In-vitro diagnostic device CE IVD

GK-20P

vial for the preparation of plasma from capillary whole blood

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

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1 Introduction

GK-20P is a sample container. It is intended for use by trained healthcare professionals or other appropriately trained individuals in combination with other products listed in these instructions for use.

This *in vitro* diagnostic device (IVD) is a primary and a secondary sample container. In the primary sample container, capillary whole blood is collected in an EDTA-coated capillary and and sealed at the bottom with a special wax. The primary sample container (the wax-sealed capillary) is placed into a glass vial, which acts as the secondary sample container.

The EDTA coating inside the capillary prevents the blood sample from clotting.

Due to its dimensions, the sample container allows easy and safe handling of the sample for subsequent centrifugation for plasma preparation.

2 Guidelines and recommendations

CLSI GP42	Collection of Capillary Blood Specimens
CLSI GP42-A6	Technique for Skin Puncture in Adults and Older Children Quick Guide
Download Practical Instructions	Laboratory Preanalytics - Standardized Collection of a Plasma Capillary Blood Sample (https://www.labor-dessau-kassel.de/unser-labor/qualitaetsmanagement/)

3 Product information

GK-20 P is an *in vitro* diagnostic device for the collection and transport of 20 µL EDTA-coated capillary whole blood for the preparation of plasma.

3.1 Name/trade name of the IVD

GK-20P vial for the preparation of plasma from capillary whole blood

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

GK-20 P is assigned to **class A**.

It consists of the following components:

- Storage container with 1 wax plate (2mm thick)
- GK-20P glass vial with glass insert and spring, screw cap with sealing disc
- GK-20P transport box
- Packaging

3.3 Purpose

GK-20P is used to collect and transport 20 µL EDTA capillary whole blood for the preparation of plasma.

3.4 Function

GK-20 P is a product designed and intended for the collection and transport of 20 µL EDTA-coated capillary whole blood for the preparation of plasma.
The capillary whole blood sample is transferred in an EDTA-coated glass capillary. The wax plate in the storage container is used to seal the capillary filled with capillary whole blood. To do this, the filled capillary is pressed down through the wax layer. The wax plug, approximately 2 mm in size, serves to seal the glass capillary at the bottom. The sealed glass capillary is then placed into the glass vial, in which the labelled sample can be transported safely and securely.

3.5 Intended user

The device is to be used by trained healthcare professionals or other appropriately trained persons 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 placed into the glass vials completely filled with capillary whole blood and free of air bubbles. Only one 20 µL glass capillary may be placed in each glass vial for transport at any one time; the vial must be clearly labelled beforehand, e.g. with a barcode. Once the 20 µL glass capillary has been transferred, the glass vial must be sealed tightly.

3.7 Description of ingredients

The GP-20P sample container is a 1.5 mL glass vial with a screw cap and sealing disc, as well as a glass insert with a spring.

The storage container with one wax disc (2 mm), which is required to seal the glass capillary. The wax plate is covered with a protective film, which must be removed before use.

The transport box is a polypropylene box with snap closure and 50 cavities (Best.Nr.: NY15.1, Carl Roth)

3.8 List of required materials

Materials required for carrying out and safely performing the sampling procedure, but not supplied with the product:

- Disinfectants

Standard disinfection procedures as for intravenous sampling.

- Sterile disposable safety lancet with blade

It is recommended to use the sterile, single-use safety lancet with blade (BD Microtainer safety lancet, catalogue number: 366594) from Becton Dickinson. The lancets can be ordered from MVZ Medizinische Labore Dessau Kassel GmbH.

- EDTA-coated glass capillary (20 µL)

It is recommended to use the glass capillary (20 µL), EDTA-coated (end-to-end capillary 20 µL, 1.3 mm, catalogue number: 19.447.001) from Sarstedt AG & Co. Capillaries with the same specifications and intended use, and bearing the CE mark (in accordance with the IVDR), may be used where appropriate, subject to consultation with the MVZ.
The recommended capillaries can be ordered from MVZ Medizinische Labore Dessau Kassel GmbH.

- Glass capillary holder

It is recommended to use the glass capillary holder (capillary holder for end-to-end capillaries, catalogue number: 061601) from Sarstedt AG & Co. The holders can be ordered from MVZ Medizinische Labore Dessau Kassel GmbH.

- Gloves and suitable clothing to protect against blood-borne pathogens
- Plasters or dressings
- dry swabs
- Waste containers for biohazardous materials
- Barcode labels

3.9 Limitations when combined with other products

If using glass capillaries (IVD product) other than the recommended end-to-end EDTA-coated ones, it is essential to use a capillary with a filling volume of 20 µL; otherwise, the determined analyte concentration will not be valid.

3.10 Storage and handling conditions

Always store the containers holding the wax discs with the lids securely closed at 15–30 °C. The container must be resealed immediately after use. A single wax disc can be used for several capillaries.

It is essential to take care to avoid cross-contamination. The maximum expiry date of the wax disc must be strictly observed.

Exceeding the recommended maximum storage temperature or failing to comply with the handling conditions set out above may impair the quality of GK-20P or the plasma sample obtained from it, and may affect analytical results!

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

Only one 20 µL glass capillary filled with whole blood may be placed in a glass vial at any one time. Once the 20 µL glass capillary has been transferred, the glass vial must be tightly sealed.

It is recommended that the sequence of capillary blood sampling be followed in accordance with the CLSI GP42-A6 guideline.

3.11 Shelf life after opening

After opening the glass vial for the first time (removing the screw cap) for transport, the 20 µL glass capillary filled with whole blood must be transferred immediately into the glass vial and resealed with the screw cap provided.

Once opened, containers such as the glass vial or storage vials (with or without wax) must either be used as intended or discarded. The glass vial is intended for single use only.

The shelf life of the GK-20P vials for the preparation of plasma from capillary whole blood in the unopened state is 12 months.

After transferring the glass capillary filled with capillary whole blood into the glass vial, it must be tightly closed again with the screw cap to ensure that the sample is protected.

3.12 Warnings, Cautions and Measures

It is recommended that the sequence for capillary blood collection be followed in accordance with 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 individual glass vial or the storage box, with or without wax, is loose.

This IVD is intended for single use only.

3.13 Disposal

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

It is recommended that used medical products, in particular used lancets, be disposed of in a waste container for biohazardous materials.

Unused or expired product components, such as storage containers with or without wax or glass vials, can be returned to the laboratory, where they will be disposed of appropriately

3.14 Serious incidents that occur

All serious incidents occurring in connection with the product (as defined in Regulation (EU) 2017/746) must be reported to the manufacturer and the competent authority.

Note: According to Article 2 of the IVDR, a ‘serious incident’ means an incident which, directly or indirectly, has had, could have had or might have the following consequences:
a) the death of a patient, user or other person,
b) the temporary or permanent serious deterioration in the state of health of a patient, user or other person,
c) a serious threat to public health

4 Contact

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5 Marking/Symbols

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

	Usable up to
	Temperature limitation
	Follow the instructions for use
	Caution
	In vitro diagnostics device
	Batch designation
	Catalogue number
	Unique product identification
	Do not use if packaging is damaged and follow instructions for use
	Country of manufacture
	Protect from sunlight
	CE mark

6 Modification information

Reversion 01: Instructions for use created