Cell3™ Preserver: Whole blood stabilization tube

For collection and stabilization of whole blood for circulating cell-free DNA (cfDNA) applications

Highlights

Stabilizes whole blood for up to 10 days at room temperature
Eliminates the need for immediate plasma processing allowing laboratories to centralize testing by sending and receiving samples. Cell-free DNA stability for up to 10 days post blood draw makes Cell3™ Preserver tubes ideal for batching samples prior to countrywide or international shipping.

Plastic, robust, evacuated tube in 10ml format
Avoids potential glass breakage during transport or centrifugation, reducing the need for resampling, repeat visits by patients to clinics and hospitals and ensures ease of use by phlebotomists using standard blood draw equipment and disposables.

Suitable for non-invasive applications
Quality and quantity of cfDNA extracted from blood and collected in Cell3™ Preserver tubes was assessed for for liquid biopsy applications, alongside the market leading cell stabilization tube, to ensure suitability for downstream applications.

Developed and verified with data
Data generated using qPCR, DNA fragment analyzer and NGS showed equivalent or better results/metrics for cfDNA analysis compared to the market leading company.

Validated for multiple platforms
Cell3™ Preserver whole blood collection tubes ensure the highest quality of cfDNA that can be used for downstream applications such as NGS, qPCR or DNA fragment analyzer. Data showed equivalent or better results/ metrics for cfDNA analysis compared to market leading company.

Introduction

Modern genetic techniques such as next generation sequencing (NGS), droplet digital PCR (ddPCR) and quantitative PCR (qPCR) are extremely sensitive and can provide a rapid and accurate assessment of genetic variants from a blood sample. Over recent years, circulating cfDNA in biological fluids has been of growing interest in oncology studies.
However, blood collection in routine EDTA tubes can have a negative impact on cfDNA based tests if plasma is not isolated within 24 hours from blood draw, due to the degradation of nucleated (white blood) cells and shedding of genomic DNA (gDNA) into the plasma. Therefore, any delays in transport of samples from collection site to analysis location can negatively impact results.

Tube format

Cell3™ Preserver tubes consist of evacuated, polyethylene terephthalate (PET) tubes designed for direct-draw blood collection. They contain an additive at the correct volume to simultaneously stabilize blood cells and impede coagulation at the time of collection.
The stabilizer acts by preserving the nucleated cells (white blood cells) in an intact state until processing and analysis can be performed. Phlebotomists can use these tubes with standard draw techniques and equipment.

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Data quality

For quality assurance purposes, Cell3™ Preserver tubes were compared to market leading cell stabilization tubes for key technical aspects.

Hemolysis

Whole blood collected using Cell3™ Preserver tubes demonstrates no or minimal hemolysis for up to 10 days post blood draw (Figure 1), allowing clear distinction between different blood layers, making it suitable for manual and automated processing.

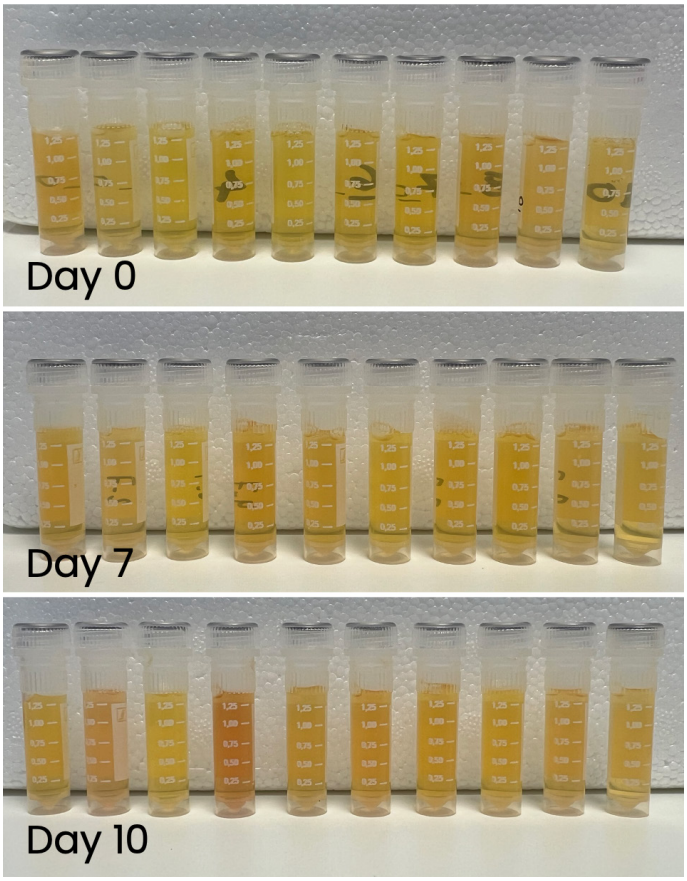

Figure 1: : The clarity of plasma for blood samples collected for 10 individual donors and stored with Cell3™ Preserver tubes across 10 days.

Sample stability

Concentration of total DNA in plasma was not impacted and kept consistent across 10 days when stored with Cell3™ Preserver tubes (Figure 2). Direct comparison against equivalent product on the market showed better performance in yield recovery for Cell3™ Preserver tubes (Figure 3).

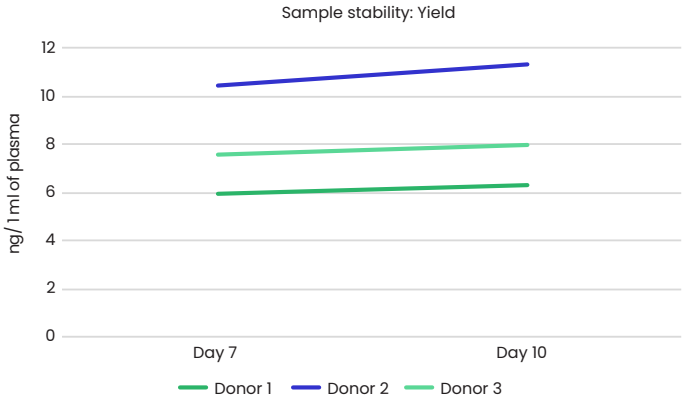

Figure 2: Stability of cfDNA yield [ng per 1ml of plasma]. Sample stability was evaluated using 3 different donors across 10 days, where total yields were shown consistent between the time points.

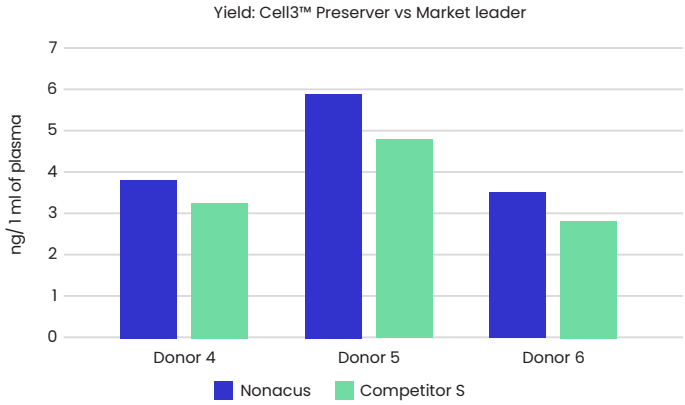

Figure 3: cfDNA yield [ng per 1ml of plasma] for Cell3™ Preserver tubes compared to Competitor S, 10 days post blood draw.

Genomic DNA contamination

Lack of stabilization of white blood cells (WBCs) can result in white blood cells lysing and releasing gDNA into plasma causing contamination which has a negative impact on downstream analysis. Cell3™ Preserver tubes ensure that WBCs are stabilized over 10 days preventing gDNA contamination and maintaining high cfDNA integrity.

cfDNA sample quality and gDNA contamination can be assessed with TapeStation 4200 cfDNA assay, the instrument software calculates the percentage of cfDNA content and gDNA contamination giving a quality metric of %cfDNA.

Cell3™ Preserver tubes preserve blood samples to a high quality ensuring good quality cfDNA. Concentrations of >70% were seen at blood draw (day 0) and provide comparable %cfDNA for up to 10 days (Figure 4). Cell3™ Preserver tubes show equivalent stability to a market leading cfDNA blood stabilization tube (Figure 5).

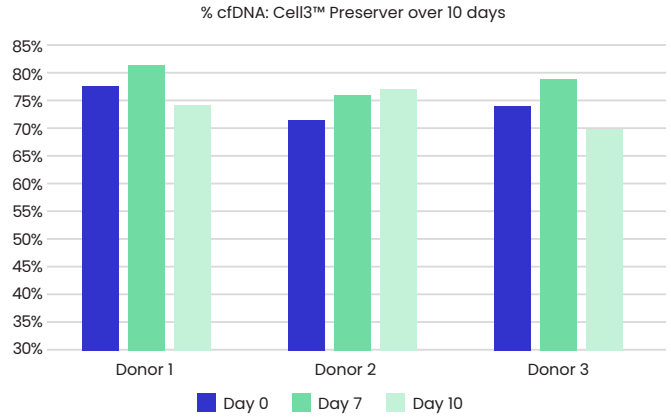

Figure 4: Stabilized %cfDNA across 10 days. WBC stability and cfDNA integrity was evaluated using 3 different donors across 10 days, measuring %cfDNA for each time point.

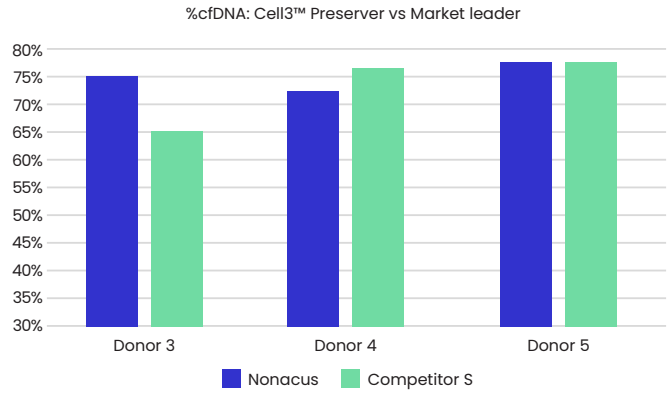

Figure 5: %cfDNA for Cell3™ Preserver blood samples stored for 10 days compared to the market leading cfDNA Blood stabilization tube from the same 3 donors.

Cell-free DNA quality

Cell-free DNA extracted from plasma stored in Cell3™ Preserver tubes provides a quality of cfDNA suitable for downstream analysis like NGS, ddPCR and qPCR.

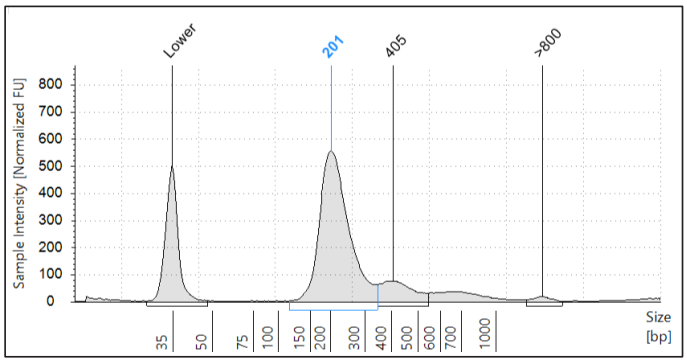

Figure 7: Electropherogram profile of cfDNA extracted* from plasma separated after 10 days, generated with TapeStation 4200, cfDNA assay.
The electropherogram shows the distinct profile typical for good quality cfDNA samples. Sample cfDNA calculated by TapeStation software is 93%.

*cfDNA extracted with Cell3™ Xtract

Summary

Preserver tubes are plastic whole blood preservation tubes that have been validated to maintain blood cell stability for 10 days after collection, matching the performance of the leading market product. The Cell3™ Preserver tubes have been designed for sample collection and shipment from around the world to centralized lab facilities to maximize diagnostic potential.

Ordering information

Product	Catalog No.
Cell3™ Preserver Whole blood stabilization tubes (10x tube pack)	PRE_C3P_WBSV_10_v2
Cell3™ Preserver Whole blood stabilization tubes (50x tube pack)	PRE_C3P_WBSV_50_v2

Nonacus Limited
Quinton Business Park
11 Ridgeway
Birmingham
B32 1AF

info@nonacus.com