

Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 1614112-1

Organization: KABE-Labortechnik GmbH
Jägerhofstr. 17
51588 Nümbrecht
Germany

Scope: Design and development, production and distribution of in vitro diagnostic devices and consumption materials for sample withdrawal, preparation and storage as well as single-use medical devices

TÜVRheinland

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 1092786-40
Effective date: 2021-10-25
Expiry date: 2024-10-15
Issue date: 2021-10-25



Dipl.-Ing. F. Schwingen
TÜV Rheinland LGA Products GmbH
Lillystraße 2 · 90431 Nürnberg · Germany



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The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o KABE-Labortechnik GmbH Jägerhofstr. 17 51588 Nümbrecht Germany	Design and development, production and distribution of in vitro diagnostic devices and consumption materials for sample withdrawal, preparation and storage as well as single-use medical devices
/02	c/o KABE-Labortechnik GmbH Werner-von-Siemens-Str. 1 51674 Wiehl Germany	Warehouse

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Capillary Blood Collection



The Capillary Blood Collection GK
with accessories
by KABE LABORTECHNIK

Quality, reliability and consistency since 1977!



Drawing on our long years of experience in medical technology, KABE LABORTECHNIK develops and produces high-quality consumables for the daily work in clinic, medical practice and laboratory. At the same time, it is our aim to offer our customers and partners innovative and optimal solutions that make every day work simpler, safer and more efficient.

Perfection right down to the smallest detail, hygienically immaculate conditions and a consistent quality management have the highest priority in manufacturing our products. Our quality management system, established on the international standard DIN EN ISO 13485 is constantly reviewed by our notified body and authorises us to label our products with the CE mark. Although our products are mass-produced, each item is subjected to the high requirements of a made-to-order production.

As varied the duties are in which our products are put to use, as manifold is our product range. This brochure provides you with a comprehensive overview of our product range of the capillary blood collection GK.



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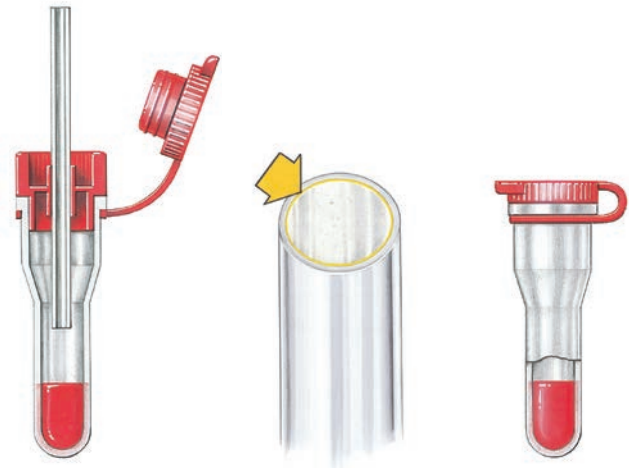
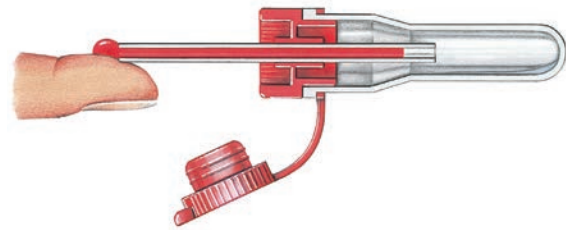
Capillary blood collection GK

For the capillary blood collection of KABE LABORTECHNIK, which was developed as an addition to the venous blood collection systems, smallest sample quantities are sufficient. The system offers special advantages for the collection of blood samples from babies, children, elderly people and emergency patients, thus everywhere, where only small amounts of blood are available.

The test vessel is prepared on the entire inner surface. Besides it can be used as centrifugal vessel. The dimension of the vessel ensures that by use of commercial pipettes and pipette tips the necessary sample material can be taken without any problems.

The capillary is made of unbreakable plastic, preventing cut and stab injuries. It is coated on the entire inner surface and guarantees an exact filling volume.

The attached stopper, which can be easily opened with one hand, offers perfect tightness. The capillary blood collection GK allows an easy, hygienically flawless handling.

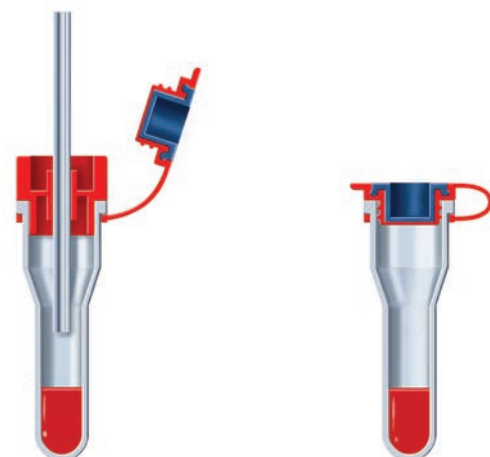
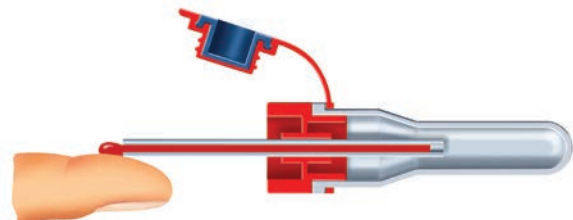


Capillary blood collection GK with rubber membrane

In addition to the normal capillary blood collection system, it is also possible to obtain the system with an integrated rubber membrane in the attached stopper.

This rubber membrane consists of an elastically re-deforming material and lies on the extremely thin bottom of the sealing cap.

The rubber membrane can be easily pierced from the sampler needle of an analyser. After the needle is removed, the rubber membrane seals completely again and thus ensures absolute tightness of the stopper.



Advantages:

- ▶ Minimisation of the risk of infection for the user
- ▶ Low risk of sample contamination
- ▶ No leakage and evaporation of sample after analysis
- ▶ Possibility of short-term storage of samples without loss of sample material
- ▶ Increased sample use due to multiple use of the sample on the analyser
- ▶ Prevention of absorption effects due to thin bottom

Sizes of the capillary blood collection GK

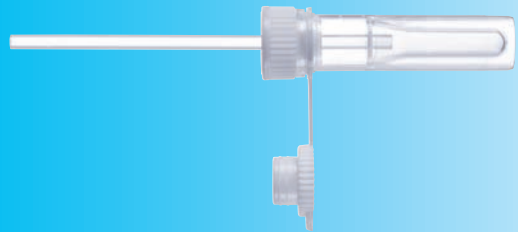
GK 150 Ø 11/8 x 39 mm



1000 A Ø 11/8 x 39 mm



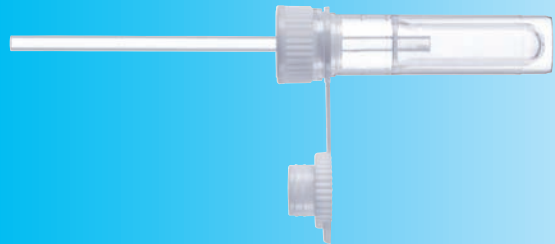
GK 150
flat bottom Ø 11/8 x 40 mm



1000 A
flat bottom Ø 11/8 x 40 mm



GK 110 Ø 11/4 x 40 mm




GK 100 Ø 11/8 x 29 mm



500 A Ø 11/8 x 29 mm



The capillary blood collection GK range

	Serum Coagulation inducer	Serum-Gel Coagulation inducer	Plasma Li.-heparin	Plasma Li.-heparin Gel
	Item no.	Item no.	Item no.	Item no.
GK 150 Ø 11/8 x 39 mm 	077101 SE 200 µl 077102 SE 300 µl 077401 *Bili SE 200 µl	077119 SE Gel 200 µl 077122 SE Gel 300 µl 077422 *Bili SE Gel 200 µl	077201 Li 200 µl	
1000 A Ø 11/8 x 39 mm 	078002 SE 1000 A 078003 *Bili 1000 A	078020 SE Gel 1000 A	078004 Li 1000 A	078022 Li Gel 1000 A
GK 150 flat bottom Ø 11/8 x 40 mm 	077166 SE 200 µl flat bottom	077126 SE Gel 100 µl flat bottom 077125 SE Gel 200 µl flat bottom	077202 Li 200 µl flat bottom	077231 Li Gel 200 µl flat bottom
1000 A flat bottom Ø 11/8 x 40 mm 	078027 SE 1000 A flat bottom	078031 SE Gel 1000 A flat bottom	078028 Li 1000 A flat bottom	
GK 110 Ø 11/4 x 40 mm 	076525 SE 200 µl			
GK 100 Ø 11/ x 29 mm 				
500 A Ø 11/8 x 29 mm 	078018 SE 500 A	078019 SE Gel 500 A	078053 Li 500 A	
Packing unit/bag	100 pcs	100 pcs	100 pcs	100 pcs

Please note!

Without rubber membrane stopper = above mentioned articles

With rubber membrane stopper = **to state with order**

* brown tinted vessels

** further information on the following pages

Plasma NH ₄ -heparin	Haematology EDTA	Coagulation Citrate**	Glucose Sodium fluoride	ESR** Citrate	Reticulocyte count**	Packing unit/box
Item no.	Item no.	Item no.	Item no.	Item no.	Item no.	
	077003 EDTA 100 µl 077002 EDTA 150 µl 077001 EDTA 200 µl 077004 EDTA 300 µl	077701 Citrat 150 µl 077704 Citrat 300 µl	077301 NaF 200 µl	077510 BSG 150 µl		4,000 pcs 300 µl: 3,000 pcs ESR and Citrate: see page 8 and 9
	078001 EDTA 1000 A					5,000 pcs
	077031 EDTA 100 µl 077033 EDTA 150 µl 077030 EDTA 200 µl all flat bottom					3,500 pcs
078032 AH 1000 A flat bottom	078035 EDTA 1000 A flat bottom					4,000 pcs
	076505 EDTA 50 µl 076604 EDTA 80 µl 076502 EDTA 100 µl 076503 EDTA 150 µl 076500 EDTA 200 µl					3,500 pcs 200 µl and more 3,000 pcs
	076001 EDTA 100 µl 076004 EDTA 50 µl				017010 GK R 30	5,000 pcs
	078045 EDTA 500 A					5,000 pcs
100 pcs	100 pcs	50 pcs	100 pcs	50 pcs	100 pcs	

Centrifugation recommendation: 2,000 g, 10 min – Serum and heparin plasma
 2,500 g, 10 min – Serum and heparin plasma for tubes with separating gel

Notice: We can provide all stopper colours with international colour code in accordance to appendix F
 “Recommended colour codes for identifying additives and accessories” of DIN EN ISO 6710.

Blood sedimentation rate/Citrate



GK 150 ESR 150 µl complete

Prepared for the measurement of the blood sedimentation rate

Anticoagulant: sodium citrate 3.8 %

Mixing ratio: 1:5

Fill. volume: 150 µl

Item no.	Description
077510	GK 150 ESR 150 µl

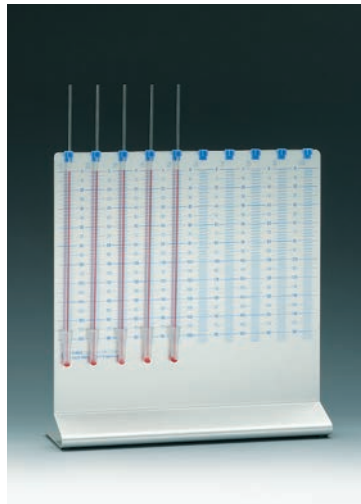
Packing unit: 50 pcs in dispenser box, 1,000 pcs in box

This blood sedimentation system was particularly developed for the use in paediatrics. It consists of a test vessel, pre-dosed with citrate, coated 150 µl plastic capillary with stopper and a sedimentation capillary with piston.

Advantages:

- ▶ Minimal patient exposure, as only 150 µl blood is required
- ▶ Bubble-free filling
- ▶ Simple and safe handling
- ▶ Economical and efficient
- ▶ Cost-effective and problem-free disposal

Sedimentation rack



Sedimentation rack for GK 150 ESR 150 µl

Item no.	Description
061751	SST 10 GK

Mix the blood sample very well. Insert the sedimentation capillary into the holding clamp of the sedimentation rack and set the blood level to 0. The sedimentation value can be taken after 1 hour.

Coagulation/Citrate



GK 150 Citrate

Prepared for coagulation physiological analyses

Anticoagulant: sodium citrate 0.1 mol/L

Mixing ratio: 1:10

Item no.	Description	Fill. volume
077701	GK 150 Citrate 150 µl	150 µl

Packing unit: 50 pcs in dispenser box, 5,000 pcs in box

Item no.	Description	Fill. volume
077704	GK 150 Citrate 300 µl	300 µl

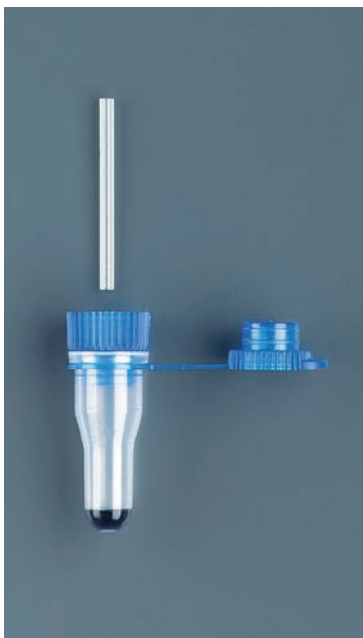
Packing unit: 50 pcs in dispenser box, 1,000 pcs in box

This system was particularly developed for use in paediatrics. It consists of a test vessel, pre-dosed with citrate solution, membrane stopper and attached stopper as well as a 150 µl or 300 µl plastic capillary.

Advantages:

- ▶ Minimal patient exposure, as only 150 µl or 300 µl blood is required
- ▶ Simple and safe handling
- ▶ Economical and efficient
- ▶ Cost-effective and problem-free disposal
- ▶ Collecting vessel serves as centrifuge vessel

Reticulocyte count



GK R 30

Prepared for reticulocyte count with 50 µl staining solution

Fill. volume: 50 µl

Item no.	Description
017010	GK R 30

Packing unit: 100 pcs in dispenser box, 5,000 pcs in box

This system consists of a test vessel, pre-dosed with a staining solution for reticulocyte count, with membrane stopper and attached stopper as well as a 50 µl plastic capillary.

Advantages:

- ▶ Minimal patient exposure, as only 50 µl blood is required
- ▶ Simple and safe handling
- ▶ Economical and efficient
- ▶ Cost-effective and problem-free disposal

Spacer sleeve



Spacer sleeve for GK vessels

Spacer sleeve Ø 13 for extending small vessels to 75 mm, can be used with all vessels with Ø 11/8 – assembled or individually available.

Item no.	Description
*	Spacer sleeve assembled or individually

Packing unit assembled: 100 pcs in bag, 1,000 pcs in box

Packing unit individually: 100 pcs in bag, 3,000 pcs in box

* Customised item no

Accessories



Safety lancets

Sterile single-use safety lancets for capillary blood collection.

Contact activation: The lancet mechanism is activated by pressing it firmly against the puncture site.

Medlance®

Item no.	Colour	Type and Size	Penetration depth
090220	purple	25 G	1.5 mm
090221	blue	21 G	1.8 mm
090222	green	21 G	2.4 mm
090223	yellow	0.8 mm (blade)	2.0 mm

Packing unit: 200 pcs in dispenser box, 2,000 pcs in box



Safety lancets

Sterile single-use safety lancets for capillary blood collection.

Activation by thumb pressure. The mechanism of the lancet is activated by holding it against the puncture site and pressing the release button.

MediSafe Solo

Item no.	Colour	Type and Size	Penetration depth
090230	pink	23 G	2.0 mm
090231	green	29 G	1.5 mm

Packing unit: 200 pcs in dispenser box, 2,000 pcs in box



Blood lancets

Sterile single-use steel lancets for capillary blood collection.

Item no.	Description
090201	Vitrex Steel 200

Packing unit: 200 pcs in dispenser box

Accessories



Disposal bags

Material: Polypropylene

Autoclavable up to 121° C

Item no.	Description	Size
090001	VB 200 x 300	200 x 300 mm

Packing unit: 1,200 pcs in box

090002	VB 600 x 780	600 x 780 mm
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Packing unit: 200 pcs in box



Disposal boxes

for syringes, cannulas, scalpels, blood pipettes, etc.

Material: Polypropylene

Item no.	Description
090014	Disposal box 1.6 ltr.
090015	Disposal box 2.1 ltr.
090016	Disposal box 3.1 ltr.

Other sizes available on request.

No more drawing blood than necessary

The so-called Patient Blood Management is an individual treatment concept for a more conscious patient care particularly in clinical routine¹. The concept provides a careful handling of patient's own blood to prevent a clinic-associated anaemia. Risk factors that usually lead to blood transfusions shall be reduced through Patient Blood Management, because transfusions of allogenic blood can have negative side-effects as a consequence².

In addition to avoiding transfusions, for example through an early treatment of an already existing anaemia, blood collection before surgery can be carried out more carefully to prohibit a clinic-associated anaemia. This can be achieved through sampling frequency, sampling routine as well as reducing of the sampling volume.

The portfolio of KABE LABORTECHNIK GmbH meets the demands of less blood volume and offers different types of tubes with minor sampling volume for various diagnostic parameters (s. chart on pages 6 and 7).

If you have any questions or requests regarding Patient Blood Management, please contact us!

¹ Hans Gombotz, Kai D Zacharowski, Donat Spahn: Patient Blood Management. Thieme Verlag, Stuttgart 2013, ISBN 978-3-131-70621-8.

² Delaney M, Wendel S, Bercovitz RS, Cid J, Cohn C, Dunbar NM, et al. Transfusion reactions: prevention, diagnosis, and treatment. The Lancet. 2016;388(10061):2825-36.

KABE LABORTECHNIK – because health is a matter of trust!



In addition to the range of the capillary blood collection GK, KABE LABORTECHNIK offers a varied range of laboratory materials for the medical laboratory:

- ▶ Venous blood collection systems for human sample collection (Primavette® S and V and KABEVETTE® G)
- ▶ Venous blood collection systems for veterinary sample collection (KABEVETTE®; Primavette®)
- ▶ Plastic and glass capillaries
- ▶ Extensive range of accessories for the above mentioned blood collection systems
- ▶ Treated test tubes and collection vessels for blood, urine and faeces analyses
- ▶ Untreated test tubes and reaction vessels, laboratory items made of plastic
- ▶ Consumables for the treatment of pathological/histological samples
- ▶ Devices and consumables for blood sugar determination
- ▶ Devices and systems for determining the blood sedimentation rate
- ▶ Mixers for blood samples and other liquid samples

We would be happy to provide you with more information material!

Or visit us online at
www.kabe-labortechnik.de

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480038/10.18

EG-KONFORMITÄTSERKLÄRUNG – EC-DECLARATION OF CONFORMITY

Name und Adresse des Herstellers Name and address of the manufacturer	KABE-Labortechnik GmbH Jägerhofstraße 17 51588 Nümbrecht-Elsenroth Deutschland/Germany
SRN	DE-MF-0000-11861

Wir erklären in alleiniger Verantwortung, dass die In-Vitro-Diagnostika der Produktgruppe
 We declare under our sole responsibility that the in-vitro-diagnostics of product group

Probenröhren
 Test tubes

Basis-UDI-DI / Basic UDI-DI	4058768plastic_tubesPP
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Probenröhren	Test tubes
<ul style="list-style-type: none"> - neutrale Probenröhren - mit oder ohne Verschlussstopfen - präparierte Probenröhren - zur Zählung der Thrombozyten aus Venen- oder Kapillarblut - zur Zählung der Retikulozyten - für hämatologische Untersuchungen - zur Gewinnung des Blutcitratgemisches für den Hepato Quick - zur Gewinnung des Blutcitratgemisches für gerinnungsphysiologische Untersuchungen - zur Serumgewinnung - zur Plasmagewinnung - zur Stabilisierung des Enzyms der sauren Phosphatase - zur Blutzuckerbestimmung - zur Bestimmung der Katecholamine - präparierte Probenröhren für Abstrichproben - Reaktionsgefäße - neutral - präpariert - mit oder ohne Verschlussstopfen - Verschlussstopfen - für Probenröhren und Reaktionsgefäße 	<ul style="list-style-type: none"> - test tubes - w/o closing stopper - treated test tubes - for platelet count from venous or capillary blood - for reticulocyte count - for haematological analyses - for preparing the blood-citrate mixture for the Hepato Quick - for preparing the blood-citrate mixture for coagulation physiological analyses - for serum collection - for plasma collection - for stabilising the enzyme of acid phosphatase - for blood sugar determination - for determination of the catecholamine - prepared sample tubes for swab samples - reaction vessels - untreated - treated - w/o closing stoppers - closing stoppers - for test tubes and reaction vessels

Risikoklasse Risk class	Klasse A Class A
Steriles Medizinprodukt Sterile medical device	Nein No

den einschlägigen Bestimmungen der IVDR (EU) 2017/746 des Europäischen Parlaments und des Rates sowie gegebenenfalls weiteren einschlägigen Rechtsvorschriften der Union, in denen die Ausstellung einer EU-Konformitätserklärung geregelt ist, entspricht. Gemäß (EU) 2017/746 Anhang VIII, Abschnitt 2.5 Regel 5c, erfolgt die Zuordnung in Klasse A. Die Konformitätserklärung gilt für die durch die KABE-Labortechnik GmbH freigegebenen Chargen.

comply with the relevant provisions of the IVDR (EU) 2017/746 and, where applicable, other relevant Union legislation regulating the issuance of an EU declaration of conformity. According to (EU) 2017/746 Annex VIII, Section 2.5 Rule 5c, the assignment is made to class A.

The declaration of conformity applies to the batches released by KABE-Labortechnik GmbH.

Verweis auf angewandte GS: es liegen keine GS vor
 Reference to applied CS: CS are not available

Konformitätsbewertungsverfahren Conformity assessment procedure:	Verordnung (EU)2017/746 gemäß Artikel 48, Absatz 10 Regulation (EU)2017/746 according to Article 48, Paragraph 10
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Die Benannte Stelle war an der Konformitätserklärung beteiligt: keine
 The notified body was involved in the evaluation of conformity: none

Diese Erklärung ist gültig bis: This declaration is valid until:	24. Mai 2025 24th May 2025
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