Protocol Guide v 2.0

Cell3™ Preserver: Whole Blood Stabilization Tube

Cell3™ Preserver Whole blood stabilization tubes
(10x tube pack) - (PRE_C3P_WBSV_10_v2)
(50x tube pack) - (PRE_C3P_WBSV_50_v2)

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ADVANCING NON-INVASIVE HEALTHCARE

Revision History

Revision	Date	Revision Description
Version 1.2	April 2023	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.
Version 2.0	November 2024	Product and full protocol update

Intended use

Cell3™ Preserver: Whole blood stabilization tube (Product codes: PRE_C3P_WBSV_10_v2 (10 tube pack) and PRE_C3P_WBSV_50_v2 (50 tube pack) is an evacuated blood collection tube intended for the collection, transport, and storage of human whole blood specimens.

This product is research use only.

Summary and principles

Cell3™ Preserver: Whole Blood Stabilization tubes contain an additive which, when mixed with whole blood, stabilizes nucleated cells and helps in the anti-coagulation of blood cells. This prevents the release of intracellular genomic DNA (gDNA) into blood plasma during transport. Cell-free DNA (cfDNA) integrity can have detrimental effects on the downstream analysis, therefore correct sample preservation is crucial. Cell3™ Preserver tubes provide a superior alternative to standard EDTA tubes, ensuring higher quality cfDNA recovery from plasma by minimizing gDNA contamination during centralized processing and global transport.

Cell3™ Preserver tubes consist of capped polyethylene terephthalate tubes designed for direct draw blood collection. They contain an additive at the correct volume to simultaneously stabilize and anti-coagulate 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 9 ml final draw volume and the vacuum contained within the tubes ensures that the Cell3™ Preserver reagent is administered at the correct ratio. Cell3™ Preserver Whole blood preservation tubes have been sterilized.

Precautions and warnings

1. Cell3™ Preserver tubes are intended for use as specified in this document. They are a research use only product.
2. Cell3™ Preserver tubes are intended for use by qualified clinical personnel.
3. Do not use when product is damaged due to foreign impurities.
4. Do not freeze the Cell3™ Preserver tubes, or blood specimens collected in Cell3™ Preserver tubes.
5. Incubation times or temperatures other than those specified may lead to erroneous results.
6. Do not use Cell3™ Preserver tubes after the expiration date on the tubes and packaging.
7. Only use Cell3™ Preserver tubes to collect human whole blood specimens.
   Do not use tubes for collection of materials to be injected into patients.
8. Do not dilute or add other components to Cell3™ Preserver tubes.
9. Under-filling of tubes will result in an incorrect blood-to-additive ratio and may lead to incorrect analytic results or poor product performance.
10. Do not transfer specimens that have been collected in other tubes or specimens treated with other preservatives/anticoagulants into Cell3™ Preserver tubes.
11. Do not use cell viability stains on blood collected in Cell3™ Preserver tubes as they are fixed instantaneously.
12. Do not re-use Cell3™ Preserver tubes.
13. Do not centrifuge Cell3™ Preserver tubes above 3000 g.
14. Cell3™ Preserver treated blood and all materials encountering it should be handled as if capable of transmitting infection.
15. Avoid contact of Cell3™ Preserver and Cell3™ Preserver treated blood samples with the skin and mucous membranes. The cell preservative is considered as hazardous and irritant and any contact should be washed off with soap and water immediately.
16. Product should be disposed with infectious medical waste.
17. Remove and reinsert the cap by grasping with a simultaneous twisting and pulling action, not by a ‘thumb roll’ method.
18. Cell3™ Preserver does not contain any antimicrobial reagents. Microbial contamination should be avoided or erroneous results may occur.
19. Product is not suitable for people with jaundice and hyperlipidemia.
20. MSDS is available and can be downloaded from our website (www.nonacus.com)

Prevention of backflow

Since Cell3™ Preserver tubes contain chemical additives, it is important to avoid possible backflow from the tube. To guard against 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.

Storage conditions and stability

Pre-sampling: Tubes can be stored at 15-25°C for twelve months before use and are stable for ambient shipment. Do not freeze Cell3™ Preserver tubes.

Cell3™ Preserver: Whole Blood Stabilization tubes come in robust carboard boxes and are available in 10 or 50 pack sizes. Tubes should be stored in the original packaging at the recommended storage temperature (15-25°C) and avoid storing tubes in direct sunlight or UV.

Post-sampling: Blood samples collected in Cell3™ Preserver tubes are stable up to 10 days at room temperature (15-25°C).

In the event of sample storage outside of the recommended conditions sample stability can be affected. See Table below for details.

	cfDNA	**WBCs**
Storage Temperature	6-35°C	6-25°C
Duration	10 days	10 days

Please note that to ensure the best results, the shortest transport times and maintaining temperatures within the recommended range 15-25°C are advised.

Instruction for use:

1. Collect blood by venipuncture according to CLSI document H3-A6.1 Cell3™ Preserver tubes are compatible with shielded needle devices from most major manufacturers..
2. Fill the 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 the results.
3. Remove the tube from the needle holder and immediately mix by inversion 10 times to distribute the reagent throughout the blood sample. Inadequate or delayed mixing may result in inaccurate test results. Do not vortex.
4. After collection, store/transport the blood-filled tubes at between 15-25°C up to 10 days.

   NOTE: Please note that to ensure the best results the shortest transport times and coolest temperatures within the above range are recommended.
5. 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 1500 g for 10 minutes using swinging bucket rotor.

   • Collect the separated plasma using a P1000 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 test results.

   • Taking care not to disturb the pellet, retrieve the supernatant using a P1000 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 column, Bead Xtract cfDNA automated extraction kit or any other high quality cfDNA specific extraction kit.

Studies have shown that moderate hemolysis does not affect sample quality and results. Higher levels of hemolyzed samples may not be suitable for processing via automation, due to loss of distinct layer separation of plasma to buffy coat and red blood cells. Samples can be processed manually, if required. Grossly hemolyzed samples should be rejected.

References

1. Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Sixth Edition. CLSI document H3-A6. Wayne, PA: Clinical and Laboratory Standards Institute; 2007. ISBN 1-56238-650-6.

Ordering information

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

Nonacus Limited
Quinton Business Park
11 Ridgeway
Birmingham
B32 1AF

info@nonacus.com

nonacus.com