

Capitainer® B50

INSTRUCTIONS FOR USE

Valid for article numbers: 210-0005 (Single Device) and 210-0025 (25 pcs box)

Intended purpose:

Capitainer® B50 sampling card is used to collect and store a specific volume of capillary blood as a dried blood stain.

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 inlet on the card which measures it into 50 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® B50 sampling cards, Capitainer® Drying pouch*

Recommended materials, not provided by Capitainer:

Disinfectant swab, disposable lancet**, gauze, adhesive bandage, sample ID. 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 50µl of dried whole blood sample from a few 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:

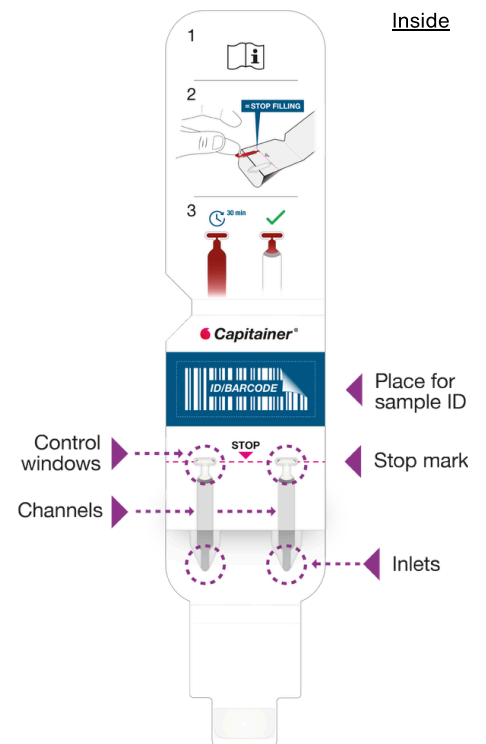
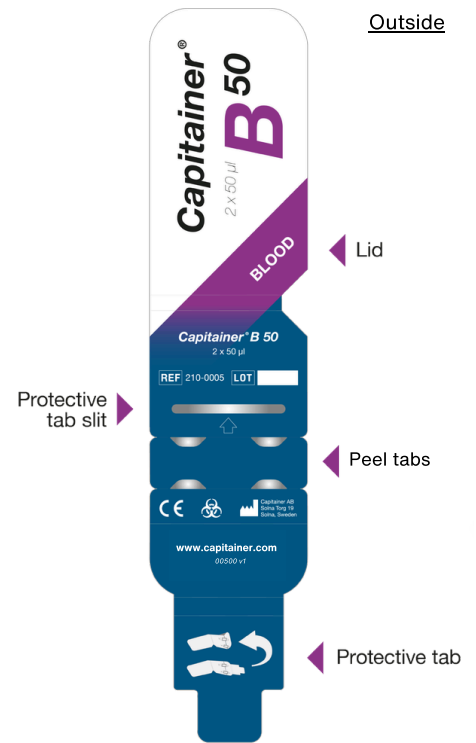
Storage conditions before use: temperature, 15°C to 28°C; relative humidity, 10% to 99%. Avoid direct sunlight and moisture. Unopened devices may be stored under the above conditions until the expiry date printed on the device packaging.

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.

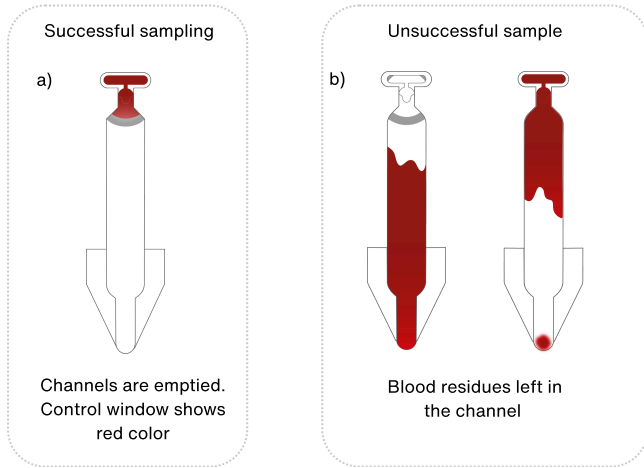
Cautions during sampling:

- Observe general precautions for blood sampling.
- Note that several drops of blood can be applied per channel until the stop line is reached. Applying more drops after reaching the stop line increases 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 inlets 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.



Sample preparations 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 control window is filled with blood, and there is no blood residual in the channel as shown in a) below:



Remove the peel tabs on the backside of the card to expose the sample discs. 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 which 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 products.
- 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.
- Do not bend or twist the card.
- BLOOD** Blood sampling.
- Place for sample ID.
- Quantitative blood sampling card 2 x 50µl.

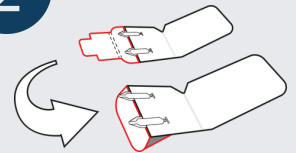
1



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 really warm.

2



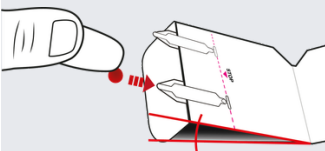
Create a stand

Open the lid of the sampling card. Fold the protective tab back and secure it in the slit on the backside of the card to create a stand. Place the card on a table so the inlets are elevated.

- Keep the card in this position during the whole sampling process.**

3

Blood application



Important step, read carefully!

Let a large blood drop form by itself. Wipe off the first drop. Approach the inlet tip sideways and touch the inlet with the second large blood drop. Make sure the blood enters into the channel and not on top of the channel.

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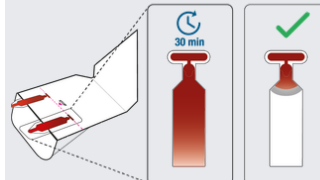


Continue application of blood drops **until** blood reaches the stop line. Remove the finger from the inlet and stop filling.

Do not reapply more blood.

Repeat blood application on the second channel.

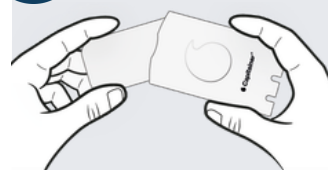
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Sample check

After blood application leave the card on the table. After 30 minutes, check the card: with successful sampling, the blood channels are emptied and only the control window is filled with blood as shown.

6



Sample return

If sampling is successful, mark the sampling cards with sample IDs. Unfold the stand and secure the protective tab with the adhesive seal in its original position. Close the lid and place the sampling card in the drying pouch. Return to the laboratory.

