

Cell3™ Preserver - Whole Blood Stabilization Tube

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

Highlights

- Stabilizes whole blood for up to 21 days at room temperature**
 Longer and wider ranging cell stability (4°C - 37°C) make Cell3™Preserver the perfect tube for batching samples prior to countrywide or international shipping
- Plastic evacuated tube with standard tube format**
 Avoids potential glass breakage and ensures ease of use by phlebotomists using standard draw equipment and disposables
- Formatted for clinical high throughput and automated workflows**
 Barcoded labels allow seamless workflow integration with automation, without the need to add barcodes manually
- Validated for non-invasive applications: NIPT and liquid biopsy testing**
 Quality and quantity of ccfDNA extracted from blood and collected in the Cell3™Preserver tube was assessed for NIPT and liquid biopsy applications alongside the market leading cell stabilization tube to ensure accuracy of genetic testing
- Data generated across multiple platforms**
 Data generated using qPCR, DNA fragment analyzer and NGS (whole genome sequencing and targeted resequencing approaches) showed equivalent or better results/metrics for ccfDNA analysis compared to the market leading company

Introduction

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 from a blood sample. Recently, circulating cell-free DNA in biological fluids has been of growing interest in oncology, prenatal and transplant studies. However, blood collection in routine EDTA tubes can have a negative impact on ccfDNA 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 into the plasma. Therefore, any delays in transport of samples from collection site to analysis location can negatively impact on results.

Tube format

Cell3™Preserver tubes consist of sterile, evacuated, polyethylene terephthalate tubes that are 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. Tubes are labelled with barcodes which can be linked to patient details for LIMS compatibility and sample tracking to assist with high throughput and automated procedures.

Data quality

For quality assurance purposes, Cell3™Preserver tubes were compared to Streck tubes in key ccfDNA testing applications, such as NIPT and liquid biopsy.

NIPT: Serenity NIPT test (Illumina technology, based on the Verifi test) kindly undertaken at CooperGenomics. Blood samples from 5 patients were collected into both Cell3™Preserver and Streck tubes for testing. Plasma was isolated at 5 days after blood draw for Streck tubes and 5 and 11 days for Cell3™Preserver tubes. CcfDNA was extracted and analyzed with the Serenity test for NIPT of fetal aneuploidies. Correct outcomes were observed for all tubes and time points (i.e. 2 male and 2 female euploid, and one monosomy X). Testing metrics showed comparable data across all time points (figures 1 and 2).

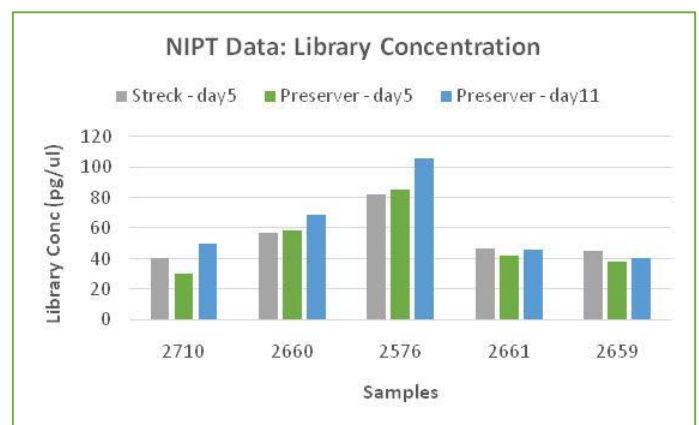


Figure 1: DNA concentration of PCR-free libraries prepared from ccfDNA for whole genome sequencing on NextSeq500 (Illumina).



Data Sheet: Blood Stabilization Tube for ccfDNA applications

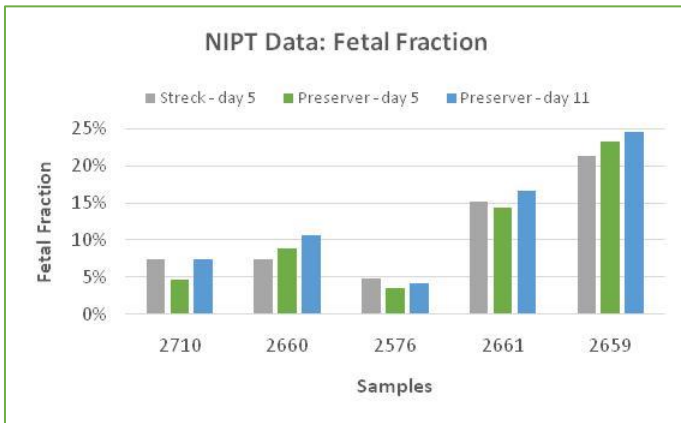


Figure 2: fetal fraction observed.

Liquid biopsy: circulating tumor DNA (ctDNA) is showing great promise as a biomarker analyte for cancer diagnosis, stratification of patient treatment and disease surveillance. To validate Cell3™Preserver technology in this field, a blood sample from a patient with metastatic breast cancer was collected in Cell3™Preserver and Streck tubes post chemotherapy. CcfDNA was extracted and tested alongside gDNA obtained from leukocytes and a FFPE biopsy sample of the primary tumor. Targeted resequencing across a panel of genes commonly associated with cancer was performed at high depth using Illumina sequencing. Bioinformatics analysis was conducted to annotate variants and identify causative actionable mutations. Variant frequencies were calculated and compared between samples collected in Cell3™Preserver and Streck tubes (figure 3)

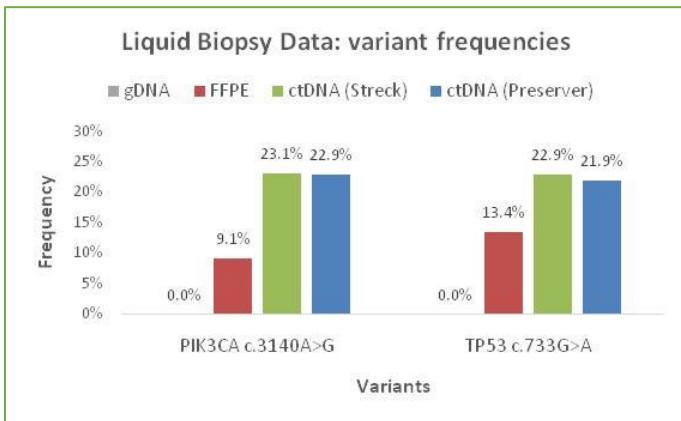


Figure 3: two identified pathogenic variants were found present in the FFPE and ctDNA samples, but not in the germline gDNA.

CcfDNA quantity and quality: to assess the quantity and quality of extracted ccfDNA, a blood sample was collected from a pregnant woman at 16 weeks of gestation in Cell3™Preserver and Streck tubes. Plasma was isolated at 3, 6, 13 and 20 days after blood draw and ccfDNA was extracted with the Cell3™Xtract kit, which was tested by quantitative PCR, fluorometric assay and DNA fragment analyzer to assess DNA quantity and quality. The house keeping gene CCR5 was targeted in qPCR testing and the Qubit 3.0 (Invitrogen) was used to measure ccfDNA concentration (figure 4); while the TapeStation 2200 (Agilent Technologies) was used to

determine fragment size distribution (figure 5). The data obtained showed superior stability for the Cell3™Preserver over Streck at the 20 day time point.

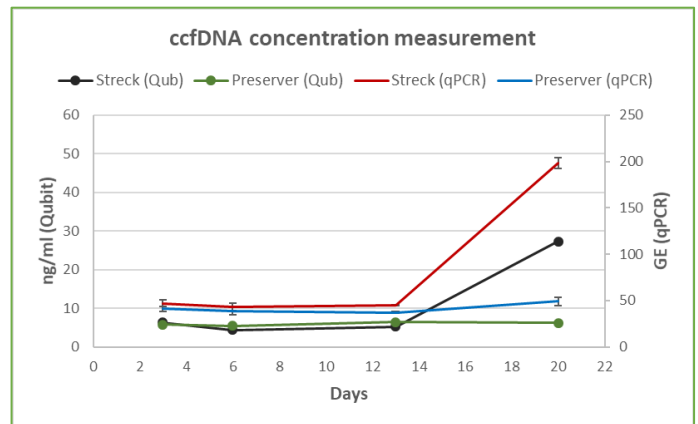


Figure 4: DNA concentration measurements by Qubit (left axis) and qPCR (CCR5 amplification) (right axis) on ccfDNA extracted from plasma collected in Cell3™Preserver and Streck tubes and isolated at 3, 6, 13 and 20 days post blood draw.

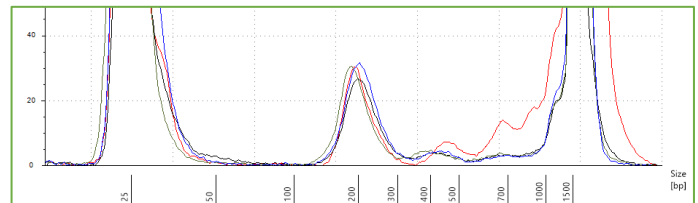


Figure 5: fragment size distribution (TapeStation) of ccfDNA extracted from plasma collected in Streck (black: 3 days; red: 20 days) and Cell3™Preserver (blue: 3 days; green: 20 days) tubes.

Summary

The Cell3™Preserver is a plastic, whole blood preservation tube validated for NIPT and liquid biopsy applications. Showing superior blood cell stability compared with the leading market company at over 13 days after blood draw, the Cell3™Preserver tube has been designed for sample collection and shipment from around the world to centralized lab facilities. A sample barcode is included to allow LIMS compatibility, sample tracking and to assist high throughput clinical and translational labs.

Learn more

To learn more about the Cell3™Preserver tubes and to download the protocols, MSDS, please visit: www.nonacus.com

Ordering Information

Product

Catalogue No.

Cell3™ Preserver 9ml, 100 Tube Pack C3009ML

If you have any questions, then please visit our website www.nonacus.com or email: info@nonacus.com

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