



CellRescue™ Preservative Tube

INSTRUCTIONS FOR USE

INDICATIONS FOR USE

For Research Use Only. Not for use in diagnostic procedures. The performance characteristics and safety and effectiveness have not been established and are not cleared or approved by the FDA.

PRODUCT OVERVIEW

CellRescue Preservation Tubes are evacuated blood collection tubes that contain EDTA anticoagulant and a cell preservative. The vacuum is designed to draw approximately 10 ml of blood. The interior of the tube is sterile. CellRescue Tubes are intended to be used in conjunction with Menarini Silicon Biosystems instruments.

PRINCIPLE OF OPERATION

CellRescue Tubes are designed to be used with standard phlebotomy supplies for venous blood collection. The tube contains 660 µl of a solution that contains Na₂EDTA and a cell preservative. The EDTA absorbs calcium ions, which prevents the blood from clotting. The preservative preserves the morphology and cell surface antigen expression. Each tube is evacuated to withdraw 10.0 ml of venous whole blood when following standard phlebotomy procedures.

LIMITATIONS

- The volume of blood drawn varies with altitude, ambient temperature, barometric pressure, tube age, venous pressure and filling technique.
- Samples must be processed within 120 hours of collection.
- For rare cell analysis using the CELLTRACKS ANALYZER II®, check sample integrity as described in the User's Guide for the CELLTRACKS ANALYZER II®.

PRECAUTIONS

- Storage of tubes at or below 0°C (32°F) may result in tube breakage.
- Do not remove rubber stopper by rolling with thumb. Remove stoppers with a twist and pull motion.
- Do not use tubes if foreign matter is present.
- Practice Universal Precautions. Use gloves, gowns, eye protection and other personal protective equipment, and engineering controls to protect from blood spatter, blood leakage and potential exposure to bloodborne pathogens.
- All glass has the potential for breakage. Examine all glass for potential damage in transit before use and take precautionary measures during handling.
- 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 event of exposure to biological samples (for example, through a puncture injury), since it might transmit viral hepatitis, HIV (AIDS), or other infectious diseases. Utilize any built-in used-needle protector, if the blood collection device provides one. Menarini Silicon Biosystems does not recommend resheating used needles. However, the policies and procedures of your facility may differ and must always be followed.
- Discard all blood collection sharps in biohazard containers approved for their disposal.
- Transferring a sample collected using a syringe and needle is not recommended. Additional manipulation of sharps such as hollow bore needles increases the potential for needle stick injury.

- Transferring samples from a syringe to a CellRescue Tube using a non-sharps device should be performed with caution for the reasons described below. Depressing the syringe plunger during transfer can create positive pressure, forcefully displacing the stopper and sample, causing splatter and potential blood exposure. Using a syringe for blood transfer may also cause over- or underfilling of tubes, resulting in incorrect blood-to-additive ratio and potentially incorrect analytic results. CellRescue Tubes are designed to draw a specific volume. Filling is complete when vacuum no longer continues to draw, though some tubes may partially fill due to plunger resistance when filled from a syringe.
- If blood is collected through an intravenous line, ensure that line has been cleared of I.V. solution before beginning to fill CellRescue Tubes.
- Caution: Samples must be transported and stored at temperatures of 15-30°C (59-86°F). Refrigerating samples prior to processing could adversely affect sample integrity.
- **WARNING:** This reagent contains Imidazolidinyl Urea. Following are the Hazard and Precautionary statements:
 - H317 May cause an allergic skin reaction.
 - Prevention:
 - P261 Avoid breathing dust/fume/gas/mist/vapors/spray.
 - P272 Contaminated work clothing should not be allowed out of the workplace.
 - P280 Wear protective gloves.
 - Response:
 - P333 + P313 If skin irritation or rash occurs: get medical advice/attention.
 - P362 + P364 Take off contaminated clothing and wash it before reuse.
 - Disposal:
 - P501 Dispose of contents/container to an approved waste disposal plant.

For additional information, please refer to Safety Data Sheet on www.cellsearchctc.com

Prevention of Backflow

Since the CellRescue Preservative Tube contains additives, it is important to avoid possible backflow from the tube, with the possibility of adverse reactions. To guard against backflow, observe the following precautions:

1. Place the patient's arm in a downward position.
2. Hold the tube with the stopper upmost.
3. Release the tourniquet as soon as blood starts to flow.
4. Make sure the solution inside the tube does not touch the stopper or end of the needle during venipuncture.

STORAGE

- Store tubes at 4-30°C (39-86°F). Do not use if the additive is not clear and colorless. Do not use after the expiration date.
- Store or transport samples at temperatures of 15-30°C (59-86°F). Proper insulation may be required for shipment during extreme temperature conditions.

PROCEDURE

Materials Provided

CellRescue Preservative Tubes. Contains: 660 ul solution containing 2.3% Na₂EDTA and 3% cell preservative, 0.18% polyethylene glycol, 0.23% inert ingredients

Materials Needed, Not Provided

Blood collection needles and adapters, alcohol wipes, tourniquet

1. Perform venipuncture according to CLSI procedure H3-A6, Procedure for the Collection of Diagnostic Blood Specimens by Venipuncture. Draw the CellRescue Tubes first, if multiple tube types are to be drawn.
2. Fill the tube until blood flow stops.
3. Remove the tube from the adapter and gently invert it 8 times to mix. Tube inversion prevents clotting. Inadequate or delayed mixing may result in inaccurate test results.
4. Process sample within 120 hours of collection. Store samples at temperatures of 15-30°C (59-86°F).

GLOSSARY OF SYMBOLS

	Use by (Year-Month-Day)		Sterile radiation
	Batch code/Lot Number		Temperature Limit
	Do not reuse		Consult Instructions for Use
	Catalog Number		Date of Manufacturer
	Caution, consult accompanying documents		Manufacturer
	Warning		

* Change bars indicate the position of a technical amendment to the text with respect to the previous version of the document.

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Menarini Silicon Biosystems Inc.
3401 Masons Mill Road, Suite 100
Huntingdon Valley, PA 19006 USA

cellsearchruo.com

Phone: 1-877-837-4339

00 8000 8374339 (EU)

Menarini Silicon Biosystems SpA
Via Giuseppe Di Vittorio 21B/3
40013 Castel Maggiore (Bologna) Italy



MENARINI
silicon biosystems