h

MiniCollect® by VACUETTE®

greiner bio-one

CE Capillary Blood Collection System USA

For In Vitro Diagnostic Use

Intended Use: Greiner Bio-One MiniCollect® Capillary Blood Collection Tubes are designed for the collection, transportation and processing of capillary blood (collected via safety lancets) whenever a small amount of blood is preferred.

Summary and Explanation: MiniCollect® Tubes are plastic, non-evacuated, non-sterile low sample volume tubes with a pre-defined nominal volume for achieving correct additive concentrations. Additive choice depends on the analytical test method selected. The manufacturer of the test reagents and/or instrument on which the test is performed provides these specifications. The tubes are fitted with color-coded MiniCollect® Cross-Cut Caps. 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. The caps are color coded according to Clinical Laboratory Standards Institute (CLSI, formerly NCCLS) color-coding recommendations.

MiniCollect® Tubes, capillaries and/or funnels are manufactured to be used together as a system. 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 analyzer 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: The MiniCollect® Tubes, additive concentrations, permitted tolerances, and blood-to-additive ratio, are in accordance with the requirements and recommendations of CLSI. The following table lists the information on the MiniCollect® tubes.

MiniCollect® Cross-Cut Cap Color Codes and Volumes

Description	Cross-Cut Cap	Fill Volume
MiniCollect® Serum Tubes		
Clot activator	red	1.0ml
Clot activator and gel	gold	0.8ml
MiniCollect® No Additive Tubes	white	N/A
MiniCollect® Plasma Tubes		
Lithium Heparin	green	1.0ml
Lithium Heparin and Gel	mint green	0.8ml
MiniCollect® Coagulation Tubes (liquid) - *for venous blood only*		
Sodium Citrate 3.2%	light blue	1.0ml
MiniCollect® EDTA Tubes		
K3EDTA	lavender	0.25ml
K3EDTA	lavender	0.5ml
K3EDTA	lavender	1.0ml
K2EDTA	lavender	0.5ml

MiniCollect® Serum Tubes
MiniCollect® Serum Tubes contain a blood clotting activator that functions to initiate the clotting process. MiniCollect® Serum Tubes with clot activator are used for testing parameters in clinical chemistry. There is also a MiniCollect® Serum tube available with no additive.

MiniCollect® Plasma Tubes
The interior of the tube wall is coated with lithium heparin. The anticoagulant heparin activates antithrombins which block the coagulation cascade. This produces a whole blood/plasma sample instead of clotted blood plus serum. MiniCollect® Plasma Tubes are used for testing parameters in clinical chemistry.

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 clot/cells and serum/plasma. During centrifugation, the gel moves upwards to form a stable barrier between the clot/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.

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 which blocks the coagulation cascade. MiniCollect® EDTA Tubes are used for testing parameters in hematology.

MiniCollect® Coagulation Tubes
MiniCollect® Coagulation Tubes are filled with a buffered trisodium citrate solution. The recommended concentration for coagulation testing is 0.109M (3.2 %). MiniCollect® Coagulation tubes are used for coagulation tests. NOTE: MiniCollect® Coagulation Tubes are for use with venous blood ONLY. Inaccurate test results can occur when using capillary blood due to tissue fluid contamination during skin puncture procedures.

Product Dimensions

MiniCollect® tube:	11 x 40mm
Carrier tube / amber carrier tube:	13 x 75mm
Capillary:	44mm

Warnings/Precautions
1. Do not use tubes if foreign matter is present!
2. Handle all biological samples and blood collection “sharps“ (e.g. safety lancets) according to the policies and procedures of your facility.
3. Obtain appropriate medical attention in the case of any exposure to biological samples (for example, through a puncture injury), because of the possible transmission of HIV (AIDS), viral hepatitis or other infectious diseases.
4. Discard all blood collection “sharps” in approved biohazard containers.
5. All liquid preservatives and anticoagulants are clear and colorless. Do not use if discoloration or precipitates are present.
6. Check all tubes to verify appropriate product and shelf life before use. Do not use the tubes after the expiration date.

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. drying out of liquid additives, coloring, etc.). Unfilled tubes can be stored down to –20°C.*

Specimen Collection and Handling: THIS ENTIRE PACKAGE INSERT SHOULD BE READ AND UNDERSTOOD BEFORE PERFORMING SKIN-PUNCTURE!

Procedure

Materials Provided
Greiner Bio-One MiniCollect® Capillary Blood Collection Tubes

Materials Required but Not Provided
Be sure that the following materials are readily accessible before performing specimen collection by skin-puncture:

1. All necessary tubes and accessories (such as safety lancets, capillaries and/or funnels) identified for size/fill volume and additive - ***NOTE****: For bilirubin testing, MiniCollect® Tubes must be used with the amber carrier tube.*
2. Labels for positive patient identification of samples.
3. Appropriate apparel, i.e., gloves (i.e., latex-free), laboratory coat, goggles for protection from exposure to bloodborne pathogens.
4. Alcohol swab for cleansing site.
5. Dry sterile gauze.
6. Warming device if required, depending on the volume of blood and the test to be performed.
7. Bandage (hypo-allergenic); (Adhesive bandages not recommended for children younger than two years old).
8. Approved biohazard container.

Recommended Order of Draw: (according to CLSI H04-A6 Standard)
If multiple specimens are to be collected, including EDTA specimens, the EDTA specimen is drawn first to ensure adequate volume and accurate hematology test results. Tubes with other additives are collected next; Serum specimens are collected last. ***NOTE****: Always follow your facility's protocol for Order of Draw.*

Skin-Puncture Technique and Specimen Collection
WEAR GLOVES DURING SKIN-PUNCTURE PROCEDURES AND WHEN HANDLING BLOOD COLLECTION TUBES TO MINIMIZE EXPOSURE HAZARD!
1. Select the tube or tubes appropriate for required specimen. Prepare the tubes with the funnel or capillary prior to collection. Push the funnel or capillary through the cross-cuts of the cap of the MiniCollect® Tube. Capillaries are color coded and are in accordance to the cap color of the tube.
NOTE*: For bilirubin testing, the MiniCollect® Serum Tube should be placed into the amber carrier tube to protect the specimen from light.*
2. Open the safety lancet package according to the device manufacturer's instructions.
3. Select the puncture site and warm it as appropriate (e.g. use a warm, slightly wet towel, no higher than 42°C, cover site three to five minutes). Prepare the puncture site with the appropriate antiseptic. Allow the area to air dry to ensure the complete action of the antiseptic.
4. Perform skin-puncture with the safety lancet according to the device manufacturer's instructions for use. After skin-puncture, dispose of the safety lancet in a biohazard sharps container approved by your facility.
5. 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.
6. Blood flow from the puncture site is increased by holding the puncture site in a downward position. 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.
7. Collect the specimen.
   Use of a funnel: Use the prepared MiniCollect® 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® Tube to collect the blood droplet. When the tip of the capillary tube touches the blood droplet, blood will flow into the MiniCollect® 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 appropriately colored capillary.
8. Drops of blood should be allowed to flow freely into the funnel and/or capillary and down the walls of the MiniCollect® 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.
9. 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 it 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 hemolysis. 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® tube may be placed in the carrier tube for ease in labelling and centrifugation.
10. 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.)

11. Once clotting has occurred, apply a hypo-allergenic bandage (adhesive bandages not recommended for children younger than two years old). 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 may result in separation of the MiniCollect® Cross-Cut Cap from the tube or extension of the tube above the carrier. MiniCollect® Tubes are recommended to be centrifuged at 3,000g (minimum 1,600g, maximum 5,000g), for a period of 10 minutes in a temperature-controlled centrifuge that maintains 15-25°C. Higher temperatures could have negative effects on the physical properties of the gel. Ideal separation of serum or plasma is achieved in this temperature range.

Disposal

- Follow OSHA and CDC Universal Precaution procedures to prevent the transmission of human immunodeficiency virus (HIV), hepatitis B virus (HBV), and other bloodborne pathogens.
- Use protective equipment and wear disposable latex gloves (sensitivity/allergy appropriate) to prevent the risk of infection.
- Follow OSHA and the policies and procedures of your facility for the disposal of contaminated equipment and specimen collection devices.

Limitations

1. Do not use MiniCollect® Plasma Tubes for TDM, blood banking or molecular diagnostic procedures.
2. Do not use MiniCollect® Plasma Tubes with Lithium Heparin for lithium determinations.
3. Do not use MiniCollect® Serum and/or Plasma Tubes with gel for TDM, blood banking or molecular diagnostic procedures. Do not use MiniCollect® Plasma Tubes with Lithium Heparin and Gel for lithium determinations.
4. MiniCollect® Coagulation tubes are only suitable for use with venous blood.
5. MiniCollect® Tubes must be used with safety lancets, capillaries and/or funnels.
6. Gel separation tubes should be centrifuged no later than 2 to 4 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.
7. There may be statistically and/or clinically significant differences in chemistry results between skin-puncture blood and venous blood. Therefore, laboratory reporting of results should indicate that the blood was collected by skin-puncture.
8. Skin-puncture blood may contain hemolyzed red blood cells, which may interfere with certain laboratory assays. The individual assay package inserts should be consulted for the effect of hemolysis on results.

Performance Characteristics

The MiniCollect® Capillary Blood Collection Tubes have been determined to be acceptable for the uses described in the Product Description section through clinical evaluations involving multiple analytes and assays. Contact Greiner Bio-One North America, Inc. Technical Support for further information.

MiniCollect® Label Information

REF	Item number		Temperature limit
LOT	LOT number: Batch number	IVD	In Vitro Diagnostic Device
	Expiry Date. Use by the end of the month indicated		Consult Instructions For Use
	Do Not Reuse		Manufacturer

References:

Clinical Laboratory Standards Institute:

- H21-A5 Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays; Approved Guideline-Fifth Edition.
- H03-A6 Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard-Sixth Edition.
- H04-A6 Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard-Sixth Edition.

Greiner Bio-One GmbH
Bad Haller Straße 32
A-4550 Kremsmünster, AUSTRIA