



## Capillary Blood Collection System For In Vitro Diagnostic Use



**Intended Use:** MiniCollect® tubes, lancets, capillaries and/or funnels are manufactured to be used together as a system. MiniCollect® tubes are designed for the collection, transportation and processing of skin-puncture blood from infants, children, geriatric and critical care patients.

The capillaries and funnels are used as transfer devices to facilitate blood transfer from the puncture site into the MiniCollect® tube. The carrier tube is used as an adapter for centrifuge rotors and/or analyser racks but also to provide easier handling of tubes for the user. The amber carrier tube is to be used in conjunction with serum and serum/gel tubes for testing bilirubin. The system is to be used by properly trained healthcare professionals only in accordance with these instructions.

**Product Description:** MiniCollect® tubes are plastic, non-evacuated, non-sterile low sample volume tubes with a pre-defined nominal volume for achieving correct additive concentrations. They are fitted with colour-coded MiniCollect® Cross-Cut Caps (see table below). The tubes, additive concentrations and their permitted tolerances, as well as the blood-to-additive ratio, are in accordance to the requirements and recommendations of the international standard Clinical Laboratory Standards Institute (CLSI). Additive choice depends on the analytical test method selected. The manufacturer of the test reagents and/or instrument on which the test is performed will specify this. Lancets are offered with varying depths, depending upon the desired blood flow and patient age and weight.

### MiniCollect® Cross-Cut Cap Colour Codes and Volumes

Description	Cross-Cut Cap	Fill Volume
<b>MiniCollect® Serum Tubes</b>		
Clot activator	red	0.5ml
Clot activator	red	1.0ml
Clot activator and gel	gold	0.5ml
Clot activator and gel	gold	0.8ml
<b>MiniCollect® Plasma Tubes</b>		
Lithium Heparin	green	0.5ml
Lithium Heparin	green	1.0ml
Lithium Heparin and Gel	light green	0.8ml
<b>MiniCollect® Coagulation Tubes (liquid)</b>		
Sodium Citrate 3.2%	light blue	0.5ml
Sodium Citrate 3.2%	light blue	1.0ml
Sodium Citrate 3.8%	light blue	1.0ml
<b>MiniCollect® EDTA Tubes</b>		
K3EDTA	lavender	0.25ml
K3EDTA	lavender	0.5ml
K3EDTA	lavender	1.0ml
K2EDTA	lavender	0.5ml
<b>MiniCollect® Glucose Tubes (not available in the US)</b>		
Potassium Oxalate and Sodium Fluoride	grey	0.25ml
Potassium Oxalate and Sodium Fluoride	grey	0.5ml
<b>MiniCollect® No Additive Tubes (not available in the US)</b>		
No Additive	white	

## MiniCollect® Capillary Blood Collection Product Range

### MiniCollect® Serum Tubes

All **MiniCollect®** Serum Tubes contain a blood clotting activator that speeds up the clotting process. **MiniCollect®** Serum Tubes are used for testing parameters in clinical chemistry.

### MiniCollect® Plasma Tubes

The interior of the tube wall is coated with lithium heparin. The anticoagulant heparin activates antithrombins, thus blocking the coagulation cascade and producing a whole blood / plasma sample instead of clotted blood plus serum. **MiniCollect®** Plasma Tubes are used for testing parameters in clinical chemistry.

**NOTE:** Do not use **MiniCollect®** Plasma tubes for TDM, blood banking procedures (PCR inhibitor) or lithium determinations (Lithium may interfere with the method of determination)

### MiniCollect® Serum / Plasma Gel Tubes

**MiniCollect®** Serum and Plasma Tubes with Gel contain an inert, acrylic barrier in the bottom of the tube. The specific gravity of the gel lies between the cells and serum/plasma. During centrifugation, the gel moves upwards to form a stable barrier between the cells and the serum/plasma. This separation allows serum/plasma to be aspirated directly from the **MiniCollect®** tube eliminating the need to transfer serum/plasma to another vessel. The barrier is also stable during transportation. **NOTE:** Do not use **MiniCollect®** Serum and/or Plasma tubes with gel for TDM, blood banking procedures (PCR inhibitor) or lithium determinations (Lithium may interfere with the method of determination)

### MiniCollect® EDTA Tubes

The interior of the **MiniCollect®** tube wall is coated with either dipotassium EDTA (K2EDTA) or tripotassium EDTA (K3EDTA). The EDTA binds calcium ions thus blocking the coagulation cascade. **MiniCollect®** EDTA Tubes are used for testing parameters in haematology.

### MiniCollect® Glucose Tubes (not available in US)

The **MiniCollect®** Glucose tubes contain an anticoagulant and a stabiliser. The tubes are coated with potassium oxalate and sodium fluoride. Glucose tubes are suitable for the analysis of blood sugar and lactate.

### MiniCollect® Coagulation Tubes

**MiniCollect®** Coagulation Tubes are filled with a buffered trisodium citrate solution. The concentration is either 0.109 mol/l (3.2 %) or 0.129 mol/l (3.8 %). The choice of the concentration depends upon the policies of the laboratory. **MiniCollect®** Coagulation tubes are used for coagulation tests. **NOTE:** **MiniCollect®** Coagulation tubes are only suitable for use with venous blood. Falsified test results can occur when using capillary blood due to tissue fluid contamination during skin-puncture procedures.

## MiniCollect® Standard Precautions/Cautions

### Precautions

Do not use tubes if foreign matter is present!

### Caution

Handle all biological samples and blood collection “sharps” (lancets, needles, Luer adapters, and blood collection sets) according to the policies and procedures of your facility.

- Obtain appropriate medical attention in the case of any exposure to biological samples (for example, through a puncture injury), since they may transmit HIV (AIDS), viral hepatitis, or other infectious diseases.
- Discard all skin-puncture “sharps” and transfer units in biohazard containers approved for their disposal.
- Additional manipulation of sharps increases the potential for needle stick injury.
- All liquid preservatives and anticoagulants are clear and colourless. Do not use if they are discoloured or contain precipitates.
- Check all tubes to verify appropriate product and shelf life before use. Do not use tubes after their 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.

## MiniCollect® Handling Procedures

### Storage

Store tubes at 4–25°C (40–77° F). **NOTE:** Avoid exposure to direct sunlight. Exceeding the maximum recommended storage temperature may lead to impairment of the tube quality (i.e. evaporation of liquid additives, colouring, etc.) Filled tubes can be stored at down to –20°C.

### Specimen Collection and Handling

THIS ENTIRE CIRCULAR SHOULD BE READ AND UNDERSTOOD BEFORE PERFORMING SKIN-PUNCTURE!

#### Equipment required for specimen collection.

Be sure that the following materials are readily accessible before performing skin-puncture:

- All necessary tubes and accessories, identified for size/fill volume and additive.
- Labels for positive patient identification of samples.

- Tubes must be used with lancets, capillaries and/or funnels.  
**NOTE:** For testing bilirubin, **MiniCollect**<sup>®</sup> tubes must be used with the amber carrier tube.
- Practice general safety precautions, use gloves and appropriate apparel for protection against exposure to blood borne pathogens.
- Alcohol swab for cleansing site
- Dry sterile gauze
- Warming device if required, depending on the volume of blood and the test to be performed
- Adhesive plaster or bandage
- Disposal container for safe disposal of used lancets, funnels, capillaries and accessories.

**Recommended Order of Draw:**

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. Other additive specimens are collected next; specimens requiring serum are collected last.

**Skin-puncture technique and Specimen Collection**

**WEAR GLOVES DURING SKIN-PUNCTURE PROCEDURES AND WHEN HANDLING BLOOD COLLECTION TUBES TO MINIMIZE EXPOSURE HAZARD!**

1. Gloves should be worn during the entire skin-puncture and blood collection procedure.
2. Select tube or tubes appropriate for required specimen. Prepare tubes with funnel or capillary before collection by pushing the funnel or the capillary through the cross-cuts of the cap of the **MiniCollect**<sup>®</sup> tube. Capillaries are colour coded in accordance to the cap colour of the tube.

**NOTE:** For testing bilirubin, the **MiniCollect**<sup>®</sup> serum tube should be placed into the amber carrier tube, to protect specimen from light.

3. Open lancet package according to instructions.
4. Select puncture site and warm as appropriate (e.g. a warm, moist towel at a temperature of no higher than 42°C may be used to cover the site for three to five minutes); prepare puncture site with appropriate antiseptic. Allow the area to air dry, so the antiseptic action can take place.
5. Perform skin-puncture with lancet according to the instruction for use. After skin-puncture dispose of the lancet in a biohazard sharps container approved by your facility.
6. The first drop of blood should be wiped away with a gauze pad, as this first drop is most likely to contain excess tissue fluids.
7. Blood flow from the puncture site is enhanced by holding the puncture site downward and gently applying intermittent pressure to the surrounding tissue (or proximal to the puncture site when the blood is obtained from a finger). Strong repetitive pressure (milking) must not be applied; it may cause haemolysis or tissue-fluid contamination of the specimen and adversely affect test results.
8. Collect the specimen.

Use of a funnel: Use the prepared **MiniCollect**<sup>®</sup> (see step 2) tube to collect the blood droplets with the gravity-flow principle of collection. The use of a scooping motion to collect blood from the surface of the skin must be avoided. After specimen collection, the funnel should be gently removed from the tube and disposed of in a biohazard sharps container approved by your facility. If more than one tube is collected, for each additional tube, use a new funnel.

Use of a capillary: Use the prepared **MiniCollect**<sup>®</sup> (see step 2) tube to collect the blood droplet. When the tip of the capillary tube touches the blood droplet, blood will flow into the **MiniCollect**<sup>®</sup> tube via capillary action. After specimen collection, the capillary should be gently removed from the tube and disposed of in a biohazard sharps container approved by your facility. If more than one tube is collected, for each additional tube, use a new capillary.

9. Drops of blood should be allowed to flow freely into the funnel and/or capillary and down the walls of the **MiniCollect**<sup>®</sup> tube. If a drop of blood becomes lodged inside the funnel and/or capillary, a gentle tap of the tube on a hard surface is sufficient to dislodge it into the bottom of the tube.

If no blood flows into tube or if blood flow ceases before an adequate specimen is collected, the following steps are suggested to complete satisfactory collection:

- a. Gently massage around the puncture site to stimulate blood flow.
- b. If blood still does not flow, repeat procedure at step 1.

10. The tubes must be filled with the proper quantity of blood; over-filling can result in clot formation, while under-filling can cause morphologic changes in cells due to excess anticoagulant. When the tube is filled according to the fill mark (nominal volume), withdraw the used funnel and/or capillary and dispose of in a biohazard sharps container approved by your facility. The specimen should be adequately mixed by gently inverting the tube without removing the cap. A gentle tap to the bottom of the tube will ensure proper mixing and additive performance. Do not shake. Vigorous shaking may cause foaming and haemolysis. Insufficient or delayed mixing in tubes with additives may result in platelet clumping, clotting and/or incorrect test results. The patient and the patient's blood sample must be positively identified at the time of collection. The specimen must be labelled immediately following collection and mixing. The **MiniCollect**<sup>®</sup> tube may be placed in the carrier tube for ease in labelling and centrifugation.
11. After blood collection, apply pressure to the puncture site with a dry sterile swab until bleeding stops. (If the infant's heel was punctured the foot should be elevated above the body)
12. Once clotting has occurred apply an adhesive bandage if desired.

13. After specimen collection, the recess in the cap may contain some residual blood. Take proper precautions when handling tubes to avoid contact with this blood.

### Centrifugation:

Ensure that tubes are properly seated in the centrifuge carrier, incomplete seating could result in separation of the **MiniCollect**<sup>®</sup> Cross-Cut Cap from the tube or extension of the tube above the carrier. **MiniCollect**<sup>®</sup> tubes are recommended to be centrifuged at 3.000g (minimum 1.600g, maximum 5.000g) for a period of 10 minutes in a cooled centrifuge. Centrifugation should be done in a Temperature of 15 - 24°C (59 - 77°F). Higher temperatures could have negative effects on the physical properties of the gel.

**NOTE:** Gel separation tubes should be centrifuged no later than 2 hours after collection. Extended contact of blood cells with the serum or plasma, may lead to erroneous analysis results. It is not recommended to re-centrifuge tubes once the barrier has been formed. The re-centrifugation of tubes can lead to possible impairment of the gel barrier, causing gel particles to separate and to appear in the serum or plasma.

### Disposal









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

## MiniCollect<sup>®</sup> Tube

### MiniCollect<sup>®</sup> Cross-Cut Caps

The **MiniCollect**<sup>®</sup> capillary blood collection system features a unique cap. The cap does not need to be removed from the tube during collection and sampling. Aerosol generation, evaporation/contamination of specimen and spillage is prevented due to the “cross-cuts” in the cap. Caps are coloured according to international colour-coding recommendations.

### MiniCollect<sup>®</sup> Label Information

	Manufacturer		Temperature limit
	Use-by date		Do not re-use
	Batch code		Consult instructions for use
	Catalogue number		In vitro diagnostic medical device

Labels are coloured according to international colour-coding recommendations. The label contains the products logo and CE mark and the following information. Nominal volume (blood + additive. **NOTE:** Gel is not considered an additive); Additive description; Item number; Lot number; Expiry date

### MiniCollect<sup>®</sup> Tube

Dimensions of the **MiniCollect**<sup>®</sup> tube: 11/40mm  
 Dimension of the carrier tube / amber carrier tube: 13/75mm

### Literature

Clinical Laboratory Standards Institute (CLSI):

- GP41-A6 Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard-6th Edition
- GP42-A6 Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard-Fifth Edition
- H21-A5 Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays; Approved Guideline-Fifth Edition



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