PAXgene® Blood DNA

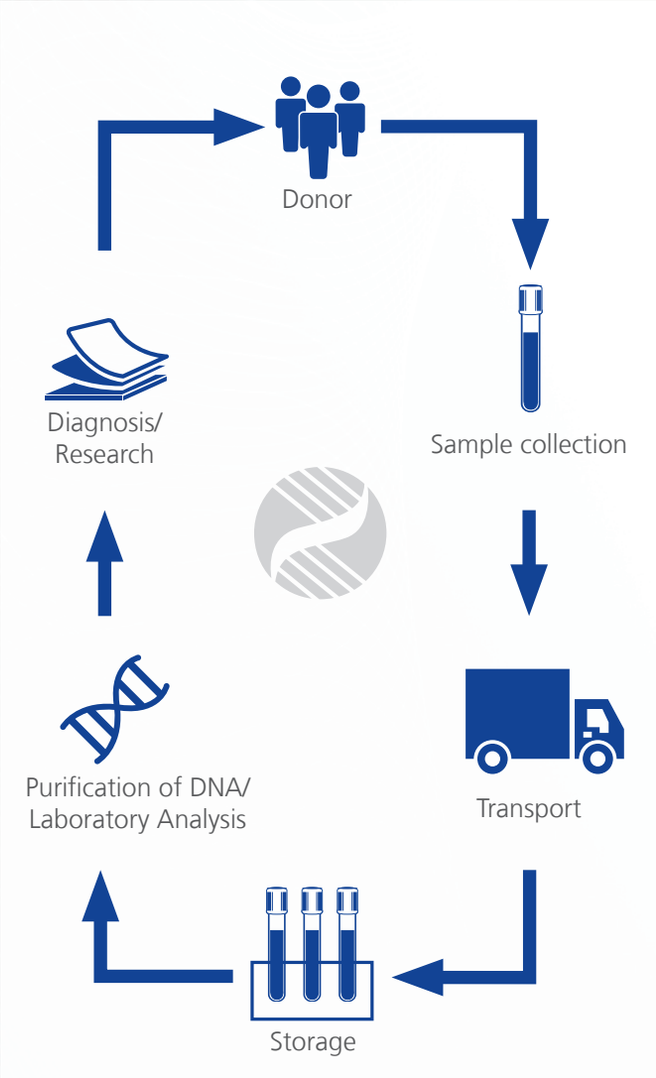
PAXgene Blood DNA Tube (IVD) for clinical use
PAXgene Blood DNA System (RUO) for research use

Explore more at **www.preanalytix.com**

PreAnalytiX
A QIAGEN / BD Company

Situation

The composition, amount, quality and integrity of nucleic acids in whole blood specimens can change dramatically upon collection. If samples are collected, transported and stored inadequately, the integrity of DNA is compromised, leading to degradation and affecting subsequent downstream analysis. Researchers do not know whether to accept or reject blood samples for achieving accurate and reliable results in genomic DNA testing if they have been exposed to prolonged transit and/or elevated temperature conditions. If re-sampling is required, project costs and time to result increase and customer satisfaction decreases.



Solution

Blood collection

Blood samples are drawn directly into PAXgene Blood DNA Tubes using standard phlebotomy technique. These tubes, based on proven BD Vacutainer® technology, contain proprietary stabilizing formulations that protect DNA in collected specimens at room temperature, refrigerated and when frozen. Thus, temperature fluctuations during transportation and storage do not impact the integrity of the DNA subsequently purified.

Minimize preanalytical variability

Using non-standardized methods for blood collection and DNA purification may influence comparisons of samples collected from different sites. The PAXgene Blood DNA Systems provide streamlined, integrated and standardized systems for collection of whole blood and straightforward DNA purification. The high-quality DNA isolated using PAXgene Blood DNA Systems performs well in a wide range of sensitive downstream applications, both when processed quickly or archived for future analysis.

Standardization

The PAXgene Blood DNA Tube (IVD) is the first blood collection tube dedicated to DNA testing with validated claims of blood sample stability over time and temperature conditions. With the streamlined blood collection and sample processing procedures, reproducible yields of high-quality DNA are rapidly achieved.

The PAXgene Blood DNA System (RUO) consists of a PAXgene Blood DNA Tube (RUO) for standardized collection, transport and storage of whole blood and a dedicated kit for straightforward isolation of DNA. The optimized single-tube protocol of the PAXgene Blood DNA Kit (RUO) for DNA purification uses prefilled-processing tubes, reducing the risk of sample mix-up and cross-contamination.

PAXgene Blood DNA Products at a Glance

PAXgene Blood DNA Tube (IVD)

- ✓ For in vitro diagnostic use
- ✓ Draw volume designed for clinical testing (2.5 ml)
- ✓ Compatible with magnetic bead- and silica membrane-based purification technologies
- ✓ Validated with QIAGEN® DSP DNA purification kits for automated workflows (QIAamp® DSP DNA Blood Mini or QIAsymphony® DSP DNA Mini and Midi Kits)

Unique benefits of the PAXgene Blood DNA Tube (IVD):

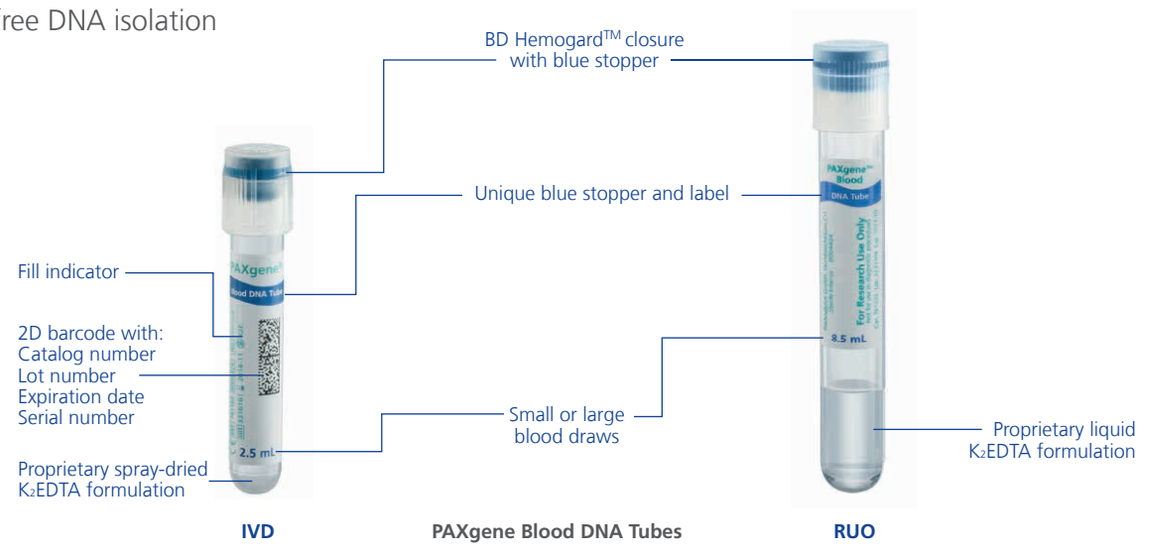
- Standardized collection method
- Expected DNA concentration from 200 µl blood aliquots for 95% of samples (µg DNA/µl eluate):
  - 18.2 ng/µl with magnetic-bead isolation (QIAsymphony; 200 µl eluate)
  - 18.6 ng/µl with silica-membrane isolation (QIAcube®; 100 µl eluate)
- Validated time and temperature claims for DNA stability:
  - 14 days at room temperature (18–25°C)
  - 28 days refrigerated (2–8°C)
  - 3 days at 35°C
  - 52 weeks frozen (–20°C)
  - 3 freeze-thaw cycles
- Increased workflow efficiency with unique sample identifier to reduce sample misidentification
- Automated processing on the QIAsymphony instrument with pre-programmed scripts and no need for aliquoting, as well as the QIAcube for hands-free DNA isolation

PAXgene Blood DNA System (RUO) comprised of PAXgene Blood DNA Tubes and Blood DNA Kit

- ✓ For research use only. Not for use in diagnostic procedures
- ✓ Large blood draw volume (8.5 ml)
- ✓ Integrated system with blood collection tube and DNA purification kit
- ✓ Manual DNA purification of each tube processed in one sample preparation column

Unique benefits of the PAXgene Blood DNA System:

- Integrated collection, transport and storage of blood and purification of genomic DNA in one system
- Standardized collection method with 8.5 ml draw volume for isolation of large amounts of DNA (DNA yield of 150–500 µg / 8.5 ml blood)
- Validated DNA stability after blood collection:
  - 14 days at room temperature (18–25°C)
  - 28 days at refrigerated (2–8°C)
  - 3 months frozen at –20°C and 2 years at –80°C (ongoing study); DNA eluate stability at 4°C and –20°C shown for 10 years
- High-quality, high molecular weight DNA with fragment sizes up to 200 kb, and predominant lengths of 50–150 kb
- Reduced risk of sample mix-up with efficient and easy to use one-tube purification system with pre-filled processing tubes



PAXgene Blood DNA Tube (IVD)

Validated solution for collection, anti-coagulation, stabilization, transport and storage of venous whole blood for in vitro diagnostic (IVD) DNA testing with flexible automated purification.

The PAXgene Blood DNA Tube (IVD) is robust to sample handling variability and is easily integrated into standard automated workflows. It can also be used with generic DNA preparation solutions to accommodate a range of in vitro diagnostic workflows. The PAXgene Blood DNA Tube (IVD) has been validated with the QIAamp DSP DNA Blood Mini Kit (IVD) for automation on the QIAcube and the QIAsymphony DSP DNA Mini and Midi Kits (IVD) for automation on the QIAsymphony instrument. Validation information, along with data from exposure to high temperatures, long-term storage at –20°C and freeze-thaw tests, is available at **www.preanalytix.com**.

Applications

PAXgene Blood DNA Tubes (IVD) can be used for blood collection formolecular diagnostic methods requiring DNA.

Performance with molecular diagnostic test methods

Evaluations of the PAXgene Blood DNA Tube has been performed for selected assays on certain instrument platforms. The performance of the PAXgene Blood DNA Tube was assessed relative to an EDTA tube control using FDA-cleared molecular diagnostic assays. Assays were evaluated at either 1 or 3 sites.

Objective	Sites	Assay	Samples tested	Incorrect calls	No-calls	% Correct calls
Site-to-site reproducibility	A, B, C	CF assay	20	0	0	100%
	A, B, C	HLA assay	20	0	0	100%
Lot-to-lot variation	A	CF assay	20	0	0	100%
	A	HLA assay	20	0	0	100%
Tube performance	A, B, C	CF assay*	117	0	1	99.1%
	A, B, C	HLA assay	120	0	0	100%
	D	Thrombophilia assay†	80	0	0	100%
	E	HLA assay	698	0	0	100%
Interference‡	E	HLA assay	100	0	0	100%

* After retest, CF assay, includes 1 sample from Site B showing a result of "No Call" that was not retested.
† Thrombophilia assay tested for mutations in MTHFR gene.
‡ Interference study included hemoglobin, bilirubin, triglycerides and albumin.

See the *PAXgene Blood DNA Tube (IVD) Product Circular* at www.preanalytix.com/reference-material for further details on performance testing.

The PAXgene Blood DNA Tube is compatible with a wide array of instruments, analyzers and assays.

Validation has been proven using common sample preparation instruments and analyzers for the following DNA tests:

- HLA testing
- CF testing
- Thrombophilia testing

DNA testing has been performed using:

DNA purification technologies

- Silica membrane
- Magnetic bead

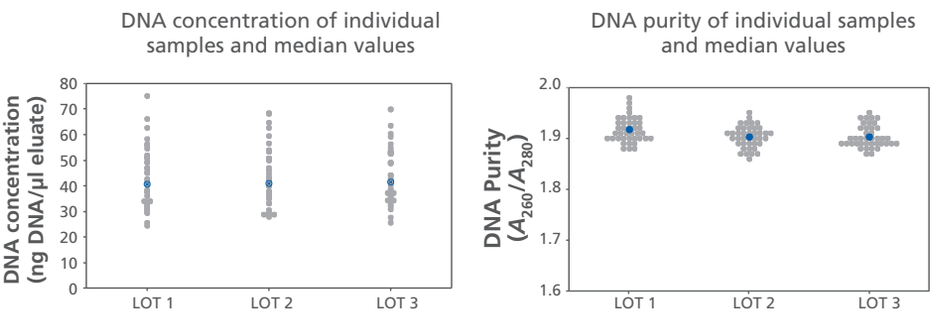
Assay technologies

- Multiplex PCR and multiplex allele-specific primer extension (ASPE) assay
- Sequence-specific oligonucleotide (SSO) PCR assay
- PCR and sandwich hybridization assay
- Sequence-specific primer (SSP) PCR assay

Assay instrument technologies

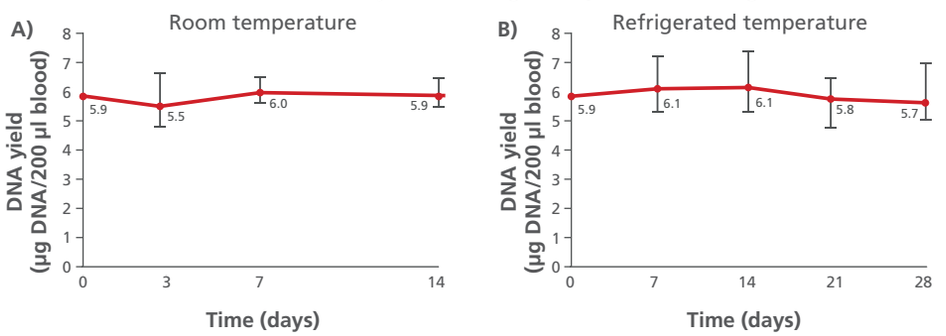
- Multiplex fluorescent microsphere-based flow cytometry
- Electrochemical detection DNA microarray
- Gel electrophoresis

Consistency of extracted DNA is critical for IVD assays



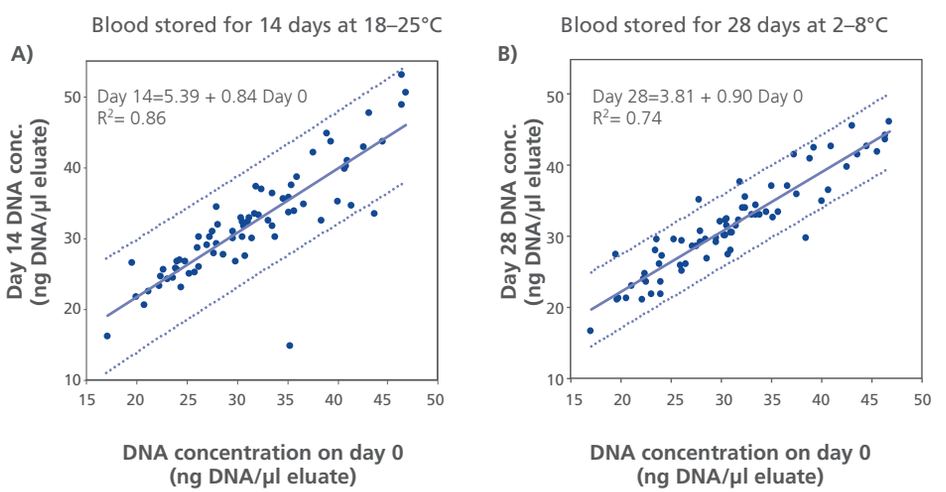
Blood was drawn from 20 subjects into PAXgene Blood DNA Tubes from 3 different lots, 2 tubes per lot. Tubes were stored at room temperature for ≤14 days. DNA was extracted from the 120 specimens using the QIAamp DSP DNA Blood Mini Kit (input blood volume: 200 µl; elution volume: 100 µl).

Stable DNA yields during transport and storage



Blood drawn from 12 subjects into PAXgene Blood DNA Tubes was stored for up to 14 days at 18–25°C [A] or up to 28 days at 2–8°C [B]. Tubes were removed from storage at different time points and DNA was extracted from the 200 µl whole blood using the QIAsymphony DSP DNA Kit (elution volume: 100 µl). Shown are the median and range of DNA yields obtained at each tested time point.

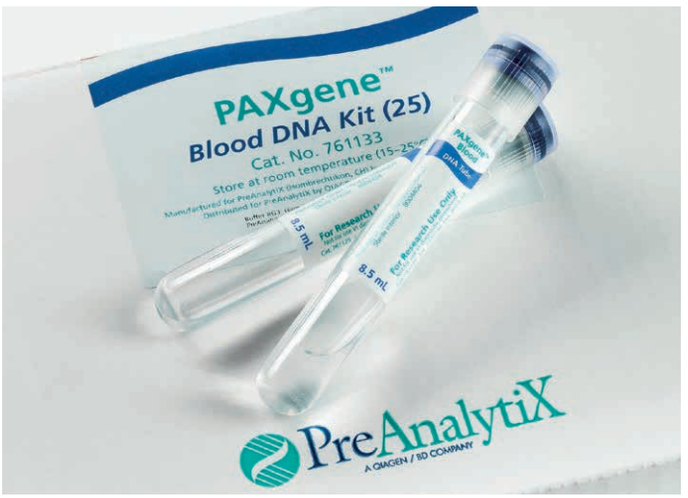
Consistent DNA concentration in blood stored under different conditions



Blood was drawn from each of 72 subjects into two PAXgene Blood DNA Tubes. One tube from each subject was processed within 2 hours of collection (day 0) and the other tube was stored at 18–25°C for 14 days [A] or at 2–8°C for 28 days [B]. After storage, DNA was extracted using the QIAsymphony DSP DNA Kit (elution volume: 200 µl). Shown is the correlation between DNA concentrations measured on day 0 and after storage (solid line), plus the corresponding 95% prediction interval (dashed lines).

PAXgene Blood DNA System (RUO)

Efficient, standardized solution for the collection, transport and storage of human whole blood with stabilization and manual purification of DNA. For Research Use Only.



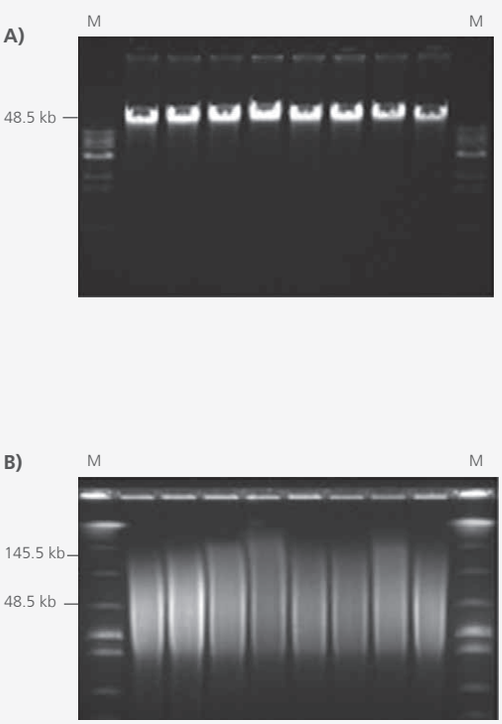
Performance

DNA from whole blood samples collected in PAXgene Blood DNA Tubes purified using the PAXgene Blood DNA Kit has an A_{260}/A_{280} ratio of 1.7–1.9. Expected DNA yield is 150–500 µg per 8.5 ml whole blood, depending on the number of nucleated cells present in the blood sample.

Applications

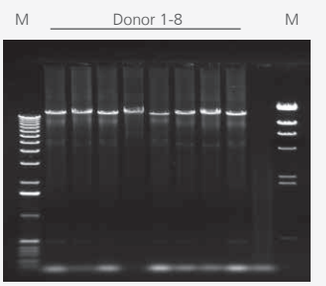
The resulting high-quality DNA can be used for down-stream aapplications requiring genomic DNA, including: PCR (multiplex, long-range and quantitative, real-time PCR), Southern blotting, SNP genotyping or sequencing.

High quality and high molecular weight DNA



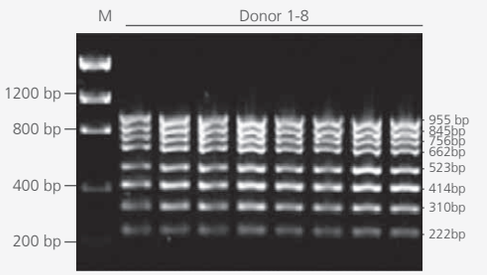
DNA isolated from 8 blood donors using the PAXgene Blood DNA System. [A] Standard agarose gel electrophoresis; [B] pulsed-field agarose gel electrophoresis for enhanced separation of high-molecular-weight genomic DNA. M: molecular weight markers.

Efficient amplification of ultralong genes



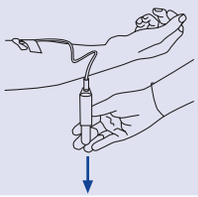
Amplification of a 15 kb fragment of the human coagulation factor IX gene, shown along with a negative control. DNA (250 ng) was isolated from 8 blood donors as starting material using the PAXgene Blood DNA System. M: molecular weight markers.

Efficient multiplex amplification of 8 fragments from single copy genes



Multiplex PCR from gene fragments using 250 ng DNA isolated from 8 blood donors using the PAXgene Blood DNA System as starting material. M: molecular weight markers.

Ordering Information

The PAXgene Blood DNA System integrates and standardizes workflows	
	Blood draw
	PAXgene Blood DNA Tube with 8.5 ml of blood
	Add contents of collection tube to prefilled 50 ml processing tube; mix, centrifuge and wash
	Protease digestion
	Isopropanol precipitation; mix, centrifuge and add 70% ethanol
 **Pure DNA**	Air-dry pellet and resuspend DNA

IVD Products	Contents	Cat. no.
PAXgene Blood DNA Tubes (IVD)	100 PAXgene Blood DNA Tubes (IVD) (2.5 ml)	761165
QIAamp DSP DNA Blood Mini Kit	For 50 preps: QIAamp Mini Spin Columns, buffers, reagents, tubes, VacConnectors.	61104
QIAsymphony DSP DNA Mini Kit	For 192 preps of 200 µl each: Includes 2 reagent cartridges and enzyme racks and accessories	937236
QIAsymphony DSP DNA Midi Kit	For 96 preps of 1000 µl each or 144 preps of 400 µl each: Includes 2 reagent cartridges and enzyme racks and accessories	937255
RUO Products		
PAXgene Blood DNA Tubes*	100 PAXgene Blood DNA Tubes (8.5 ml). To be used in conjunction with PAXgene Blood DNA Kit	761115
PAXgene Blood DNA Kit*	Processing tubes and buffers for 25 preparations. To be used in conjunction with PAXgene Blood DNA Tubes	761133
Accessories		
BD Vacutainer Eclipse™ Blood Collection Needle with Pre-Attached Holder	21G 1¼ inch (0.8 mm x 32 mm) needle, 100/case	368650
BD Vacutainer Eclipse Blood Collection Needle	21G 1¼ inch (0.8 mm x 32 mm) needle, 48/box, 480/case	368607 NA 368609 CE
BD Vacutainer Safety-Lok™ Blood Collection Set	21G ¾ inch (0.8 × 19 mm) needle, 12 inch (305 mm) tubing with luer adapter. 50/box, 200/case	367281 NA 367286 CE
BD Vacutainer One Use Holder	Case only for 13 mm and 16 mm Diameter, 1000/case	364815

***For research use only. Not for use in diagnostic procedures.**

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