



# Strive for consistent, optimized, and standardized sample collection and processing in clinical trials

Optimize preanalytical steps and increase efficiency of clinical trials

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# Don't compromise the accuracy of your clinical trials

Liquid biopsy can enable more frequent and efficient biomarker detection and monitoring, using biomarkers like cell-free DNA (cfDNA) for real-time insights in oncology, non-invasive prenatal testing (NIPT) and transplant medicine. However, preanalytical errors and lack of standardization can impact diagnostic accuracy and clinical trials.

To ensure sample reliability and compliance with EU IVDR, validated preanalytical technologies are essential.

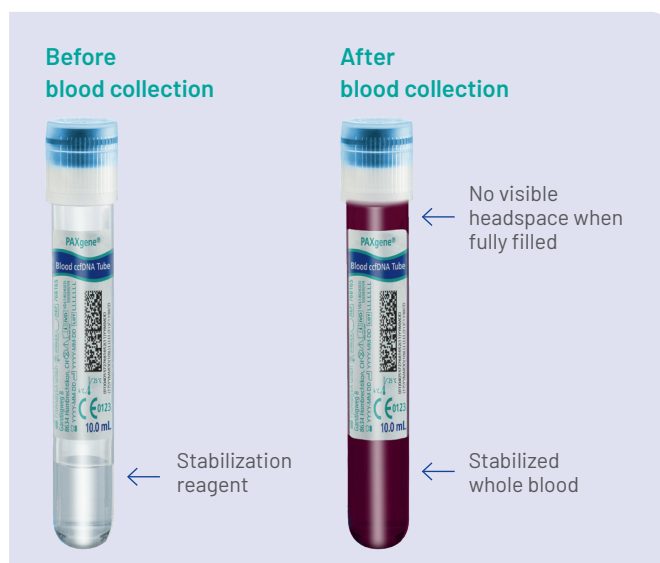
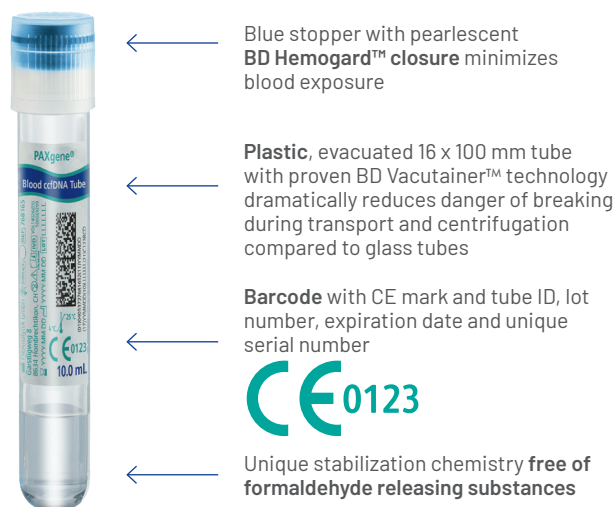
PAXgene® Blood ccfDNA Tubes have been CE certified for In Vitro Diagnostic Use according to the Regulation (EU) 2017/746 on Vitro Diagnostic Medical Devices (IVDR) and offers a benefit of sample stabilization and preservation for analysis of rare cfDNA mutations.

**Improve workflow efficiency in preparing cfDNA samples by using a fit-for-purpose tube**

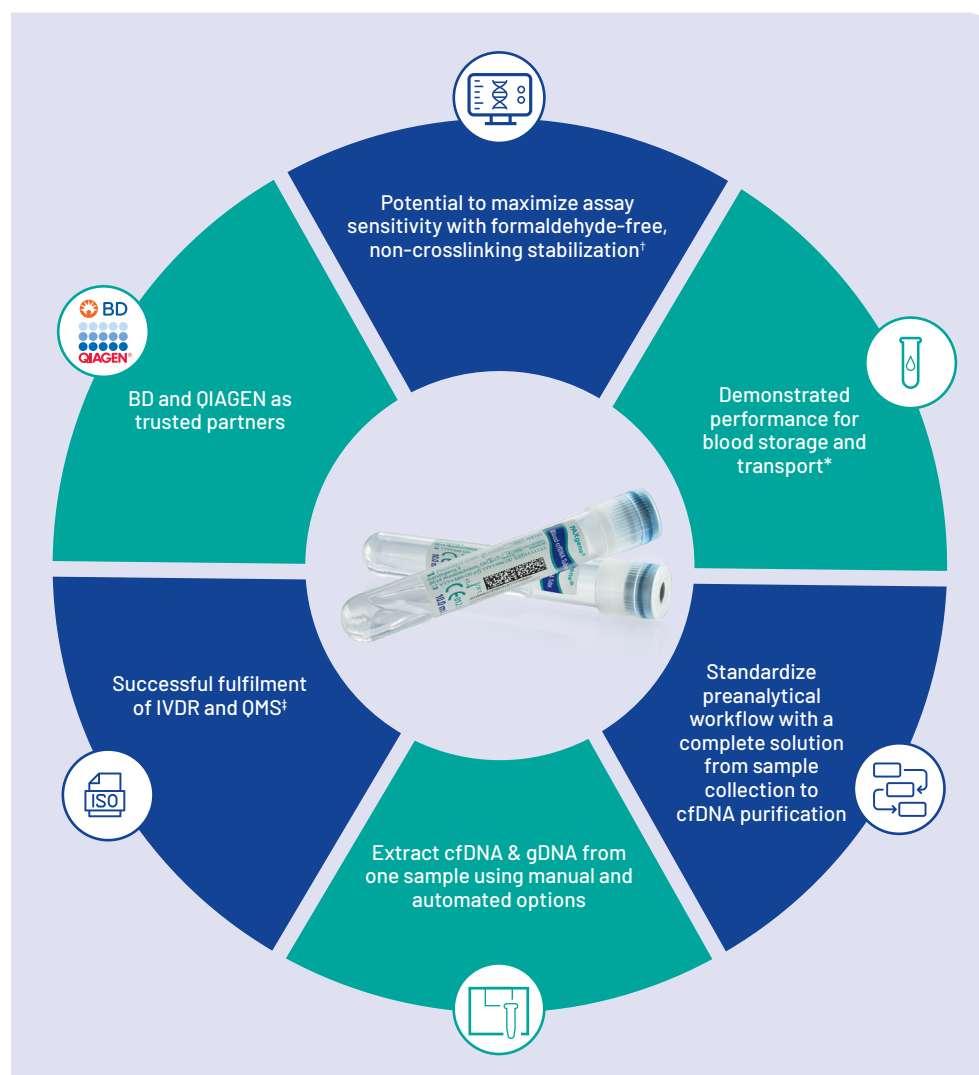


## Preserve limited ccfDNA present in samples by optimizing clinical research workflows and standardize the collection and processing of whole blood with the PAXgene Blood ccfDNA Tube (CE-IVD)

### Key features



Don't compromise the accuracy of your clinical trials choose PAXgene Blood ccfDNA products

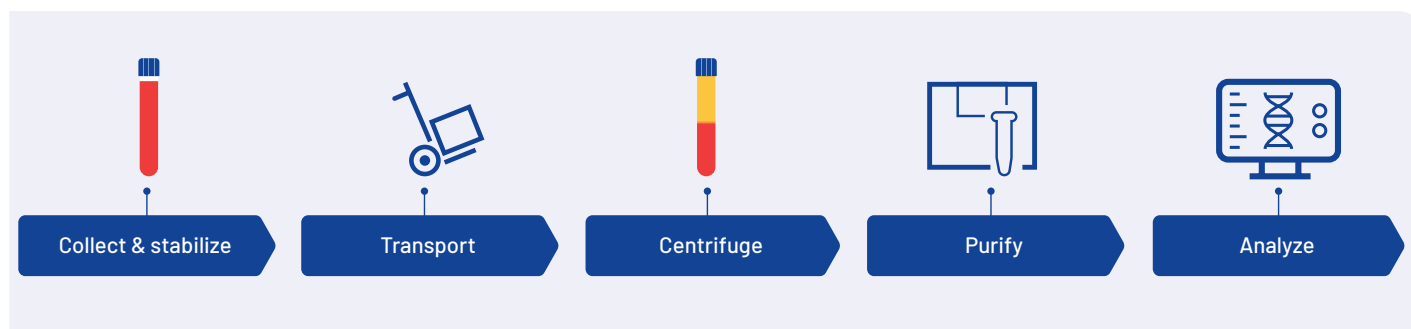


- <sup>\*</sup> Check performance characteristics for sample durations and temperatures instructions for use for more detail
- <sup>†</sup> Voss, T. et al. (2021) Sensitivity assessment of workflows detecting rare circulating cell-free DNA targets: A study design proposal. PLOS ONE 16(7): e0253401
- <sup>‡</sup> Quality Management System (QMS) according to ISO 13485 and compliance to EU IVDR 2017/748 for In Vitro Diagnostic Medical Device (IVDR)



# PAXgene Blood ccfDNA CE-IVD workflow

Complete workflow solution for ccfDNA and gDNA analysis from whole blood



## Ordering information

Product	Contents	Cat. no.
PAXgene Blood ccfDNA Tube (CE-IVD)(100)	100 PAXgene Blood ccfDNA Tubes (10 mL)	768165*
Accessories	Contents	Cat. no.
BD Vacutainer UltraTouch Push Button Blood Collection Set	23 G 3/4" (0.6×19 mm) needle, 12" (305 mm) tubing with luer adapter. 50/box, 200/case	367364
BD Vacutainer One-Use Holder	White, standard plastic holder for 13mm and 16mm diameter tubes	364815

Notes: To be used by trained professional. ccfDNA and gDNA yields depend on the patient and the quality of the specimen. Please refer to the IFU for the full list of limitations, warnings, and precautions.

For In Vitro Diagnostic Use according to EU Regulations on in vitro diagnostic medical devices (Regulation (EU) 2017/746). Every component of the ccfDNA workflow is compliant to IVD.

\* Sold by BD. Not available in all countries.

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**Better samples. More to explore.**

Discover more about the PAXgene Blood ccfDNA products at:  
[www.preanalytix.com](http://www.preanalytix.com)

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