

INSTRUCTIONS FOR USE

TFN-Specimen Collection Card

1. Product Description and Intended Use

Ahlstrom-Munksjö TFN-Specimen Collection Cards are sample vessels developed for the collection, transport and storage of human whole blood samples.

The cards are used as specimen collection devices with the object in preparing dry blood samples (DBS) for in vitro diagnostic tests.

TFN-Specimen Collection Cards are manufactured with the filter paper Ahlstrom-Munksjö TFN. The filter paper is made of pure, absorbent liners and is designed as dried specimen storage reservoir.

The product fulfills all essential requirements of the European Directive 98/79/EC. A Declaration of Conformity according Directive 98/79/EC, Annex III can be obtained by the manufacturer.

2. General Warnings and Precautions

- For hygienic reasons always wash your hands and wear powder-free gloves before handling TFN-Specimen Collection Cards!
- Change gloves between each new sample!
- Do not touch the filter paper without gloves because oils and other materials from hands might affect or contaminate the specimen collection device!
- Do not touch sample collection area!
- Biological samples are potentially infectious. Follow universal precautions when handling biological specimens!
- Do not use spoiled or damaged cards or cards from damaged boxes!
- Product is for single use only! In case of multiple uses, e.g. blood droplet on an already dried blood spot the product performance is no longer guaranteed!
- Product is for in vitro diagnostics only.
- Anti-coagulants, especially EDTA and citrate can cause interference with some test assays!
- Do not allow water, feeding formulas, antiseptic solutions, glove powder, hand lotion or other materials to come into contact with the filter paper segment or specimen collection device (card) before or after use!
- Avoid using disinfectants (hexachlorophene, povidone-iodine, etc.) due to possible interferences with the screening analysis only!
- For cards with printed circles on both sides, the blood may only be applied on one side of the card!
- The sample collection must be carried out in accordance with the instructions for blood sampling!

3. Instructions for Blood Collection

- a) Assemble all necessary materials and put the card on a clean, dry and flat surface.
- b) Label the card accordingly for clear sample identification.
- c) Avoid direct body contact. The paper should not touch the skin of the person being examined.
- d) Select prick site and clean the selected area of skin with alcohol swab and allow to air dry for 30 seconds.
- e) To achieve sufficient flow of blood, prick the finger or heel. Use a sterile lancet to prick at a depth of 1.0 – 2.0 mm. Point the prick site down.
- f) While holding the finger or the foot correctly, apply and release pressure to allow a drop of blood to form.
- g) Wipe away first blood drop.
- h) Drop the blood onto the card at the center of a printed circle area. The drop will quickly spread and soak in. Make sure that the circular sample collection areas are completely soaked with blood (front and back).
- i) Blood sample must be applied from the front side only.
- j) Allow the blood samples to dry completely for at least 3 hours at ambient temperature (18-25 °C). To avoid cross-contamination during the drying process, place the cards so that the blood spots from different cards do not touch each other. Do not dry the cards with heat or direct exposure to sunlight to shorten the drying time. High humidity (>50 % relative humidity) may cause longer drying time.
- k) Dried blood spots appear darker than freshly spotted ones.
- l) When the blood spot is dry, the sample is ready for downstream analysis, or it can be packaged for transport or storage at room temperature.

4. Scope of Delivery

Parts included in the package are only the TFN-Specimen Collection Cards and the Instructions for Use. All other materials which are needed for the blood collection such as gloves, lancets, swabs and shipping bags must be provided separately, and are not included in the package.

5. Storage of unused cards

- Store unused cards in their original packaging, protected from moisture and contaminations.
- The expiry date is indicated on the product or packaging. If stored in the original package (opened or originally closed) the test card will remain viable for up to 3 years.
- Opened packages must be closed again so that the product is protected.

6. Storage of used cards with dried blood

- To avoid cross-contamination during drying and storage, the cards should be stacked so that they not touch each other.
- As humidity and UV light can damage the dried blood spots, always keep the cards in zip-lock bags or other protective envelopes with desiccant, in the dark.
- The performance for long-term storage of the specimen collection device should be validated by the testing site.

7. Transport of unused cards

- Make sure that the TFN-Specimen Collection Cards are not being compressed during transport. Do not ship it with chemicals.
- Transport in the original packaging is recommended.

8. Transport of used cards with dried blood

- The dried blood specimens should be transported or mailed to the laboratory as soon as the sample is dried.
- Biological samples are potentially infectious. Special precautions must be taken during transport. Please follow local postal, courier and other transport regulations.
- The cards should be separated from each other during transport by barriers such as protective envelopes or parchment paper. Direct sample-sample contact is not appropriate and cross-contamination can occur.
- Do not use plastic bags or other airtight transport containers. If local regulation require enclosure in airtight, leak-proof sealed containers please include a sufficient number of desiccant packages.
- Do not ship the cards with chemicals or other samples.

9. Disposal of unused cards

- Disposal of the product must be in accordance with local statutory regulations. Disposal of the filter paper test cards follows the European Waste Catalogue (EWC).
- Collection and disposal of these wastes are not subject to special requirements for infection prevention reasons (EWC 20 01 01 / EWC 18 02 03).

10. Disposal of used cards with dried blood

- Collection and disposal of these wastes are subject to special requirements for infection prevention reasons (EWC 18 02 02).

Legende/Legend/Légende

	Nicht zur Wiederverwendung Do not reuse Ne pas réutiliser
LOT	Chargenbezeichnung Batch Number Numéro de lot
REF	Artikelnummer Product Number Code produit
	Bitte Gebrauchsanweisung beachten Please note the manual Merci de lire les instructions d'utilisation
IVD	Einsatz für die In-vitro-Diagnostik In vitro diagnostic device Dispositif médical de diagnostic in vitro
	Hersteller Manufacturer Fabricant
	Haltbarkeit Shelf life Durée de vie
	Biologische Risiken Biological Risk Risque biologique
	Vor Feuchtigkeit schützen Protect from moisture Protéger de l'humidité
SN	Seriennummer Serial Number Numéro de série
CE	CE-Kennzeichnung CE-Mark Marquage CE

Erscheinungsdatum/Release Date/
Date de révision: 04.09.2019

Revision/Revision/Révision: 08

Hersteller/Manufacturer/Fabricant **Ahlstrom-Munksjö Germany GmbH**
Niederschlag 1
09471 Bärenstein, Germany



Phone: +49 (0) 37347 83-0
Fax: +49 (0) 37347 83-64
E-Mail: info@ahlstrom-munksjo.com
diagnostics@ahlstrom-munksjo.com
Homepage: www.ahlstrom-munksjo.com

Learn more: www.ahlstrom-munksjo.com