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
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 pre-filled-processing tubes, reducing the risk of sample mix-up and cross-contamination.
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 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)
✓ 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 (QIAasyphony; 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 Products at a Glance
- PAXgene Blood DNA Tubes
  - BD Hemogard™ closure with blue stopper
  - Unique blue stopper and label
  - 2D barcode with:
    - Catalog number
    - Lot number
    - Expiration date
    - Serial number
  - Proprietary spray-dried K2EDTA formulation
- PAXgene Blood DNA System
  - Fill indicator
  - Unique blue stopper and label
  - Proprietary liquid K2EDTA formulation
- Small or large blood draws
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 for molecular 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.

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

* 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
**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 downstream applications 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**


**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.
The PAXgene Blood DNA System integrates and standardizes workflows

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood draw</td>
<td>Blood draw</td>
</tr>
<tr>
<td>PAXgene Blood DNA Tube with 8.5 ml of blood</td>
<td>PAXgene Blood DNA Tube with 8.5 ml of blood</td>
</tr>
<tr>
<td>Add contents of collection tube to prefilled 50 ml processing tube; mix, centrifuge and wash</td>
<td>Add contents of collection tube to prefilled 50 ml processing tube; mix, centrifuge and wash</td>
</tr>
<tr>
<td>Protease digestion</td>
<td>Protease digestion</td>
</tr>
<tr>
<td>Isopropanol precipitation; mix, centrifuge and add 70% ethanol</td>
<td>Isopropanol precipitation; mix, centrifuge and add 70% ethanol</td>
</tr>
<tr>
<td>Air-dry pellet and resuspend DNA</td>
<td>Air-dry pellet and resuspend DNA</td>
</tr>
</tbody>
</table>

**Ordering Information**

### IVD Products

<table>
<thead>
<tr>
<th>Description</th>
<th>Contents</th>
<th>Cat. no.</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAXgene Blood DNA Tubes (IVD)</td>
<td>100 PAXgene Blood DNA Tubes (IVD) (2.5 ml)</td>
<td>761165</td>
</tr>
<tr>
<td>QIAamp DSP DNA Blood Mini Kit</td>
<td>For 50 preps: QIAamp Mini Spin Columns, buffers, reagents, tubes, VacConnectors.</td>
<td>61104</td>
</tr>
<tr>
<td>QIAsymphony DSP DNA Mini Kit</td>
<td>For 192 preps of 200 µl each: Includes 2 reagent cartridges and enzyme racks and accessories</td>
<td>937236</td>
</tr>
<tr>
<td>QIAsymphony DSP DNA Midi Kit</td>
<td>For 96 preps of 1000 µl each or 144 preps of 400 µl each: Includes 2 reagent cartridges and enzyme racks and accessories</td>
<td>937255</td>
</tr>
</tbody>
</table>

### RUO Products

<table>
<thead>
<tr>
<th>Description</th>
<th>Contents</th>
<th>Cat. no.</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAXgene Blood DNA Tubes*</td>
<td>100 PAXgene Blood DNA Tubes (8.5 ml). To be used in conjunction with PAXgene Blood DNA Kit</td>
<td>761115</td>
</tr>
<tr>
<td>PAXgene Blood DNA Kit*</td>
<td>Processing tubes and buffers for 25 preparations. To be used in conjunction with PAXgene Blood DNA Tubes</td>
<td>761133</td>
</tr>
</tbody>
</table>

### Accessories

<table>
<thead>
<tr>
<th>Description</th>
<th>Contents</th>
<th>Cat. no.</th>
</tr>
</thead>
<tbody>
<tr>
<td>BD Vacutainer Eclipse™ Blood Collection Needle with Pre-Attached Holder</td>
<td>21G 1¼ inch (0.8 mm x 32 mm) needle, 100/case</td>
<td>368650</td>
</tr>
<tr>
<td>BD Vacutainer Eclipse Blood Collection Needle</td>
<td>21G 1¼ inch (0.8 mm x 32 mm) needle, 48/box, 480/case</td>
<td>368607 NA 368609 CE</td>
</tr>
<tr>
<td>BD Vacutainer Safety-Lok™ Blood Collection Set</td>
<td>21G ¾ inch (0.8 x 19 mm) needle, 12 inch (305 mm) tubing with luer adapter. 50/box, 200/case</td>
<td>367281 NA 367286 CE</td>
</tr>
<tr>
<td>BD Vacutainer One Use Holder</td>
<td>Case only for 13 mm and 16 mm Diameter, 1000/case</td>
<td>364815</td>
</tr>
</tbody>
</table>

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

For up-to-date licensing information and product-specific disclaimers, see respective handbooks or user manuals at www.preanalytix.com, www.bd.com or www.qiagen.com. BD and QIAGEN product handbooks and user manuals are available at www.bd.com or www.qiagen.com and can be requested from BD or QIAGEN Technical Services or your local distributor.

**Trademarks:** PAXgene®, PreAnalytiX® (PreAnalytiX GmbH); QIAGEN®, QIAamp®, QIAsymphony®, QAcube® (QIAGEN Group); BD Vacutainer®, BD Hemogard®, Eclipse®, Safety-Lok™ (Becton, Dickinson & Company).

**BLOOD • TISSUE • BONE MARROW**

The better the source, the more to explore.