

Cell3™ Preserver

Whole Blood Stabilization Tube Protocol

Cell3™ Preserver 9 ml Whole Blood Tube
50 Tubes (PRE_C3P_WBS_50)

Revision History

Revision	Date	Revision Description
Updates from version 1.1	April 2023	<ol style="list-style-type: none">1. Updated storage conditions for Cell3™ Preserver tubes prior to blood collection to remove the need for storage at 4-8 °C.2. Updated shelf life, pre- and postblood draw stability related to change in storage conditions.

Intended Use

Cell3™ Preserver Whole Blood Stabilization tube is an evacuated blood collection tube intended for the collection and storage of human whole blood specimens. The Cell3™ Preserver tubes contain an additive inside which when mixed with the whole blood stabilizes nucleated cells and helps in the anti-coagulation of blood cells. This prevents the release of intracellular DNA into plasma and prevents a change in the cell-free DNA fraction during transport.

Summary and Principles

Modern genetic techniques such as next generation sequencing and droplet digital PCR are extremely sensitive and can provide a rapid and accurate assessment of genetic variants in a blood sample. More recently circulating cell-free DNA in biological fluids has been discovered and is of growing interest in oncology, prenatal and transplant studies. However, when blood is collected in routine EDTA tubes, any delay in testing, for example when samples need to be transported between collection site and a central analysis location, can have a negative impact on results by allowing degradation of nucleated (white blood) cells. The resulting shedding of intracellular genomic DNA into the blood plasma can contaminate the original cell-free DNA in the sample, negatively affecting results. Blood sample preservation using Cell3™ Preserver provides a solution for using cell-free DNA in genetic testing that supports centralised processing of samples and the transport of blood collection tubes from global locations without adversely affecting the sample quality.

Cell3™ Preserver tubes consist of blue capped polyethylene terephthalate tubes that are designed for direct draw blood collection. They contain an additive at the correct volume to simultaneously stabilize and anticoagulate human whole blood at the time of collection. The stabilizer acts by preserving the nucleated cells (white blood cells) until processing and analysis can be performed. Cell3™ Preserver tubes provide 9ml final draw volume. The vacuum contained within the tubes ensures that the Cell3™ Preserver reagent is administered at the correct ratio. Cell3™ Preserver tubes are sterilized by gamma radiation.

Precautions and warnings

1. Cell3™ Preserver tubes are intended for use as specified in this document. They are a research use only product.
2. Do not freeze the Cell3™ Preserver tubes, or blood specimens collected in Cell3™ Preserver tubes. Incubation times or temperatures other than those specified may lead to erroneous results.
3. Do not use Cell3™ Preserver tubes after the expiration date on the tubes and packaging.
4. Only use Cell3™ Preserver tubes to collect human whole blood specimens. Do not use tubes for collection of materials to be injected into patients.
5. Do not dilute or add other components to Cell3™ Preserver tubes.
6. Under-filling of tubes will result in an incorrect blood-to-additive ratio and may lead to incorrect analytic results or poor product performance.
7. Cell3™ Preserver tubes should only be used by trained phlebotomists.
8. Do not transfer specimens that have been collected in other tubes or specimens treated with other preservatives / anticoagulants into Cell3™ Preserver tubes.
9. Do not use cell viability stains on blood collected in Cell3™ Preserver tubes as they are fixed instantaneously.
10. Do not re-use Cell3™ Preserver tubes.
11. Cell3™ Preserver treated blood and all materials encountering it should be handled as if capable of transmitting infection.
12. Avoid contact of Cell3™ Preserver and Cell3™ Preserver treated blood samples with the skin and mucous membranes. The cell preservative is considered an irritant and any contact should be washed off with soap and water immediately.
13. Product should be disposed with infectious medical waste.
14. Remove and reinsert the cap by grasping with a simultaneous twisting and pulling action, not by 'thumb roll' method.
15. Cell3™ Preserver does not contain any antimicrobial reagents. Microbial contamination should be avoided or erroneous results may occur.
16. SDSs available on request via support@nonacus.com.

Prevention of backflow

1. Keep patient's arm in the downward position during the collection procedure.
2. Hold the tube with the cap in the uppermost position so that the tube contents do not touch the stopper in the cap or the end of the needle during sample collection.
3. Release tourniquet once blood starts to flow in the tube, or within 2 minutes of application.
4. Tube contents should not touch stopper in cap or the end of the needle during collection.

Indications of product deterioration

1. Cloudiness or precipitate visible in Cell3™ Preserver of unused Cell3™ Preserver tubes.
2. Reagent change from liquid to solid in unused Cell3™ Preserver tubes.
3. If indications of product deterioration occur, do not use Cell3™ Preserver tubes and immediately contact support@nonacus.com with details of the problem and the lot number.

Storage conditions and stability

Pre-sampling: Cell3™ Preserver tubes are supplied in a sealed foil pouch that contains a humidified environment in order to minimize the effect of Cell3™ Preserver evaporation from the tubes. Tubes in an unopened pouch are stable at 18–25 °C until the expiration date on the label. Once the pouch is opened, Cell3™ Preserver tubes have a shelf life of 3 months from the date that the pouch is opened. Do not freeze Cell3™ Preserver tubes.

Storage temperature	Product expiry (unopened pouch)	Product stability (Post open pouch)	Product stability (Post blood draw)
18–25 °C	12 months	3 months	15 days

Instructions for use

1. Complete tube label with relevant information.
2. Collect blood by venipuncture according to CLSI document H3–A62. Cell3™ Preserver tubes are compatible with shielded needle devices from most major manufacturers.
3. Fill tube completely. Blood will be aspirated up to the correct total volume and no further. This is important to avoid an incorrect Cell3™ Preserver to blood ratio that could affect results.
4. **Remove the tube from the needle holder and immediately mix by gentle inversion 10 times to distribute the Cell3™ Preserver throughout the blood sample. Inadequate or delayed mixing may result in inaccurate test results. Do not vortex.**
5. After collection, store/transport the blood-filled tubes at between 18–25°C for up to 15 days. Please note that to ensure the best results the shortest transport times and coolest temperatures within the above are recommended.

NOTE: Heavier cells and blood components will likely sediment over the 15 day period, forming two distinct layers. This is normal. Re-suspend the cells thoroughly by repeating step 4 if necessary.

6. Immediately process the blood once received. The following is a recommended protocol for separating plasma from the cellular blood portion.
 - Centrifuge the blood sample at 2,000 g for 10 minutes using a swinging bucket rotor.
 - Collect the separated plasma using a 1,000 µl pipette **ensuring that the buffy coat remains undisturbed.**
 - Aliquot into labelled 1.5–2 ml sterile 'PCR Clean' microcentrifuge tubes.
 - Centrifuge at maximum speed (minimum 10,000 g) for 10 minutes in a microcentrifuge.

NOTE: the second centrifugation step ensures that isolated plasma is free of cell debris, which can otherwise affect genetic results.

- Taking care not to disturb the pellet retrieve the supernatant using a 1,000 µl pipette and aliquot into a fresh sterile labelled 'PCR Clean' microcentrifuge 1.5–2 ml tube.
- Plasma can now be stored at –20°C for long term storage. The sample is now ready for cell free DNA extraction using the Nonacus Cell3™ Xtract spin columns, Bead Xtract cfDNA automated extraction kit or any other high-quality cell-free DNA specific extraction kit.

Studies have shown that moderately high levels of hemolysis, icterus and lipemia do not affect the results. Grossly hemolyzed samples should be rejected. A certificate of analysis and a certificate of conformity can be provided with every Cell3™ Preserver lot.










References

1. Clinical and Laboratory Standards Institute. H3-A6, Procedures for the Collection of Diagnostic Blood. Specimens by Venipuncture; Approved Standard—Sixth Edition

Ordering information

Please contact Nonacus: info@nonacus.com for information, assistance and quotes. Alternatively, information can be found online at www.nonacus.com.

Glossary of harmonized symbols

			
Catalogue No.	Use by	Batch code	Manufacturer
			
Temperature limitation	Consult instructions for use	Do not re-use	Biological risk
			
Irritant	Suspected carcinogen	Sterile by	Research use only

Nonacus Limited
Quinton Business Park
11 Ridgeway
Birmingham
B32 1AF

info@nonacus.com

nonacus.com