

Capitainer®B10

INSTRUCTIONS FOR USE

Valid for article numbers: 210-0001 (Single Device) and 210-0050 (50 pcs box)

Intended purpose:

Capitainer®B10 sampling cards are used to collect and save a specific volume of capillary blood as a dried blood stain.

Introduction:

The intended user is a healthcare professional or a layperson. The sample is taken by pricking the finger. A drop of blood is added to each sample well on the card, which measures it into 10 µl and stores it in a paper disc. Sampling is performed correctly when the disc in the control window is coloured red with blood. The lid is closed, and the card is then placed in the associated drying pouch. The sample can then be dried during transport to the laboratory, where it is analysed.

Provided by Capitainer:

Capitainer®B10 sampling cards, Capitainer®Drying pouch*

Recommended materials, not provided by Capitainer:

Disinfectant swab, disposable lancet**, gauze, adhesive bandage, and sample ID. Always follow the manufacturer's instructions for all materials used.

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

Product performance:

The product generates 2 x 10µl of dried whole blood sample from two drops of blood with a precision of < 2% volume CV in the range of 25-55% 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 90%. Avoid direct sunlight and moisture. Unopened devices may be stored under the above conditions until the expiry date printed on the device packaging.

Post-sampling transport:

It is the responsibility of each analysing 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 aluminium-coated plastic bags and the inclusion of desiccant pouches.

Cautions during sampling:

- Observe general precautions for blood sampling
- Note that only one (1) drop of blood can be applied per sample well. More drops increase the likelihood of an incorrect sample.
- Check that the expiry date has not passed.
- Use the card within 30 minutes of opening the package.
- Do not touch the sample wells before sampling.
- Any serious incident that has occurred in relation to the medical device should be reported to Capitainer AB and the competent authority of the Member State in which the user and/or the patient is established.

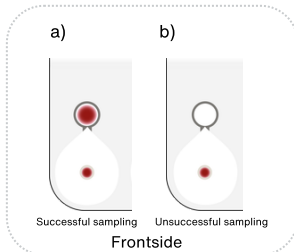


INSTRUCTIONS FOR SAMPLING

Sample preparation and downstream analysis:

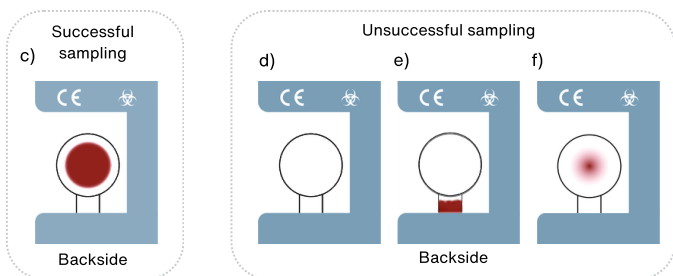
Take general safety precautions when handling blood. Samples should be completely dried before removal from the card. Depending on the environment, drying times may vary: drying times between 8 and 24 hours are common. Inspect that the sampling was successful according to the description below:

For patient



- For patient: successful sampling as in a) red colour in control window or unsuccessful as in b) white control window.
- Laboratory personnel: remove the peel tab on the backside of the card to expose sample discs c) successful sampling - red disk, clean channel.
- Unsuccessful sampling; d) white disk, e) blood in channel, f) substantially smaller red spot in disc. e) and f) may indicate undersampling, which happens infrequently during misuse.

For laboratory personnel



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. 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.

Cautions during laboratory use:

- The product is only validated for use with fresh blood.
- For validation experiments with pipetted venous blood, do not use blood older than seven days that has been stored in a refrigerator. Let the blood come to room temperature and ensure each sample is well mixed before using it on the cards.
- Do not use with lyophilised blood.
- Make sure that the sample disc is completely dry before storage, use, and analysis. A wet disc might not detach correctly from the card. It is recommended to let the sample disc dry overnight.

Symbols and Explanations:



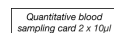
Use the card within 30 minutes of opening the package.



Place for sample ID.



Do not bend or twist the card.



Quantitative blood sampling card 2 x 10µl.

BLOOD

Blood sampling.

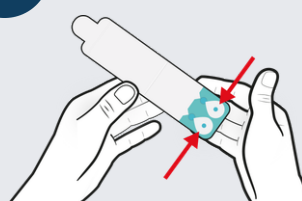
1



Before you start

- Read through the full instructions.
- Place all sampling materials on a table.
- Open all packages.
- Wash your hands with warm, soapy water until they are warm.

2



Open the card

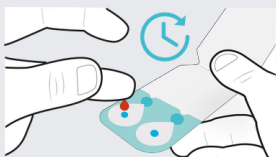
Open the lid of the sampling card and place it on the table.



Do not touch the sample wells on the card.

3

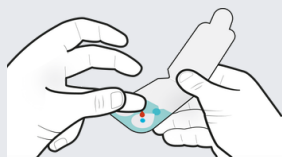
Blood application



Important step, read carefully!

Wipe off the first drop of blood, then let a **large drop** of blood form by itself. **Wait** for the drop to almost fall off by its own weight before applying it to one of the sample wells.

4



Apply only one drop per sample well.

Repeat blood application on the second sample well.

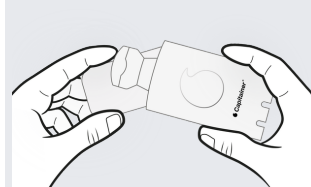
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Sample check

After applying blood, wait for about 30 seconds and then check the control window. Upon successful sampling, the control windows should turn red, as shown in the picture.

6



Sample return

Mark the sampling card with the sample ID. Place the sampling card with the lid closed in the drying pouch and return to the laboratory.

