution (ready to use)	1 vial, 700 mL
Wash solution (stock solution)	1 vial, 75 mL
Dilution segments	1 pack of 90
Filters	4 filters

630 tests based on maximum usage.

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

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.

WARNING : Do not use marketed deionized water, such as water for ironing for example (risk of important capillaries damage). Use only water with ultrapure quality, such as injection grade water.**1. BUFFER****Preparation**

The buffer is ready to use. It contains : buffer solution pH 9.4 ± 0.5 ; additives, nonhazardous at concentrations used, necessary for optimum performance.

Use

Buffer for analysis of hemoglobins in CAPILLARYS 2 & CAPILLARYS 2 FLEX-PIERCING.

Storage, stability and signs of deterioration

Store the buffer refrigerated (2 to 8 °C). It is stable until the expiration date indicated on the kit package or buffer vial labels. Avoid storage at room temperature (15 to 30 °C) for a long time or close to a window or to a heat source.

DO NOT FREEZE.

IMPORTANT: When stored at 2 - 8 °C and prior to use, it is necessary for the buffer to reach room temperature (15 to 30 °C); when it is full, let the buffer vial at room temperature for at least 3 hours prior to use. If this precaution is not respected, the performances of the procedure may be affected.**WARNING:** Do not pre-heat the buffer in hot water.Once the buffer vial has been opened and positioned on the CAPILLARYS 2 & CAPILLARYS 2 FLEX-PIERCING system, it is stable for a maximum of **1 month** (accumulated) at room temperature (15 to 30 °C). **After each use, the buffer must imperatively be stored refrigerated (between 2 and 8 °C) without any delay**, it is then stable until the expiration date indicated on the buffer vial label.**IMPORTANT:** The accumulated time of the buffer stored at room temperature (15 to 30 °C) must not exceed **1 month**. This time of 1 month storage takes account of the time for the buffer to come to room temperature.

Discard buffer if it changes its appearance, e.g., becomes cloudy due to microbial contamination.

2. HEMOLYSING SOLUTION**Preparation**

Hemolyzing solution is ready to use. It contains buffer solution pH 8.5 ± 0.5 ; additives, nonhazardous at concentrations used, necessary for optimum performance.

Use

To dilute and hemolyze red blood cells and whole blood.

Storage, stability and signs of deterioration

Store Hemolyzing Solution at room temperature (15 to 30 °C) or refrigerated (2 to 8 °C). It is stable until the expiration date indicated on the kit package or Hemolyzing Solution vial label. DO NOT FREEZE.

Once the Hemolyzing solution vial has been opened and positioned on the CAPILLARYS 2 FLEX-PIERCING instrument, it is stable for a maximum of 3 months (accumulated). If the Hemolyzing solution vial is planned to be used for more than 3 months, it must be removed from the instrument after each use and stored at room temperature (15 to 30 °C) or refrigerated (between 2 and 8 °C). Hemolyzing solution is then stable until the expiration date indicated on the Hemolyzing solution vial label.

Discard Hemolyzing Solution if it changes its appearance, e.g., becomes cloudy due to microbial contamination.

3. WASH SOLUTION**Preparation**

The vial of the stock wash solution should be diluted up to 750 mL with distilled or deionized water.

After dilution, the wash solution contains an alkaline solution pH ≈ 12.

Use

For washing the capillaries before and after hemoglobin electrophoresis.

IMPORTANT: Before filling the wash solution container, it is recommended to wash the opening of the container, the connector and the tube with plenty of distilled or deionized water to avoid salts deposit.**Storage, stability and signs of deterioration**

Store the stock and working wash solutions in closed containers at room temperature (15 to 30 °C) or refrigerated (2 to 8 °C). The stock wash solution is stable until the expiration date indicated on the kit or wash solution vial label.

Working wash solution is stable for 3 months.

Discard working wash solution if it changes its appearance, e.g., becomes cloudy due to microbial contamination.

4. DILUTION SEGMENTS

Use

Single use dilution segments for the preparation of biological samples to analyze with the automated instrument. To be placed on the sample rack. One dilution segment is intended for the analysis of 8 samples (7 samples in the presence of a diluent).

WARNING : *After use, dilution segments with biological samples have to be handled with care. When the analysis is completed, dilution segments must be discarded with biological waste products and they must NEVER be reused.*

Storage

Before use, store the dilution segments in their sealed package in a clean and dry place and at a temperature comprised between 2 and 30 °C.

5. FILTERS

Use

Disposable filters for filtration of analysis buffer, hemolysing solution (**for CAPILLARYS 2 FLEX-PIERCING system**), working wash solution and distilled or deionized water (used for capillaries rinsing).

IMPORTANT : When kit replacement, change systematically all the filters. Wear clean gloves for handling and installation of filters.

Screw one filter at the connector situated at the extremity of each tube that plunges in the vials of buffer, hemolysing solution, wash solution and distilled or deionized water. When setting filters on CAPILLARYS 2 & CAPILLARYS 2 FLEX-PIERCING system, rinse the connectors and the tubes with distilled or deionized water.

Storage

Before use, store the filters in their sealed package in a dry place at room temperature (15 to 30 °C) or refrigerated (2 to 8 °C).