MiniCollect®

greiner BIO-ONE

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MiniCollect® K2E K2EDTA Tubes

For In Vitro Diagnostic Use

Instructions for use

EN

Intended Use

MiniCollect® K2EDTA Tubes are non-evacuated blood collection devices, used to collect, transport, store, and evaluate capillary blood specimens for the following hematology parameters: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, Platelets, RDW, Lymphocytes, Neutrophiles, Monocytes, Eosinophils and Basophils.

Product Description

MiniCollect® Tubes are plastic, non-evacuated, non-sterile low sample volume tubes with integrated collection devices. The closure is colour coded to identify the additives which are present in varying concentrations depending on the tube type and stated volumes.
The caps of the **MiniCollect®** Tubes are pierceable for automated instruments with cap-piercing functionalities.
The interior of the tube wall is coated with dipotassium EDTA (K2EDTA). The EDTA binds calcium ions thus blocking the coagulation cascade.
The product is to be used by appropriately trained healthcare professionals in accordance with these instructions.

Tube Type	Matrix	Cap colour
MiniCollect® K2E K2EDTA Tubes	Capillary blood	Lavender

Product versions

MiniCollect® Tubes with optional 13x75 mm carrier tubes (clear, amber)
MiniCollect® Complete Tubes pre-assembled with 13x75 mm carrier tubes

Storage before use

Store tubes at 4–25°C (40–77°F). Avoid exposure to direct sunlight. Exceeding the maximum recommended storage temperature may lead to impairment of the tube quality (*i.e. colouring, etc.*)

Sample Stability and Storage

Remix K2EDTA samples immediately prior analysis to avoid result variations.
Refer to the instrument assay instructions for use or literature for information on the correct sample material, correct storage and stability.

Precautions/Cautions

- Insufficient or delayed mixing of tubes with additives may result in platelet clumping, clotting and/or incorrect test results.
- Do not use tubes if foreign matter is present.
- Handle all biological samples and blood collection devices according to the policies and procedures of your facility.
- Obtain appropriate medical attention in the case of any exposure to biological samples.
- Check all tubes to verify appropriate product and shelf-life before use. Do not use tubes after the expiration date.
- It is the laboratory's ultimate responsibility to verify that a change from one tube to another does not significantly affect analytical results obtained from patient samples.
- Single use only.
- To prevent contamination or leakage, make sure to avoid any blood in the recess around the scoop in the upper tube rim before closing the tubes. In case there is blood in the recess, it is recommended to clean it before closing the tube.

Only applicable for member states of the European Union: Should any serious incidents occur in relation to the product, these must be reported to the manufacturer and the competent authority in the member state, in which the user/patient is established.

Specimen Collection and Handling

Equipment required but not provided

- Labels for positive patient identification of samples
- Gloves and appropriate apparel for protection against exposure to blood borne pathogens
- Alcohol swab
- Dry gauze
- Warming device if appropriate, depending on the volume of blood needed and the test(s) to be performed
- Adhesive plaster or bandage
- Biohazard disposal container
- Safety lancet

Recommended Order of Draw (based on CLSI GP42-A6)

If multiple specimens are to be collected, including EDTA specimens, the EDTA specimen is drawn first to ensure adequate volume and accurate haematology test results. Specimens with other additives are collected next; serum specimens are collected last.

1 EDTA
2 Heparin / Heparin Sep
3 Glycolytic inhibitor tubes
4 Serum / Serum Sep

Cap Removal

The ribbed area around the tube top indicates the cap opening location. Remove the cap by applying gentle pressure on the cap in an upward direction. The triangle indicator is positioned opposite of the collection scoop.

Specimen Collection

For the collection of blood by skin puncture, please refer to the instructions for use for the lancet device used.
Blood flow from the skin puncture site is increased by holding the puncture site in a downward position. The first drop of blood should be wiped away with a gauze pad if appropriate for the test method, as it is likely to contain excess tissue fluids. Apply gentle, intermittent pressure to the surrounding tissue (or proximal to the puncture site when using a finger). Strong, repetitive pressure (milking), must not be applied. It may cause hemolysis or tissue-fluid contamination of the specimen and adversely affect test results.

Drops of blood should be allowed to flow freely into the tube and down the walls of the **MiniCollect**® Tube. If a drop becomes lodged inside the scoop or to mix the contents as specimen is collected, gently tap the tube on a hard surface. Do not shake and avoid flicking the open tube. For correctly filled tubes, observe the fill mark. After collection, close the tube with the original cap, an audible click indicates correct closure. Invert until the blood completely mixes with the additive (approximately 8-10x). Vigorous shaking may cause foaming and hemolysis. The patient must be positively identified, and the patient's blood sample must be properly labeled at the time of collection. The specimen should be labelled immediately following collection and mixing.

Disposal

- The general hygiene guidelines and legal regulations for the proper disposal of infectious material should be considered and followed.
- Always wear gloves during blood collection and disposal.
- Contaminated or filled blood collection tubes must be disposed of in suitable biohazard disposal containers, which can then be autoclaved and incinerated afterwards.

Limitations

Testing was performed on the following instrumentation: Sysmex XE-5000™ (can only be used in the manual aspiration mode), Beckman Coulter DxH 800 and Abbott CELL-DYN Sapphire.

NOTE: *For detailed performance data, please refer to the White Papers/Clinical Documentation at www.gbo.com.*

Label Information

	Manufacturer		Temperature limit
	Use-by date		Do not re-use
LOT	Batch code		Consult instructions for use
REF	Catalogue number	IVD	*In vitro* diagnostic medical device
Rx Only (USA)	Prescription device (USA)		Keep away from sunlight

Caution: U.S. Federal Law restricts this device to sale by or on the order of a physician.

Literature
CLSI. *Collection of Capillary Blood Specimens.* 7th ed. CLSI standard GP42. Clinical and Laboratory Standards Institute; 2020.


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Appendix – Log of changes since last revision

Location in the document	Change description
Precautions/Cautions	Addition of a precaution regarding blood in the recess around the scoop of the tube.
Precautions/Cautions	Addition of a note regardig reporting of serious incidences in the European Union.
Label Information	Adaption of the *Rx Only* symbol to *Rx Only (USA)* and addition of a caution indicating the product as prescription device.
Label Information	Addition of the *Keep away from sunlight* symbol.
Literature	Update of CLSI reference.