Transport Under Various Conditions: Evaluating Blood Sample Stability Across Seasons

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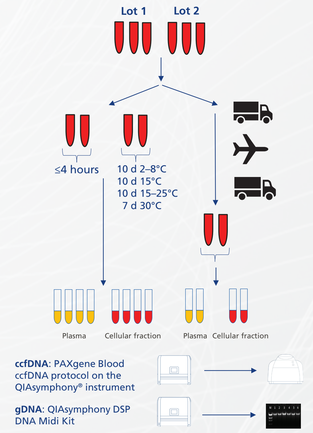
Introduction

- For analysis of circulating cell-free DNA (ccfDNA) in cancer research or monitoring, specialized blood collection tubes – such as the PAXgene® Blood ccfDNA Tube (PreAnalytiX) – offer a reliable solution for users who are unable to process samples within 4 hours of collection. These tubes stabilize ccfDNA profiles by preventing blood cells from releasing genomic DNA (gDNA) during transport, thereby preserving sample integrity for sensitive downstream ccfDNA analyses.
- According to international standards and regulations (ISO 20186-3:2019, (EU) 2017/746 on In Vitro Diagnostic Medical Devices), preanalytical conditions such as sample collection, transport and storage must be validated to ensure that the quality of ccfDNA is maintained if used in downstream workflows.
- Here, we evaluated sample packaging, temperature fluctuations during transit, and the impact of shipment on assay performance to assess whether blood samples in PAXgene Blood ccfDNA Tubes can be reliably transported at ambient temperature.

Methods

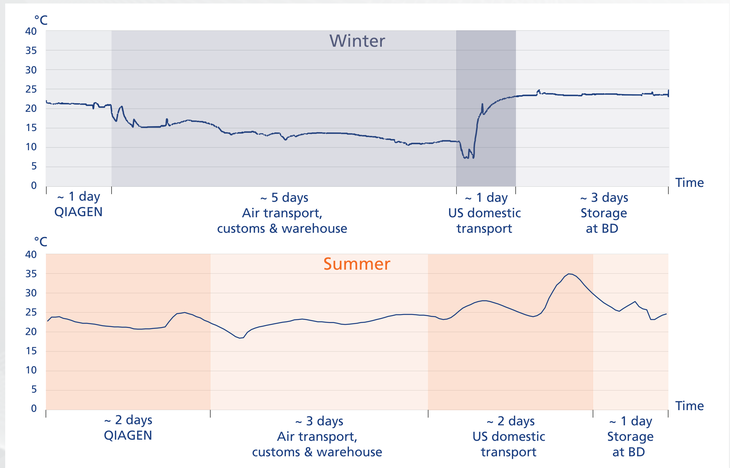
- Blood was collected from 29 or 30 apparently healthy, consented donors into two lots of PAXgene Blood ccfDNA Tubes for a single transport shipment during summer (June) or winter (January), respectively. Additional samples were processed under the following conditions:
  - Within 4 hours of phlebotomy (T0)
  - After storage at 2–8°C for 10 days
  - After storage at 15°C or at room temperature (15–25°C) for 10 days
  - After storage at 30°C for 7 days
- For international transport, tubes were shipped from the collection site (QIAGEN, Hilden, Germany) to an external processing site (BD, Franklin Lakes, USA). Samples were placed in insulated boxes compliant with IATA standards and without active temperature control. This included a leakproof triple packaging concept with a primary receptacle, a secondary package, and a rigid outer package.
- Upon arrival, blood samples were processed directly. For samples transported during winter, an additional sample from each donor was subjected to an additional transport simulation test according to requirements defined in the standard ASTM D4169.
- Plasma and cellular fraction were separated, frozen and shipped back to the collection site (QIAGEN) for ccfDNA and gDNA extraction and analysis.



Results

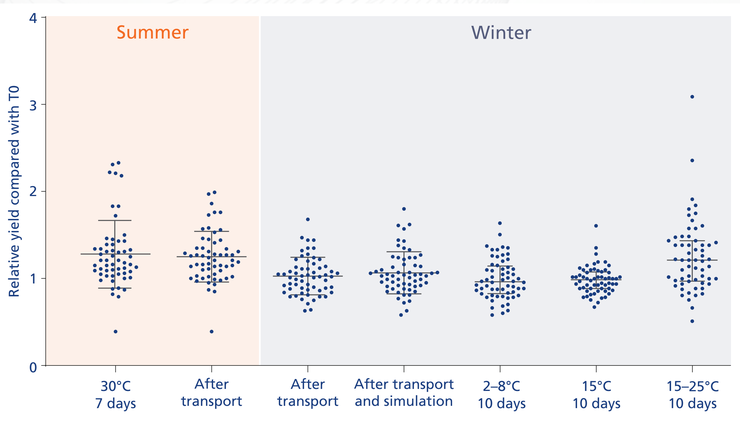
Temperature profiles during winter and summer transport

Whole blood samples were collected into PAXgene Blood ccfDNA Tubes and transported from QIAGEN (Hilden, Germany) to BD (Franklin Lakes, USA) by air and ground transportation.



ccfDNA after transport or storage

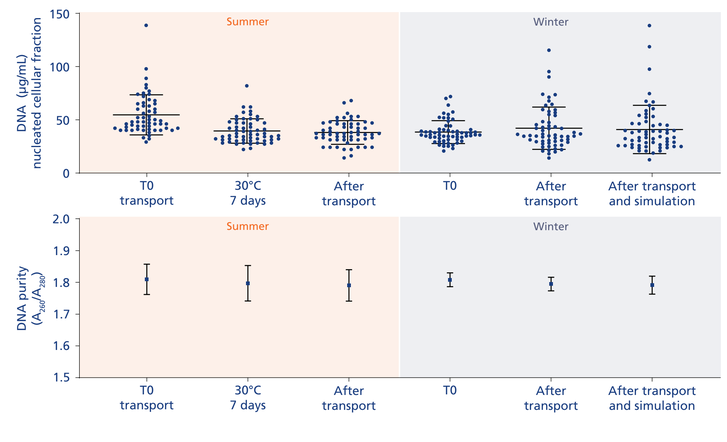
Relative yield of ccfDNA compared to T0 extracted from PAXgene Blood ccfDNA samples after storage under controlled conditions or transportation during summer and winter time.



Relative ccfDNA yield from 29 (summer) or 30 (winter) apparently healthy donors' blood samples collected into two lots of PAXgene Blood ccfDNA Tubes (n = 58 or n = 60). Relative yield calculated as the ratio of the 18S rDNA copy numbers from samples after transport or storage, compared to copy numbers of samples from the same donor processed within 4 hours after blood collection (T0). Automated ccfDNA purification was performed using the 2.4 mL PAXgene Blood ccfDNA plasma protocol using the QIAsymphony SP instrument. Quantification with probe-based validated qPCR assay (target 18S rDNA gene, 66 bp amplicon) on the QIAGEN® Rotor-Gene® Q instrument. Medians and the 25th and 75th percentiles are shown. Transport simulation followed applicable schedules and requirements listed by ASTM D4169, which includes drop, altitude and vibration testing to simulate air and truck transportation.

Genomic DNA after transport or storage

Genomic DNA yield and purity from PAXgene Blood ccfDNA samples after storage under controlled conditions or transportation during summer and winter time.



Genomic DNA yield and purity from 29 (summer) or 30 (winter) apparently healthy donors' blood samples collected into two lots of PAXgene Blood ccfDNA Tubes before and after sample transport or storage (n = 58 or n = 60). gDNA was extracted from the nucleated cellular fraction using the QIAsymphony DSP DNA Mini Kit on the QIAsymphony SP instrument. Genomic DNA yield and purity were determined by spectrophotometry. For gDNA yield medians and the 25th and 75th percentiles, for gDNA purity mean with standard deviation are denoted. Transport simulation followed applicable schedules and requirements listed by ASTM D4169, which includes drop, altitude and vibration testing to simulate air and truck transportation.

Conclusions

- Excellent sample stability was demonstrated in whole blood samples collected into PAXgene Blood ccfDNA Tubes under both controlled storage and real-world transport conditions.
- The data confirm that sample integrity is maintained in PAXgene Blood ccfDNA Tubes following air and ground transportation at ambient temperatures across both summer and winter seasons.

Disclaimer

This poster is only for use in Europe. The PAXgene Blood ccfDNA Tube (CE-IVD) is intended for in vitro diagnostic use.

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