

Capitainer® SEP10

INSTRUCTIONS FOR USE

Valid for article numbers: 110-0001 (Single Device) and 110-0050 (50 pcs box)

Intended purpose:

The Capitainer®SEP10 sample collection cards are used to collect and separate whole blood and store a specific volume of the filtrate as a dried stain for future analysis.

Introduction:

The intended user is a healthcare professional or a lay person. The sample is taken by pricking the finger. Blood is added to each sample inlet on the cards, plasma/serum is extracted and each sample unit separates 10µl of the plasma/serum and stores it in a paper disc. Sampling is performed correctly when the disc in the control window is colored blue. After closing the lid, the card is placed in the designated drying pouch. The sample dries during transport to the laboratory, where analysis is performed.

Provided by Capitainer:

Capitainer®SEP10 sampling cards, Capitainer®Drying pouch*

Recommended materials, not provided by Capitainer:

Disinfectant swab, disposable lancet**, gauze, adhesive bandage, sample ID, and a 1-2cm high, flat surface (e.g., a box). Always follow the manufacturer's instructions for all materials used.

*Purchased separately. **Use a contact-activated lancet with a wide (1.5mm) and deep (2mm) cut to obtain sufficient blood without squeezing the finger.

Product performance:

The product generates 2 x 10µl of plasma/serum-like dried sample from 2 x 58 µl whole blood with a precision of < 3% volume CV from whole blood in the range of 30-53% HCT.

Waste disposal:

All used materials, such as cards, lancets, gauzes, and swabs with blood residues, must be handled and disposed of safely and in accordance with local regulations.

Product storage and handling:

Storage conditions before use: Temperature, 15°C to 28°C; relative humidity, 10% to 99%. Avoid direct sunlight and moisture. Unopened devices may be stored under the above conditions until the expiration date printed on the device packaging.

Post-sampling transport:

It is the responsibility of each analyzing laboratory to validate appropriate shipping conditions for the analytes to be tested in that laboratory. It is recommended to use the designated drying pouch for return shipment post-sampling to ensure optimal drying conditions. Our paper-based shipping method has been designed to reduce waste and minimize the carbon footprint of your workflows. However, sensitive analytes may require the use of aluminum-coated plastic bags and the inclusion of desiccant pouches.

Cautions during sampling:

- Note that several drops of blood may be applied per sample inlet until the stop line is reached. Applying more drops after reaching the stop line increases the likelihood of unsuccessful sample collection.
- Use the card within 30 minutes of opening the package.
- Check that the expiration date has not passed.
- Leave the card flat on the 1-2cm high, flat surface (e.g., a box) during the entire sampling process. Do not put any pressure on the card during sampling.
- Do not place Sample ID during sampling. Sample ID may be placed either before blood application or after sample collection, before packing up.
- Do not apply blood on top of the channel; approach the channel sideways.
- Any serious incident related to the medical card should be reported to Capitainer AB and to the competent authority of the Member State in which the user and/or patient is established.

Outside



Sample discs

Inside



Lid

Control window

Place for sample ID

Stop line

Sample inlet



Capitainer AB, Solna Torg 19, SE-171 45 Solna
info@capitainer.com
www.capitainer.com

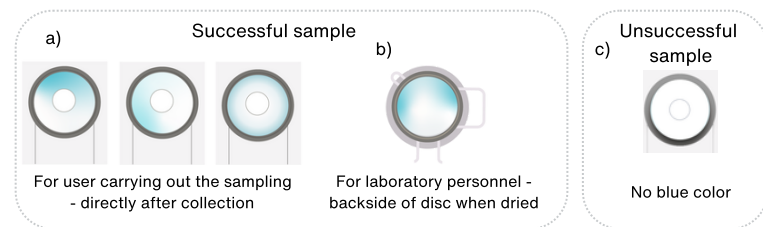
COPYRIGHT 2020 © CAPITAINER AB, ALL RIGHTS RESERVED



INSTRUCTIONS FOR SAMPLING

Sample preparation and downstream analysis:

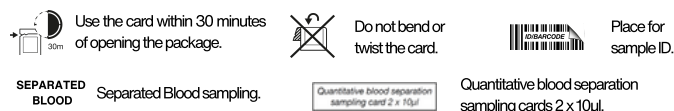
Take general safety precautions when handling blood. Samples should be completely dried before removal from the card. Depending on the environment, drying times may vary; drying times between 8 and 24 hours are common. Tear off the lid of the card to expose the sample discs on the back side of the card, and confirm that they display a blue color, as shown in b) below.



Cautions during laboratory use:

- The product is only validated for use with fresh blood.
- For validation experiments with pipetted venous blood, let the blood come to room temperature and ensure that it is well mixed before using it on the cards. Do not use blood older than three days stored in the refrigerator.
- Do not use with lyophilized blood.
- Make sure that the sample disc is completely dry before storage, use, and analysis. A wet disc may not detach correctly from the card.
- The eluted sample will contain a blue dye, Patent Blue VF.

Symbols and Explanations:



Remove the disc using a flat-tip tweezer or a disc removal instrument. When removing the discs manually with tweezers, ensure that most of the paper material is removed; only a thin layer of paper residue may remain on the card. For more information, go to <https://capitainer.com/product/capitainersep-10/>. After collecting the sample discs, proceed with elution. The choice of elution protocol and buffer depends on the target analyte(s) and the downstream analysis platform. Published methods for conventional DBS samples are also applicable to Capitainer's sampling products and may serve as useful guidelines. Read more at <https://capitainer.com>. The laboratory performing the analysis is responsible for validating assay results versus gold standard methods.

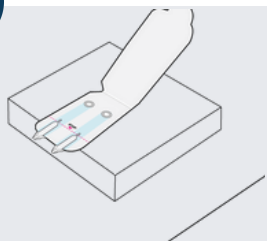
Before you start:

- Read the full instructions carefully before use.



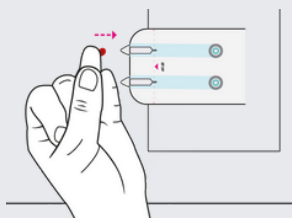
- Warm hands are essential for correct fingerstick blood collection. Cold hands cause unsuccessful sampling.
- Disinfect your finger prior to pricking

1



Open the lids of the sampling card and place the card on a 1-2cm high, flat surface (e.g., a box) on the table with the sample inlet tips protruding over the edge as shown.

2

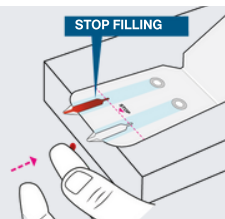


Let a **large blood drop** form by itself. Wipe off the first drop. With your hand resting on the table, approach the inlet tip sideways with the second large drop. Ensure the blood enters the channel.



Do not tilt the card.

3



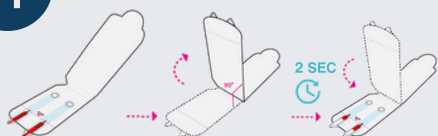
Continue to apply blood until it reaches the **stop line**. Remove the finger from the inlet. Do **not** apply more blood.

Repeat and fill the second channel.



Do not tilt the card.

4



After applying blood to both channels, tilt the card to a 90-degree angle with the inlets facing upwards for two seconds, and then leave the card flat on the table for 30 minutes.

5

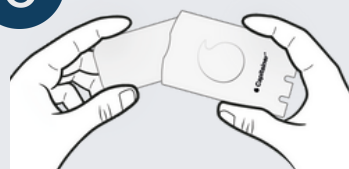


After 30 minutes, observe that both channels are emptied and the control window shows a blue color.



Never touch, press or write on the card after blood application; this can ruin your sample.

6



If sampling is successful, ensure that sample ID is correctly placed. Place the sampling card with the lid closed in the drying pouch and return to the laboratory.

