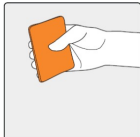
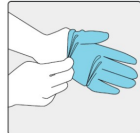


## Quick guide and Instructions for Use of the *Capitainer B*

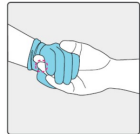


1. Heat cold hands. The patient's hand should be warm and relaxed, for a good blood flow. The heat source (for example heat pad or glove filled with warm water) should be at a temperature of about 42 degrees when placed directly against the skin. Take caution in patients with impaired sensation and those who, for other reasons, cannot assess what is too hot. The heat pad can reach 54 degrees and should have protective paper all around. Keep the hand low.

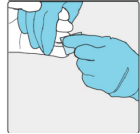


2. Wear gloves. Observe basic hygiene procedures for blood sampling.

3. Hold the patient's fingers firmly to prevent sudden movements



4. Choose the ring finger or the middle finger



5. Disinfect with Isopropanol and let air dry.

6. Stimulate the finger blood flow by pushing the thumb lightly from the outer finger joint and towards the fingertip.

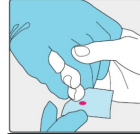


7. Place the lancet against the patient's fingertip and stick to the side of the finger. Release the pressure of the grip immediately after the stick so that the blood can flow.

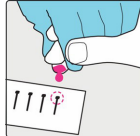


8. Wipe away the first droplet of blood with a gauze, as the first drop may contain an unknown amount of intracellular fluid.

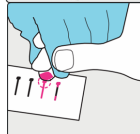
9. Lower the hand to increase blood flow. Turn the hand so that the hand points downwards and let the drop hang down against the channel inlet. It is important to get a large hanging drop.



10. Press your thumb and forefinger lightly from the outer joint to the fingertip. Release. Repeat until you get as much blood as is needed. Do not push too hard, pull or milk. It may cause hemolysis and lead to an increased amount of intracellular fluid.



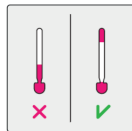
11. When a large hanging drop is formed, let it touch the input on the card by carefully holding the finger against the opening. Not too hard, since the input channel can be blocked. Hold the finger against the opening until you see the channel filled.



12. Make sure the channel filled up and worked properly.

Repeat from point 10 to fill as many channels as requested.

Take your sample as soon as possible so that the blood does not start to coagulate.



References;  
 Vårdhandboken.se .  
 WHO guidelines on drawing blood: best practices in phlebotomy.

 **Capitainer**

Instructions for use

Revision: 3 EN, 2018-11-01

### Intended Use

The device is intended to be used by healthcare professionals, to collect volume-defined blood spot samples in the microliter range. The sample is stored in the device for future examination, in the form of a dried blood spot. By finger prick techniques, a whole blood droplet is allowed to contact the device at the defined point and by that apply sufficient amount of whole blood to the inlet portion of the device.

### Indications for Use

The Capitainer B sample card is intended for the collection and storing of a whole blood sample as a dried blood spot in a cotton DBS paper for further analysis in lab, to determine the quantitative presence of any targeted compound. A blood drop from a finger prick of about 20 – 80µl shall be applied to each inlet portion of the device. When the channels are filled, the card must be closed and put in the supplied return pouch. The sample will then dry in the pouch. The Return pouch can be dispatched to the Lab.

### Contra indications

The Capitainer B card is only Validated for blood. Only use freshly drawn blood. Other substances should not be used. The Capitainer B card is intended for indoor use only, excessive as well as very low temperature and/or low humidity shall be avoided. Since there is a small risk for over/under sampling, the device is not considered for clinical diagnosis assays, or appropriate precautions shall be taken.

### Safety notices and precautions

- Make sure to use the card within 30 min from opening the moisture barrier bag.
- Avoid touching the inlet portions of the card to minimize the risk of contamination.
- General precautions for blood handling shall be taken.
- Check that the expiry date has not passed.
- Don't bend the card
- Use clean hands and or gloves to handle the card.
- Any material, card, lancet, gauze or swabs with residuals of blood may carry contaminants and should be disposed of in safe controlled way, according to local regulations.
- Use only the provided Return Pouch for the drying and return.

### Explanation of used symbols



Notification to read the User manual



Attention: Read all warnings and precautions in the instructions for use



Responsible manufacturer



This Product is certified to comply with the EU IVD Directive 98/79/EC



This device is an IVD product



LOT / Batch number



The device is intended for Single use



Handle with care, do not bend.



Product type identifier



Expiry date



Indicates acceptable temperature range for storage. Deg. C.



Do not use if package is broken



Indicates that there is a potential risk of biohazard.



Use the card within 30min from opening of the bag



Do not bend or fold the card.

### Handling of the Capitainer B card

1. Prepare the all the equipment needed for the sampling.
  2. Use a single use, contact-activated lancet, preferably a type with a wider (1,5mm) and deeper (2mm) cut, to get a sufficient amount of blood, without having to squeeze.
  3. Open the moisture barrier bag by the tear notch to take out the Capitainer B card.
  4. Prepare the subject for the sampling.
  5. Unfold the card. Avoid touching the inlets marked with circles.
  6. When having a sufficient amount of blood (a good droplet, 20-80µl) available on the finger, apply it to the channel inlet, touching it lightly, without pressing, and subsequently remove the finger to extract more blood for next channel.
  7. Continue for as many channels that you are required to fill.
  8. When the channels have been filled properly, they will automatically empty into the collector pad.
- NOTE:** If the channel can't fill or empty properly; either not enough blood is applied, or the channel is malfunctioning. Continue with another channel. Do not attempt to refill the channel.
8. After the procedure, the card should be closed and sealed on the back side with a sticker, preferably a test identifying bar code label.
  9. Open the Return Pouch and insert the closed Capitainer B Card. The Return Pouch is ventilated and will allow water to evaporate from the blood, to create a Dry Blood Spot.
  10. Make sure to close the Return Pouch properly.
  11. The Capitainer B card can now safely be dispatched to the analysing laboratory.

### Functioning method

When a sufficient amount of blood is applied to the inlet portion of the device, the microchannel is automatically filled with blood through capillary action. A dissolvable valve at the inlet is activated. When the microchannel is filled, a similar dissolvable valve at the end of the microchannel is also activated. Because of the time-lag of filling the microchannel, the inlet valve opens first, causing the excess blood to empty into a waste paper. This action causes the blood in the microchannel to detach. Consequently, the microchannel contains a geometrically controlled volume of blood. Once the valve at the end of the microchannel opens, the blood gets absorbed into the outlet paper pad. As the blood in the paper dries, a Dried Blood Spot with a pre-defined volume is generated.

### Performance specification

The Capitainer B card collects a specific volume of 13,5 µl whole blood in a cotton paper matrix.

*Reproducibility:* Less than 0,7µl as one Standard Deviation (SD), (CV< 5%).  
*Outliers:* Rate of over or under-sampling (Deviation > 3 SD) <0,1%

### Usage and storage conditions

The performance is valid under the following conditions:

*Operating Conditions:*  
Temperature range: +15°C to +35°C.  
Relative Humidity range: 15% to 90%  
Hematocrit value: 25% - 55%

**CAUTION:** The Card must be used within 30 min from opening the package

*Storage Conditions:*  
Temperature range: +2°C to +40°C.  
Relative Humidity range: 10% to 99%  
Shelf life: One year from manufacturing

*Transport:*  
For a limited period, e.g. during shipping;  
Temperature range: -20°C to +60°C.  
Keep away from direct sunlight and rain.

*DBS sample storage:*  
The finished and dried samples can be stored under operating conditions for at least one month: (This may depend on analyte and should be validated by the responsible lab)

### Technical specifications

*Type:* Capitainer B  
*Article number:* 18-01-001  
*Materials:*  
PET films, Paper, Ahlstrom grade 222 and 270 DBS paper, Pouch; Paper  
Card Size: 83 x 53 x 3 mm

*Nominal sampled blood volume:*  
Determined by the channel geometry: 13,5 µl

Dispose according to local regulations.  
Take care with blood stained materials and sharps.

*Responsible manufacturer:*  
Capitainer AB  
Norr Mälarstrand 54  
112 20 Stockholm, Sweden

*For support contact;*  
Capitainer AB  
Norr Mälarstrand 54  
112 20 Stockholm, Sweden  
info@capitainer.se / www.capitainer.se