

## MiniCollect® 9NC Coagulation Tubes

For In Vitro Diagnostic Use  
Instructions for use



### Intended Use

The **MiniCollect®** 9NC Coagulation Tube is intended for collection of citrate anticoagulated whole blood samples for coagulation assays.

### 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 **MiniCollect®** 9NC Coagulation Tubes are filled with a buffered trisodium citrate solution in a concentration of 0.109 mol/L (3.2%).

The product is to be used by appropriately trained healthcare professionals in accordance with these instructions.

Tube Type	Matrix	Cap colour
<b>MiniCollect®</b> 9NC Coagulation Tubes 3.2% - for venous blood only – not available in USA	Venous blood	Light blue

### Product versions

**MiniCollect®** Tubes with optional 13x75 mm carrier tubes (clear, amber)

### Storage before use

Store tubes upright 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. evaporation of liquid additives, colouring, etc.*).

### Sample Stability and Storage

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.
- Unused tubes need to be stored upright as otherwise the risk of evaporation of the additive and crystallization in the cap may increase, which could further lead to leakage.
- 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
- Adhesive plaster or bandage
- Biohazard disposal container
- Needleless transfer device
- Venous blood collection device and accessories

#### 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 venous blood, please refer to your institution's policies. The specimen should be subsequently transferred to the tube by means of a safe, needleless system (such as a plastic syringe).

## General Handling

Drops of blood should be allowed to flow freely into the tube and down the walls of the **MiniCollect**<sup>®</sup> 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 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 4-5x until the blood completely mixes with the additive. 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.












## Centrifugation

Ensure that tubes are properly seated in the centrifuge carrier. **MiniCollect**<sup>®</sup> tubes are recommended to be centrifuged at 3000g for a period of 10 minutes. Other centrifugation settings need to be validated by the user. Centrifugation should be done at a temperature of 15-24°C (59-75°F).

## 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.

## Label Information


	Manufacturer		Temperature limit
	Use-by date		Do not re-use
	Batch code		Consult instructions for use
	Catalogue number		<i>In vitro</i> diagnostic medical device
	Prescription device (USA)		This way up
	Keep away from sunlight		

## Literature

CLSI. *Collection of Diagnostic Venous Blood Specimens*. 7th ed. CLSI standard GP41. Wayne, PA: Clinical and Laboratory Standards Institute; 2017.

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

CLSI. *Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays; Approved Guideline-Fifth Edition*. CLSI document H21-A5. Wayne, PA: Clinical and Laboratory Standards Institute; 2008.

 Greiner Bio-One GmbH  
Bad Haller Str. 32  
4550 Kremsmünster, Austria

[www.gbo.com/preanalytics](http://www.gbo.com/preanalytics)  
[office@at.gbo.com](mailto:office@at.gbo.com)  
Phone +43 7583 6791

## 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 regarding reporting of serious incidences in the European Union.
Centrifugation	Clarification that other centrifugation settings must be validated by the user.
Label Information	Adaption of the <i>Rx Only</i> symbol to <i>Rx Only (USA)</i> .
Label Information	Addition of the <i>Keep away from sunlight</i> symbol.
Literature	Update of CLSI references.