

Instructions For Use (IFU) – Capitainer®qDBS

Intended Use

The device is intended to be used by a health care professional or anyone with appropriate training, to be used with assistance, or for self-sampling, to collect and produce accurate volume-defined blood samples in the micro liter range, from the subject individual. The sample is stored in the device as dry blood spot on a paper matrix for future examination.

Description

The sample card is for collection and storing of a capillary whole blood sample, as a dried blood spot in a cotton DBS paper, for future analysis in a lab. The sample can be used to determine the quantitative presence of any targeted compound. A blood drop of about 18µl-50µl from a finger prick of shall be applied to each inlet port of the device. The sample is correctly received when the outlet disc changes colour. When this is confirmed, the card must be closed and put in the supplied return pouch for drying. The Return pouch can be dispatched to the Lab. Use of the Capitainer®qDBS in Laboratory Developed Tests (LDTs) requires the establishment of performance characteristics and successful validation by the laboratory, consistent with local regulations.

Contra indications

The Capitainer®qDBS card is only validated for blood. Only use freshly drawn blood. Other substances should not be used. The Capitainer®qDBS card is intended for indoor use only, excessive as well as very low temperatures and/or low humidity shall be avoided. The device is not considered for clinical diagnosis assays, or appropriate precautions shall be taken.

Functioning method

When a sufficient amount of blood is applied to the inlet port 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 wastepaper. This action causes the blood in the microchannel to detach from the inlet blood volume. Consequently, the microchannel contains a geometrically controlled volume of blood. Once the

valve at the end of the microchannel opens, the blood will be absorbed by the outlet paper pad. As the blood in the paper dries, a Dried Blood Spot with a pre-defined volume is formed.

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.
- General best-praxis regarding capillary sampling must be considered.
- 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.

Handling of the Capitainer®qDBS card

1. Prepare 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®qDBS card.
4. Prepare the subject for the sampling, clean the puncture site.
5. Unfold the card. Avoid touching the inlets marked with circles.
6. When having a sufficient amount of blood (a good droplet, 18-50µl) available on the finger, apply it to the channel inlet,

touching it briefly once, without pressing, and subsequently remove the finger to extract more blood for next channel.

7. When the channels have been filled properly, they will automatically empty into the collector pad.
 8. Confirm that the card worked properly by checking that the exit area for the blood turns dark. (This is the DBS disc that fills with the blood).
- NOTE:** If the channel can't fill or empty properly; either not enough blood is applied, or the channel is impaired. Continue with the next channel or a new card. Do not attempt to refill the channel.
9. After the procedure, the card should be closed and sealed on the back side. Add a test identifying barcode label.
 10. Open the Return Pouch and insert the closed Capitainer®qDBS Card. The Return Pouch is vented and will allow water to evaporate from the blood, to create a Dried Blood Spot.
 11. Make sure to close the Return Pouch properly.
 12. The Capitainer®qDBS card can now safely be dispatched to the analyzing laboratory.

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Explanation of used symbols

	Notification to read the User manual
	Attention: Read all warnings and pre- cautions 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. Degrees Celsius
	Do not use if package is broken
	Indicates that there is a potential risk of biohazard
	Use the card within 30 minutes from opening of the moisture barrier bag
	Do not bend or fold the card

Performance specification

The *Capitainer®qDBS* card collects a specific volume of 10 µl whole blood in a cotton paper matrix.

Reproducibility:

Better than 0,5µl as one Standard Deviation (SD), (CV< 5%)

Outliers:

Rate of over or under-sampling (with a deviation > 3 SD) <0,1%

Non-sampling: < 5%

Usage and storage conditions

CAUTION:

The Card must be used within 30 minutes from opening the package, due to sensitivity to low Relative Humidity.

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%

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 should be stored under operating conditions, the time may depend on analyte and should be validated by the responsible lab.

Technical specifications

Type: Capitainer®qDBS

Article numbers: 18-01-001 Single device

18-01-002 50pcs

Materials:

PET films, Paper, Ahlstrom grade 222 and 270 DBS paper Pouch; Paper

Card Size:

78 x 43 x 3 mm

Nominal sampled blood volume:

Determined by the channel geometry: 10 µl

Dispose according to local regulations.

Take care with blood stained materials and sharps.

Responsible manufacturer:

Capitainer AB

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171 45 Solna, Sweden

For support contact:

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Regulatory information

The device is registered with the FDA as Device Class 1, exempt from premarket notification. The Product code is NNK. It is for specimen collection and transport, not specific for any clinical test and not intended for diagnostic procedures. Listing number D355892.