In-vitro diagnostic device CE IVD

GK-20

micro vials with sample transport medium

	Please read the following instructions carefully before using the GK-20 device!

Contents

1 Introduction

GK-20 is a micro vial with sample transport medium. It is intended for use by healthcare professionals in combination with other products listed in these instructions for use.

This *in-vitro* diagnostic device (IVD) is a secondary sample container into which an EDTA-coated glass capillary filled with 20 µL of capillary whole blood is placed. The sample transport medium ensures optimal storage conditions, analyte stability, and shipment free of contamination. Due to its dimensions, the storage tube allows easy and safe sample handling for later analysis, even if the glass capillary within the vial is broken off.

The sample transport medium lyses the blood cells in the collected EDTA whole blood sample, inactivates enzymes, and stabilizes volatile analytes. It has a bactericidal and at least limited virucidal effect.

2 Guidelines and recommendations

CLSI GP42 (Ed7E)	Collection of Capillary Blood Specimens (7th Edition)
CLSI GP42-A6	Technique for Skin Puncture in Adults and Older Children Quick Guide
Download Practical Guide GK-20	Preanalytical laboratory service - Standardized capillary blood sampling – GK-20 https://laborpraxis-dessau.de/qualitaetsmanagement

3 Product information

GK-20 is an *in-vitro*-diagnostic device for collecting a defined capillary blood volume from the fingertip or earlobe according to the currently applicable guidelines (CLSI GP42-A6).

3.1 IVD name/trade name

GK-20 micro vial with sample transport medium

3.2 Classification of the in vitro diagnostic medical device and its components

GK-20 is assigned to **Class A**.
It consists of the following components: micro vial with sample transport medium

3.3 Intended purpose

GK-20 is used for the collection and shipment of 20 µL EDTA whole blood for the analysis of drugs, medications, and alcohol biomarkers.

3.4 Principle of the device

GK-20 is a secondary sample tube in which a capillary filled with capillary whole blood is placed. The sample transport medium ensures optimal storage conditions, analyte stability, and shipment free oft contamination. Due to its dimensions, the storage tube enables easy and safe sample handling for later analysis, even if the glass capillary in the tube is broken off.

3.5 Intended user

The device is used by healthcare professionals for taking samples from patients, in combination with other products listed in these instructions for use.

3.6 Description of restrictions, interfering substances, or limitations

The 20 µL glass capillaries must always be filled and free of air bubbles with capillary whole blood when placed into micro vial with sample transport medium. Only one 20 µL glass capillary may be placed in a micro vial, which must be clearly labelled, e.g., with a barcode. After transferring the 20 µL glass capillary, the micro vial must be tightly closed and shaken several times vigorously. The micro vial may only be opened briefly.

3.7 Description of components

The micro vial is a 2.0 mL polypropylene vial with a screw cap and sealing ring (O-ring). It is filled with 240 µL of the sample transport medium.

The sample transport medium is a buffered isopropanol-water-mixture with adjusted pH (75.8% isopropanol, 24.2% aqueous pH stabilizer).

3.8 List of required materials

Materials required but not provided with the product to safely perform sampling:

- Disinfectant

Standard measures for disinfection similar to intravenous sampling.

- Sterile disposable safety lancet with blade

Using the sterile disposable safety lancet with blade (BD Microtainer Safety Lancet, Catalogue Number: 366594) by Beckton Dickinson is recommended. The lancets may be ordered from MVZ Medizinische Labore Dessau Kassel GmbH.

- EDTA-coated glass capillary (20 µL)

An EDTA-coated glass capillary (20 µL) (End-to-End Capillary 20 µL, 1.3 mm, Catalogue Number: 19.447.001) by Sarstedt AG & Co. is recommended. CE-marked (according to IVDR) capillaries with the same exact specifications and intended purpose may be used after consultation with the MVZ. The recommended capillaries may be ordered from MVZ Medizinische Labore Dessau Kassel GmbH.

- Glass capillary holder

Using the glass capillary holder (Capillary Holder for end-to-end capillaries, Catalogue Number: 061601) by Sarstedt AG & Co. is recommended. The holder may be ordered from MVZ Medizinische Labore Dessau Kassel GmbH.

- Gloves and suitable clothing to protect against blood-borne pathogens.
- Band-aids or dressings
- Dry swabs
- Disposable container for biologically hazardous substances
- Barcode labels

3.9 Limitations when combined with other products

When using products other than the recommended end-to-end EDTA-coated glass capillaries (IVD products), it is essential to use a capillary with a fill volume of 20 µL. Otherwise, the determined analyte concentration will be invalid.

3.10 Storage and handling conditions

Store the micro vial with sample transport medium at 4-30°C. Avoid exposure to direct sunlight. Exceeding the recommended maximum storage temperature may lead to a deterioration of the quality of GK-20 (discoloration, alteration of sample transport medium, etc.).

The expiry date of GK-20 is listed on the product packaging.

Please note that only one 20 µL glass capillary filled with capillary blood may be placed into the micro vial at a time. After transferring the 20 µL glass capillary, the micro vial must be tightly closed and shaken several times vigorously. The micro vial should only be opened briefly.

It is recommended to follow the order of capillary blood collection described in the CLSI GP42-A6 guidelines.

3.11 Shelf-life after opening

After the first opening (removal of the screw cap) of the micro vial, the 20 µL glass capillary filled with capillary whole blood must be transferred immediately into the micro vial, re-closed with the screw cap provided for this purpose, and shaken (5x). Once opened, the micro vial must either be used as intended or discarded. The micro vial is designed for single use only.

The shelf life of the sample transport medium in the unopened micro vial is 6 months.

After transferring the glass capillaries filled with the sample into the micro vial, close it tightly with the screw cap to ensure no liquid is spilled.

3.12 Warnings, precautions, and measures

It is recommended to follow the capillary blood collection sequence described in the CLSI GP42-A6 guideline.

Avoid exposure to direct sunlight.

Do not use if the packaging is damaged. Do not use if the screw cap of the single micro vial is loose.

The IVD is intended for single use only.

3.12.1 Specimen transport medium

The micro vial contains 240 µL sample transport medium consisting of 75.8% isopropanol and 24.2% aqueous pH stabilizer.

Hazard statements:
H225: Highly flammable liquid and vapour.
H319: Causes serious eye irritation.
H336: May cause drowsiness or dizziness.

Precautionary statements:
P210: Keep away from heat, hot surfaces, sparks, open flames, and other ignition sources. No smoking.
P240: Ground and bond container and receiving equipment.
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present, and easy to do. Continue rinsing.
P403+P233: Store in well-ventilated place. Keep container tightly closed.

3.13 Disposal

All products used and any required accessories should be disposed of in accordance with national and local disposal procedures.

Disposing of used swabs and lancets in a biohazard disposal container is recommended.

Unused or expired micro-sample tubes may be returned to the laboratory for proper disposal.

3.14 Potentially serious adverse incidents

All serious adverse incidents (defined according to Regulation (EU) 2017/746) related to the product must be reported to the manufacturer and the responsible authorities.

Please note: In accordance with IVDR, Article 2, a ”Serious Incident“ is an incident that has led to, could have led to, or may lead, directly or indirectly, to any of the following consequences:
a) the death of a patient, user, or other person,
b) the temporary or permanent severe deterioration of a patient’s, user’s, or other person’s state of health,
c) a serious risk to public health.

4 Contact details

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5 Labelling/Symbols

The symbols in these instructions for use are based on the standards DIN EN ISO 15223-1:2022 and (EG) 1272/2008 CLP.

	Use by/Expiration date
	Temperature limitation
	Consult instructions for use
	Attention
	In vitro diagnostic medical device
	Batch code
	Catalogue number
	Unique device identification

	Do not use if package is damaged and consult instructions for use
	Country of manufacture
	Protect from sunlight
	CE mark
	GHS07 Attention Toxic Cat. 4 (Harmful) Corrosive or irritant effect Cat. 2 Low systemic health hazard
	GHS02 Danger or caution Flammable

6 Amendments

Reversion 01: Instructions for use created.