

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60150763 0001

Report No.: 21234760 013

Manufacturer: KABE LABORTECHNIK GmbH
Jägerhofstr. 17
51588 Nümbrecht
Deutschland

Products:
- Cannulas for blood collection
- MBU Capillaries
(see attachment for details)

Replaces certificate, Registration No.: HD 60105393 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-10-07

Date: 2020-10-07

Notified Body


Dr. K. Kluge



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC
concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60150763 0001
Report No.: 21234760 013

Manufacturer: KABE LABORTECHNIK GmbH
Jägerhofstr. 17
51588 Nümbrecht
Deutschland

Products included:

- Cannulas for blood collection

For the following devices the scope covers only
the aspects of the manufacture concerned with
the securing and maintaining sterile conditions:

- MBU Capillaries

Date: 2020-10-07

Notified Body

Dr. K. Kluge
Dr. K. Kluge





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

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

- **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

• neutrale Reaktionsgefäße

- mit oder ohne Verschlussstopfen

• Verschlussstopfen

für Probenröhren und Reaktionsgefäße

• test tubes

- **untreated 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

• untreated reaction vessels

- w/o closing stoppers

• closing stoppers

for test tubes and reaction vessels

der Klasse / of class

Andere IVD-Produkte
Other IVD-devices

den einschlägigen Bestimmungen der IVD-Richtlinie 98/79/EG und deren Umsetzungen in nationale Gesetze entspricht. Die Konformitätserklärung gilt für die durch die KABE LABORTECHNIK GmbH freigegebenen Chargen.

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it.

This declaration is valid for the batches released by KABE LABORTECHNIK GmbH.

Konformitätsbewertungsverfahren:
Conformity assessment procedure:

Richtlinie 98/79/EWG Anhang III
Directive 98/79/EC Annex III

Nümbrecht-Elsenroth, 24.09.2019


André Kolpe, Geschäftsführer / Managing director

KABE LABORTECHNIK GmbH
Jägerhofstraße 17
51588 Nümbrecht-Elsenroth
Telefon 02293 / 596

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

KABE LABORTECHNIK GmbH
Jägerhofstr. 17
51588 Nümbrecht
Deutschland

has established and applies a quality management system for medical devices
for the following 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**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-10-16

Certificate Registration No.: SX 60133221 0001

An audit was performed. Report No.: 21234760 009

This Certificate is valid until: 2021-10-15

Certification Body



Date 2018-10-12



Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

Certificate

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TÜV Rheinland LGA Products GmbH

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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
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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

kapillare Blutentnahme / capillary blood collection

• Kapillarblutentnahmesystem (GK)	• capillary blood collection system (GK)
<ul style="list-style-type: none">• präpariert zur Serumgewinnung• präpariert zur Plasmagewinnung• präpariert für hämatologische Untersuchungen• präpariert für gerinnungsphysiologische Untersuchungen• präpariert zur Blutzuckerbestimmung• präpariert für die Messung der Blutkörperchensenkungsgeschwindigkeit• präpariert zur Zählung der Retikulozyten	<ul style="list-style-type: none">• prepared for serum collection• prepared for plasma collection• prepared for haematological analyses• prepared for coagulation physiological analyses• prepared for blood sugar determination• prepared for the measurement of the blood sedimentation rate• prepared for reticulocyte count
• Zubehör für die kapillare Blutentnahme / accessories for capillary blood collection	
<ul style="list-style-type: none">• Senkungsständer	<ul style="list-style-type: none">• sedimentation rack

der Klasse / of class	Andere IVD-Produkte Other IVD-devices
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den einschlägigen Bestimmungen der IVD-Richtlinie 98/79/EG und deren Umsetzungen in nationale Gesetze entspricht. Die Konformitätserklärung gilt für die durch die KABE LABORTECHNIK GmbH freigegebenen Chargen.

meets the provisions of the directive 98/79/EEC and its transpositions in national laws which apply to it. This declaration is valid for the batches released by KABE LABORTECHNIK GmbH.

Konformitätsbewertungsverfahren: Conformity assessment procedure:	Richtlinie 98/79/EWG Anhang III Directive 98/79/EEC Annex III
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Nümbrecht-Elsenroth, 18.03.2021

KABE LABORTECHNIK GmbH
Jägerhofstraße 17
51588 Nümbrecht-Elsenroth
Telefon 02293 / 500



André Kolpe, Geschäftsführer / Managing director

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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The capillary blood collection GK range
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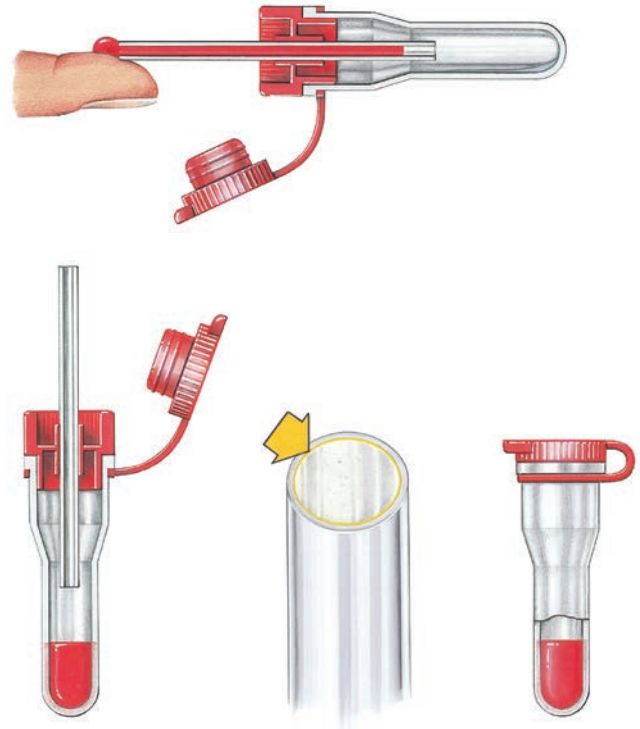
Capillary blood collection GK

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.

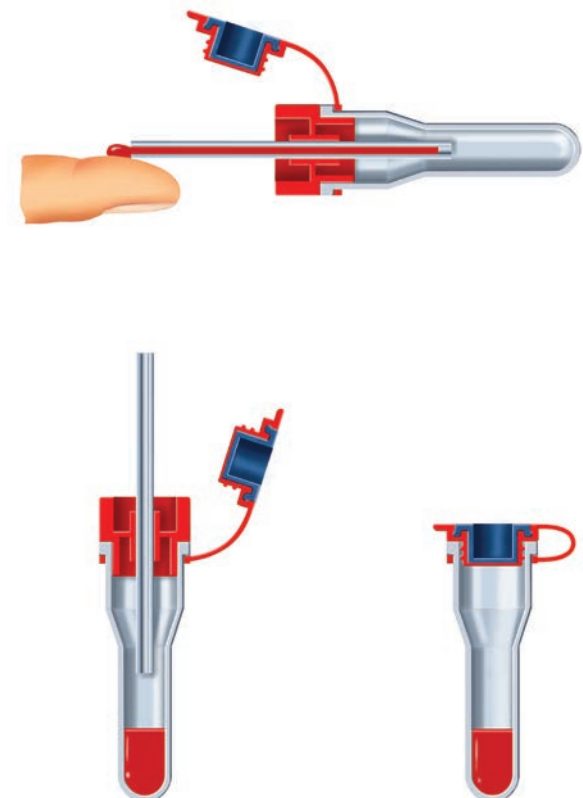


Capillary blood collection GK with rubber membrane

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

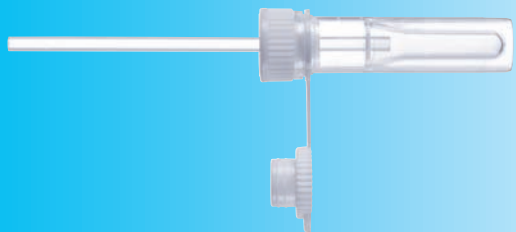
GK 150 Ø 11/8 x 39 mm



1000 A Ø 11/8 x 39 mm



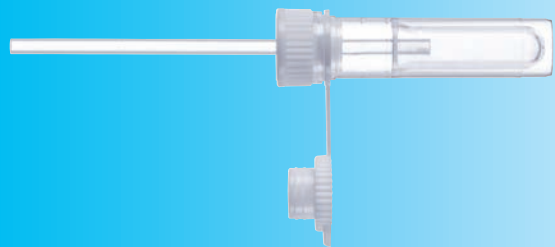
GK 150
flat bottom Ø 11/8 x 40 mm



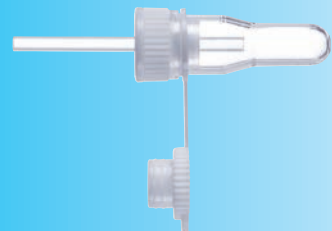
1000 A
flat bottom Ø 11/8 x 40 mm



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

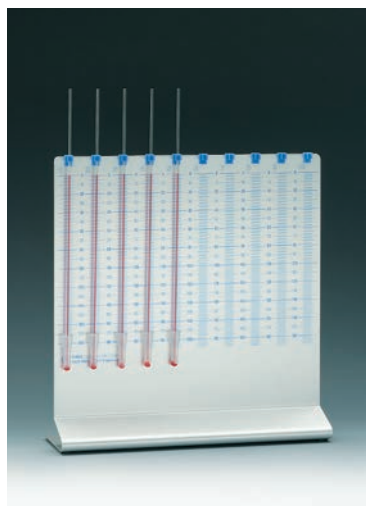
Packing unit: 50 pcs in dispenser box, 1,000 pcs in box

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

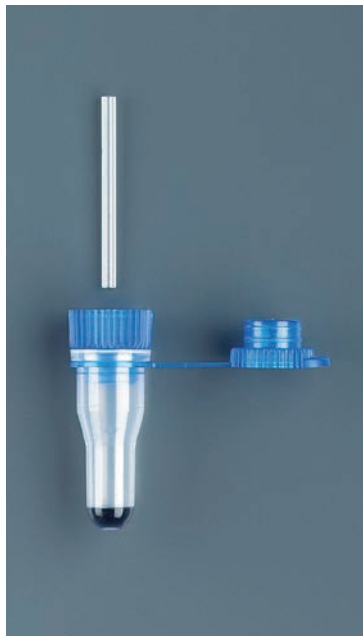
Packing unit: 50 pcs in dispenser box, 1,000 pcs in box

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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