

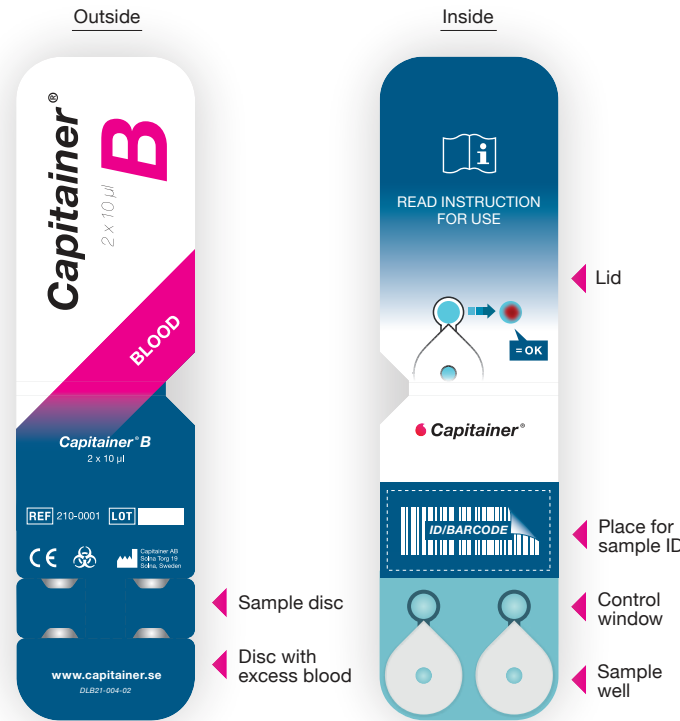
B

Capitainer®B

INSTRUCTIONS FOR USE

Applies to article number:
210-0001 one unit, 210-0050 50 units
www.capitainer.se

Capitainer®



Start ▶ Read the entire instruction before use!

Intended purpose:

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

Introduction:

The intended user is a healthcare professional or a Lay person. The sample is taken through a prick in the finger. A drop of blood is added to each sample well on the card and the channels measure the volume 10µl. When the channels are filled, they are automatically emptied on a paper disc. Sampling is performed correctly when the disc in the control window is colored red with blood. The lid is closed and the card is then placed in the associated return pouch. The sample can then be dried during transport to the laboratory where it is analyzed.

Provided by Capitainer:

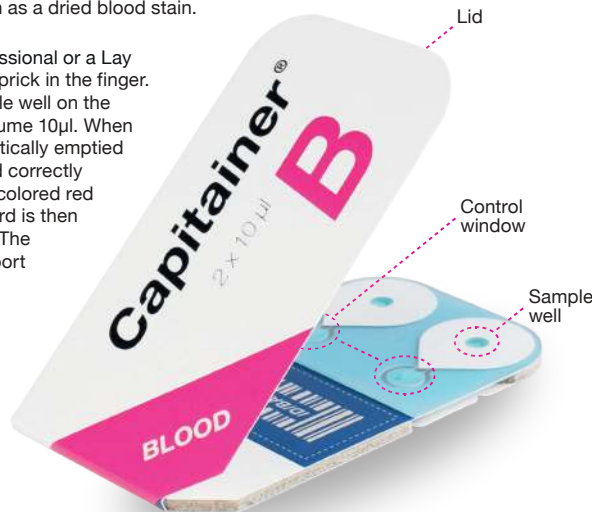
- (a) Capitainer®B Sampling card,
- (f) Capitainer®Return pouch*

Recommended materials, not provided by Capitainer:

- (b) disinfectant swab, (c) disposable lancet**, (d) gauze, (e) adhesive bandage, (g) sample ID

*Purchased separately.

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



| Symbol | Explanation |
|--------|--|
| | Read the enclosed instruction manual before use. |
| | Attention: Read the warnings and caution instructions in the instruction manual. |
| | Legal Manufacturer. |
| | The label shows that the product meets the requirements of IVD Regulation (EU) 2017/746. |
| | This product is intended for in vitro diagnostics. |
| | BATCH/Batch number. |
| | The product is intended for single use only. |
| | Product code. |
| | Expiration date (YEAR-MON-DAY). |
| | Indicates the appropriate temperature range for storage. Degrees Celsius. |
| | Do not use if the packaging is damaged. |
| | Indicates that there is a risk of biological contamination. |
| | Use the card within 30 minutes of opening the package. |
| | Do not bend or twist the card. |
| | Number of articles. |
| | Blood sampling. |
| | Place for sample ID. |
| | Quantitative blood sampling card 2 x 10µl. Prescription-only. |

Product specifications

Sample volume:

10µl per sample channel.

Material:

PET film, PVA film, Paper, Ahlstrom 222 and 270 DBS paper, Patent Blue VF.

Reproducibility:

Standard deviation less than 0.5 µl (CV < 5%).

Outliers:

Probability of overfilling or underfilling (deviation > 3 SD) < 0.1%. Risk of no sample: < 5%.

Use:

Temperature: 15°C to 35°C. Relative humidity: 15% to 90%. Hematocrit: 25% to 55%.

Storage:

Temperature: 15°C to 28°C. Relative humidity: 10% to 99%. For a shorter time, e.g. during transport. Temperature: -20°C to + 60°C. Avoid direct sunlight and being wet.

Sample storage:

The guidelines for sample storage is analyte dependent. Many analytes are stable for at least one month in the use climate.

Warnings and cautions ⚠

- Note that only one (1) drop of blood can be applied per sample well. More drops increase the likelihood of incorrect sample.
- Use the card within 30 minutes of opening the package.
- Do not touch the sample wells before sampling.
- Check that the date of expiration has not passed.
- Do not bend or twist the card.
- When removing the card from the package, handle it with clean hands.
- Use only the enclosed return pouch for storage and return after sampling.
- The product is only validated for use with fresh blood.
- The card is intended for indoor use only.
- Do not use at temperature or humidity outside specified range.
- Observe general precautions for blood sampling and handling of potentially infected blood.
- All used materials such as cards, lancets, gauzes, swabs with blood residues must be handled and disposed of safely and in accordance with local regulations.
- 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.

IVD

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REF DLB22-011-02D REV DATE: 2022-07-06

Capitainer®

Instruction for sampling

1

- Read the entire instruction before you start!
- Open all packages.
- Place all the material on a table.
- Mark the sampling card with sample ID (g).



(a) Capitainer®B sampling card



(b) Disinfectant swab



(c) Disposable lancet



(d) Gauze



(e) Adhesive bandage



(f) Capitainer® Return pouch

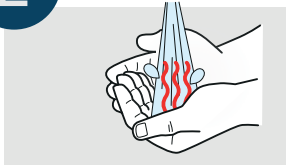


(g) Sample ID



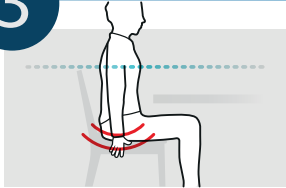
Use the QR code for instructional videos

2



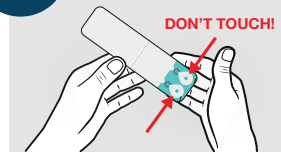
Wash your hands with soap and **warm** water. A clean and **warm** hand is crucial for easy sampling.

3



Sit down and allow your hands to hang at your sides. Shake them to increase blood circulation. Always keep your hands below your heart.

4



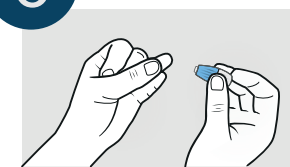
Open the lid of the sampling card (a) and place it on the table. Do not touch the sample wells on the card.

5



Choose a finger to prick, middle or ring finger. Then disinfect by wiping your finger with disinfectant swab (b) and allow to dry for 15 seconds.

6



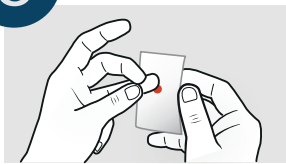
Remove the protective cover of the lancet (c). Gently press with your thumb to fill the fingertip with blood.

7



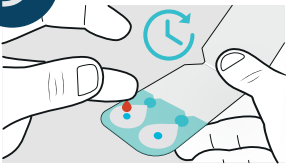
Prick the side of your fingertip by an assertive pressure to activate the lancet (c).

8



Release the pressure on the fingertip and wait a few seconds for the blood to appear. Wipe off the first drop with the gauze (d).

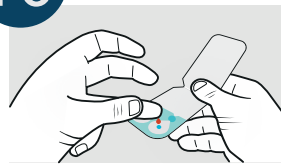
9



Important step, read carefully! Let a new **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.

Apply only **one** drop. *More drops may result in an incorrect sample.*

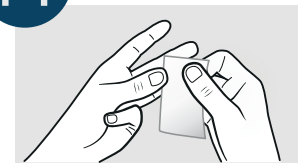
10



Important step, read carefully! Let a new **large drop** of blood form by itself. **Wait** for the drop to almost fall off by its own weight before applying it to the **second** sample well.

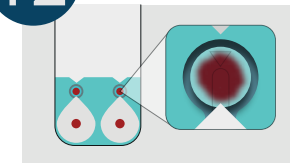
Apply only **one** drop. *More drops may result in an incorrect sample.*

11



Stop the bleeding with the gauze (d). Apply the adhesive bandage (e).

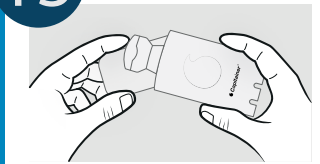
12



Check the sampling.

Upon successful sampling, the control windows should be filled with blood as shown in the picture.

13



If sampling is successful, ensure that sample ID (g) is in the designated place. Place the sampling card with the lid closed in the return pouch (f) and return to the laboratory.

If you have any questions, contact your healthcare provider.