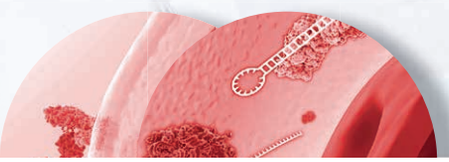
PAXgene® Blood RNA

PAXgene Blood RNA System (IVD) for clinical use

PAXgene Blood RNA and miRNA Isolation Kits (RUO) for research use



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

PreAnalytiX
A QIAGEN / BD Company

Situation

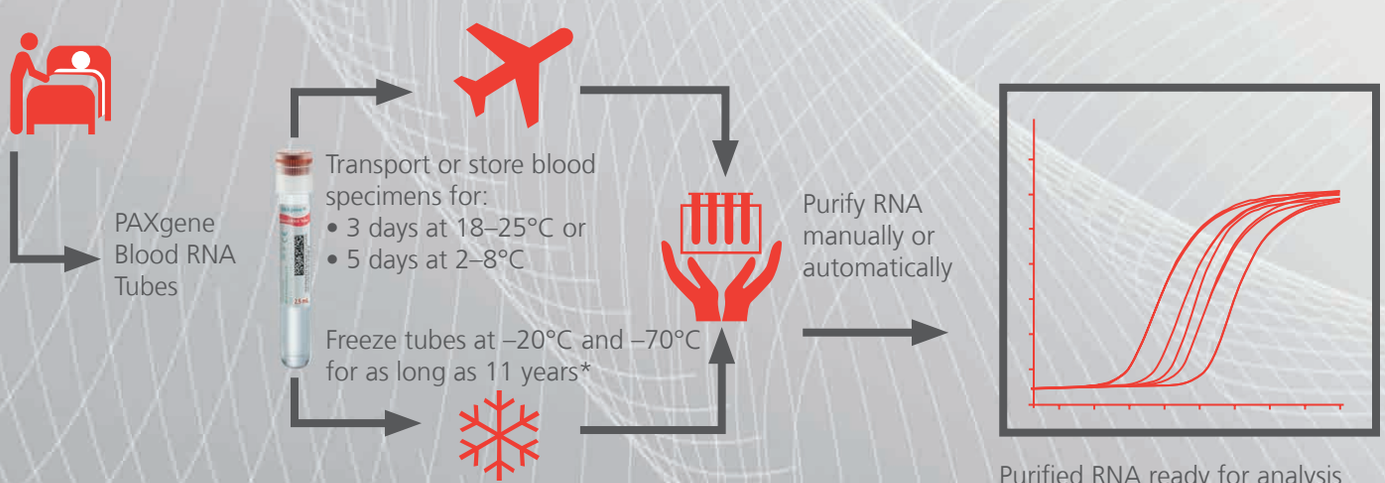
The composition, amount, quality and integrity of nucleic acids in whole blood specimens can change dramatically upon collection. For example, enzymatic activity causes degradation of nucleic acids, apoptosis leads to the release of genomic DNA from blood cells and ex vivo gene induction and downregulation can skew transcript profiles.

Solution

The PAXgene Blood RNA and miRNA Systems consolidate and integrate the key steps of whole blood collection, intracellular RNA profile stabilization, sample storage and transportation and RNA purification. By minimizing the unpredictability associated with RNA processing, these systems generate high yields of quality intracellular RNA for enhanced accuracy of RNA analysis. Each system consists of the PAXgene Blood RNA Tube and different purification kits that accommodate analyte, throughput and automation needs. RNA purified from blood using the PAXgene Blood RNA and miRNA Systems is optimal for a range of downstream applications, including RT-PCR, quantitative real-time RT-PCR and cDNA synthesis.

Transport and long-term storage of blood samples

Whether your blood specimens were in transport for a few days or frozen for as long as 11 years,* the RNA test results will be unaffected.



* Studies ongoing, see **www.preanalytix.com.**

One blood collection tube, many RNA purification options*

PreAnalytiX offers a complete preanalytical solution from, blood collection to RNA purification, that enables RNA-based research and molecular studies. The RNA purification step can now be performed in a number of ways to meet your throughput and automation needs today and in the future.

- Manual or automated RNA purification (IVD)
- miRNA enrichment (RUO)

* The PAXgene Blood RNA System is available for IVD use only when the PAXgene Blood RNA Tube (762165) is used in combination with the PAXgene Blood RNA Kit (762164 or 762174).

An introduction to the **PAXgene** Blood RNA System (IVD)

Key features and benefits of the PAXgene Blood RNA workflow
Detection and quantification of intracellular RNA transcripts.

Challenge

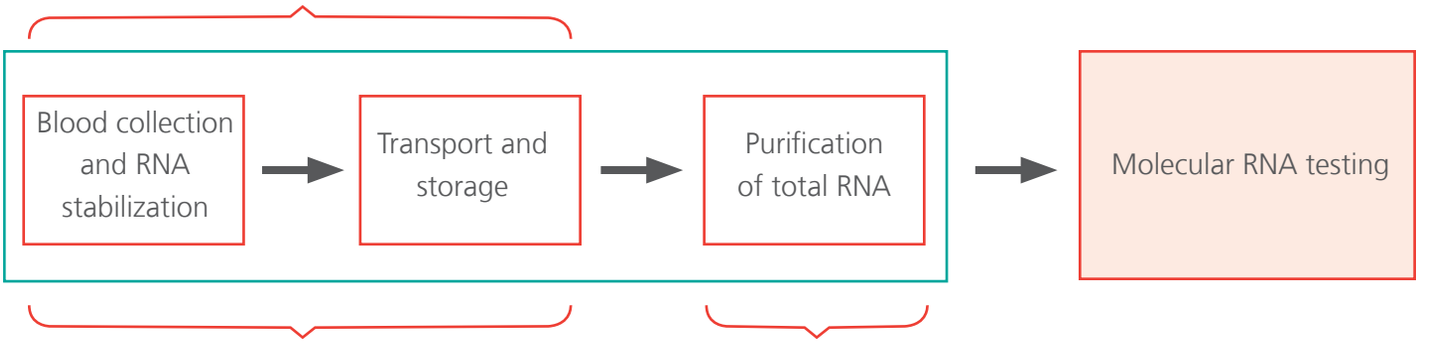
- RNA transcript levels change dramatically, often within minutes of blood collection, as a result of postphlebotomy gene induction, cell death or enzymatic RNA degradation. This can lead to artificial up or downregulation of gene expression levels that are not representative of the real RNA transcript profile in the body.
- Lack of standardized methods for RNA collection and purification from blood increases variability in RNA quality and yield.

Solution

- Stabilize intracellular RNA at the point of blood collection.
- Integrate and standardize the workflow from blood collection to pure RNA.

The PAXgene Blood RNA System is the first IVD-marketed* product for the collection, storage and transportation of whole blood with stabilization of intracellular RNA in a closed tube and subsequent isolation and purification of intracellular RNA for RT-PCR used in molecular diagnostic testing. Performance characteristics for the PAXgene Blood RNA System have only been established with FOS and IL1B gene transcripts. The user is responsible for establishing appropriate PAXgene Blood RNA System performance characteristics for other target transcripts.

PAXgene Blood RNA workflow



PAXgene Blood RNA Tube:

- A single tube for blood collection, RNA stabilization, specimen transport and storage
- Prefilled with RNA stabilization reagent to provide RNA stabilization
- Blood cell lysis in tube simplifies RNA purification
- Consistent blood draw volume and blood-to-additive ratio

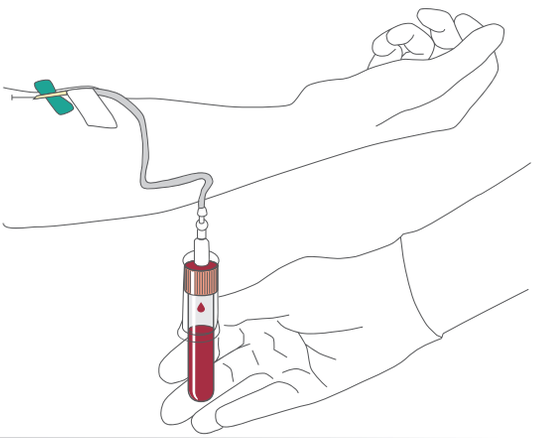
PAXgene Blood RNA Kit:

- Optimized for purification of cellular RNA from stabilized blood
- Generates quality RNA
- Efficient and easy-to-follow manual or automated protocols
- Multiple processing options available

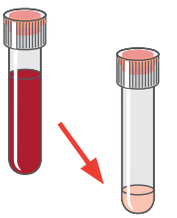
* Only when the PAXgene Blood RNA Tube (762165) is used in combination with the PAXgene Blood RNA Kit (762164 or 762174).

The **PAXgene** Blood RNA Workflow

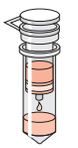
Collect blood according to instructions into a PAXgene Blood RNA Tube.



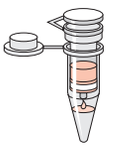
Transport and store the filled PAXgene Blood RNA Tube as described in the product circular. Incubate tubes for at least 2 hours at room temperature prior to processing.



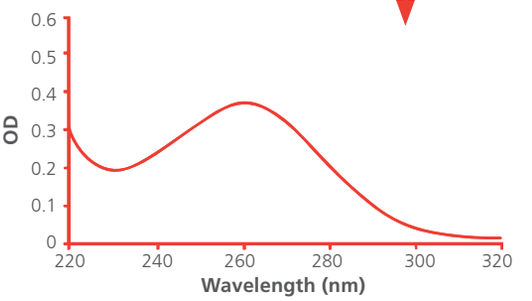
Follow instructions in the kit handbook to pellet and wash nucleic acids and transfer as instructed for processing. Follow the manual or automated protocol of your chosen PAXgene RNA or miRNA purification kit to obtain quality RNA.



Complete purification with a final elution and heat denaturation of RNA.



The PAXgene Blood RNA System results in quality RNA ready to be used in downstream applications.

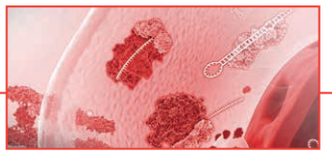


Watch the video: How to collect blood into PAXgene Blood RNA Tubes

Choose the right product for your needs: RNA and miRNA purification options

PAXgene Blood RNA Tube (IVD)

RNA purification*



IVD

- Low throughput
  - QIAcube®

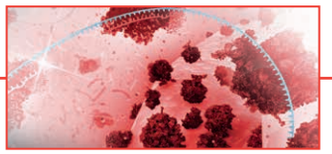
  - Manual

- Medium throughput
  - QIAsymphony®

RUO

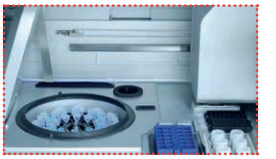
- High throughput
  - 96-well manual

RNA with miRNA purification



RUO

- Low throughput
  - QIAcube

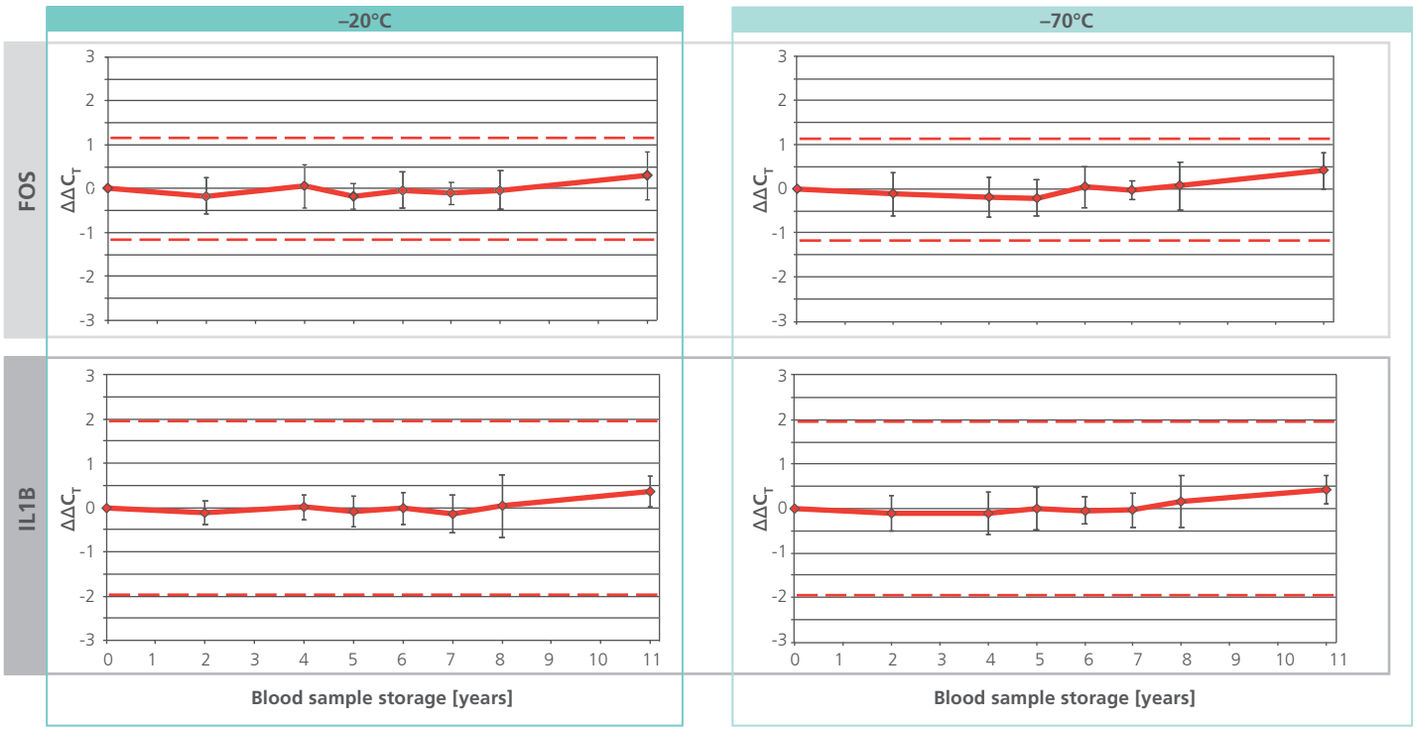


  - Manual

- Medium throughput
  - QIAsymphony

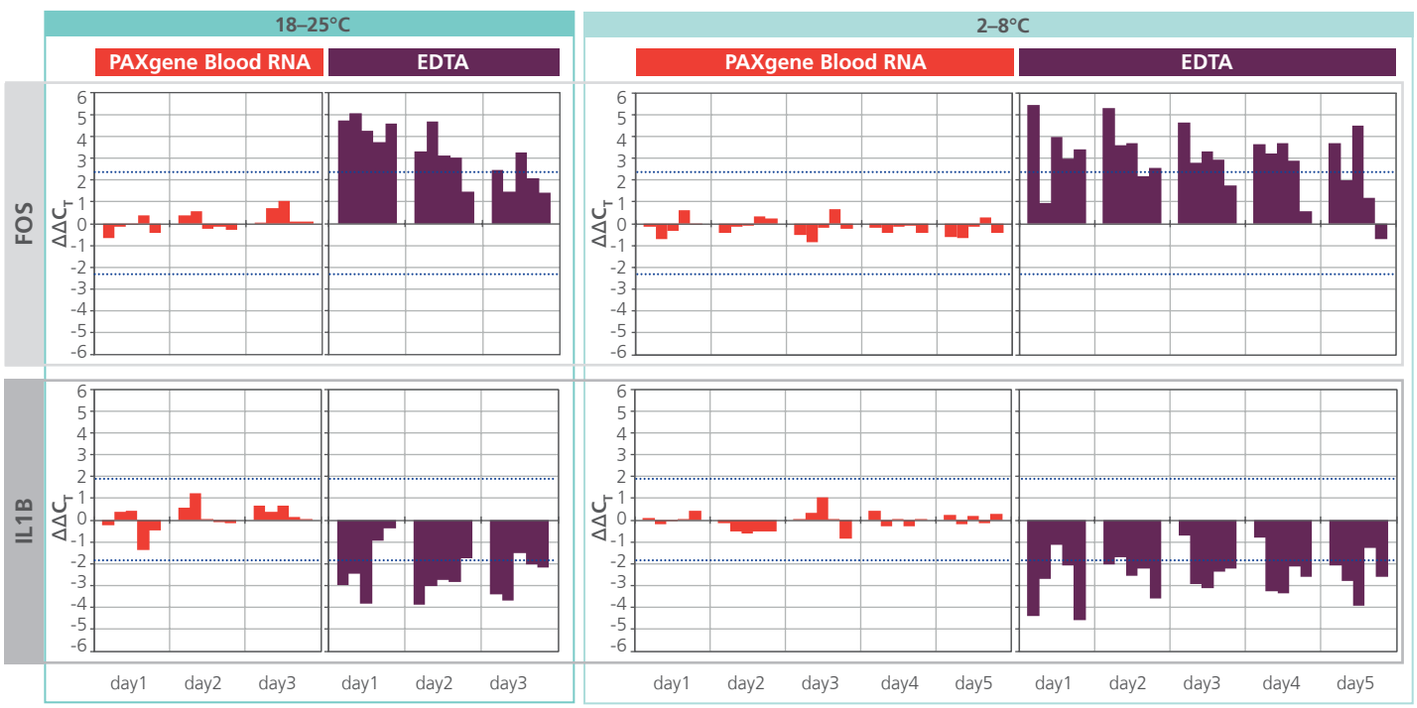
* The PAXgene Blood RNA System is available for IVD use only when the PAXgene Blood RNA Tube (762165) is used in combination with the PAXgene Blood RNA Kit (762164 or 762174).

RNA stability in blood samples stored at –20 and –70°C.



Blood was drawn into PAXgene Blood RNA Tubes from multiple donors and stored at –20°C or –70°C. Total RNA was purified manually with the PAXgene Blood RNA Kit. Relative transcript levels of FOS and IL1B were determined by real-time, duplex RT-PCR, using 18S rRNA as an internal standard. Plotted are the mean and standard deviation of all samples analyzed at a given time point. The dotted lines indicate the ±3x total precision of the assays (FOS: 1.16 C_T; IL1B: 1.98 C_T). Transcripts stayed stable over time at both temperatures.

RNA stability in blood samples stored at room temperature (18–25°C) and refrigerated (2–8°C).



Blood was drawn into PAXgene Blood RNA Tubes from multiple donors and stored at 2–8°C or 18–25°C. Total RNA was purified manually with the PAXgene Blood RNA Kit. Relative transcript levels of FOS and IL1B were determined by real-time, duplex RT-PCR, using 18S rRNA as an internal standard. Data from all donors are represented as individual bars. The dotted lines indicate the ±3x total precision of the assays (FOS: 2.34 C_T; IL1B 1.93 C_T). Transcript levels remained stable over time at both temperatures in samples collected and processed with the PAXgene Blood RNA System, whereas unstabilized blood collected into EDTA tubes showed significant variability in transcript levels.

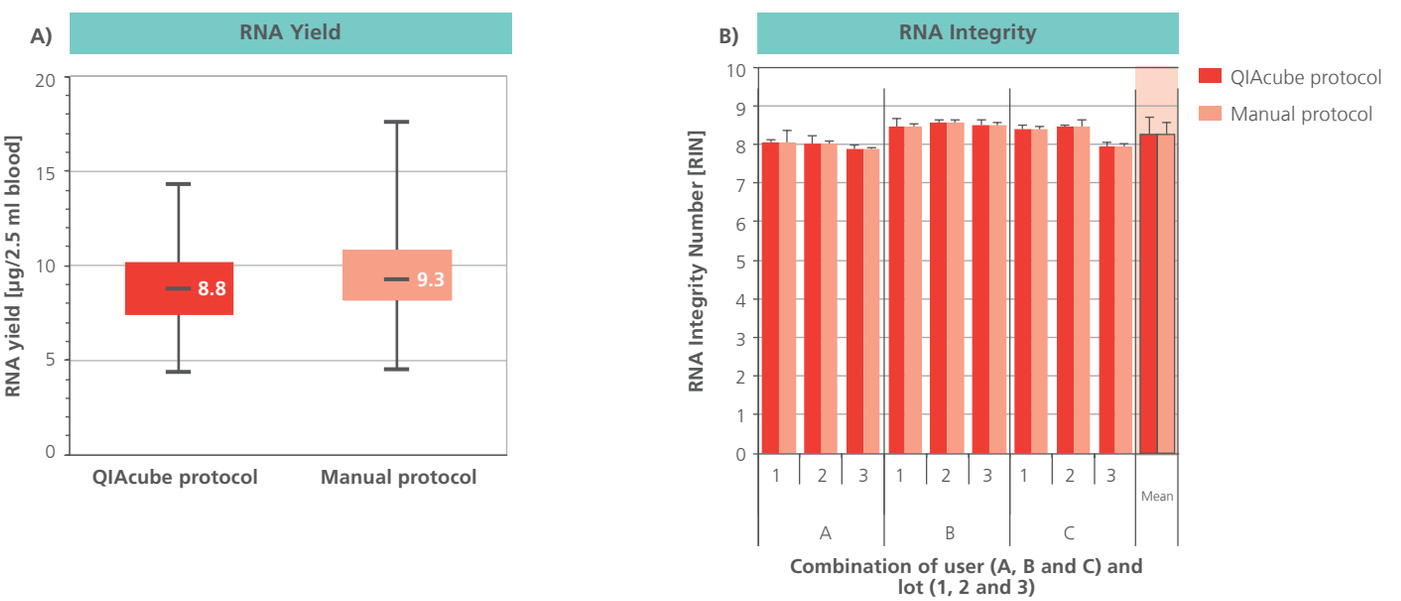
RNA purification with the **PAXgene** Blood RNA System (IVD)*

Consisting of the PAXgene Blood RNA Tube and PAXgene Blood RNA Kit (IVD)

- Ready-to-use, quality RNA (A_{260} /A_{280} ratio 1.8–2.2 for at least 95% of all samples)
- Consistent RNA yield (≥3 µg for >95% of samples)†
- Genomic DNA contamination of less than 1% in ≥95% of all samples
- Reproducible and reliable quantitative RT-PCR results
- No significant RT-PCR inhibition when using up to 30% of the eluate
- With automation:
  - Less user interaction and hands-on time
  - Minimizes the chance of manual errors resulting in a higher degree of standardization
  - Low user-to-user variability

Protocol performance

- The same kit can be used for manual or automated RNA purification on the QIAcube instrument.
- As part of the system, both protocols are available for in vitro diagnostic (IVD) use.*



Blood samples were collected in PAXgene Blood RNA Tubes (576 tubes in total) and processed both manually and automatically on multiple QIAcube instruments. To show reproducibility, multiple users (A, B and C) used multiple kit lots (1, 2 and 3) with both protocols. (A) RNA yield was analyzed by UV spectroscopy. Median, lower/upper quartile and min./max. RNA yields of all samples were calculated and are shown for both protocols (n = 288 per protocol). (B) All RNA samples from one randomly chosen donor were selected for RNA integrity analysis. RIN values were calculated with the Agilent® Bioanalyzer Nanochip. The mean and standard deviation of RIN values from 36 samples per protocol were also calculated (supporting data only). There is no significant difference in performance between the QIAcube and the manual procedure.

* The PAXgene Blood RNA System is available for IVD use only when the PAXgene Blood RNA Tube (762165) is used in combination with the PAXgene Blood RNA Kit (762164 or 762174).

† For healthy donors with white blood cell (WBC) count in the range of 4.8–11.0 x 10^6 WBC/ml.

RNA/miRNA purification options (RUO)*

- Fully integrated system allows manual and automated processing
- Choose the kits that are tailored to your specific needs
- Optimized miRNA protocol for copurification of RNA/miRNA

PAXgene Blood miRNA Kit (RUO)

- Manual or automated (on QIAcube) purification of total RNA including miRNA
- Low-throughput processing of 1–12 samples in parallel

miRNA Kit

QIAsymphony

QIAsymphony PAXgene Blood RNA Kit (RUO)

- Fully automated RNA purification, including an optimized protocol for the effective copurification of miRNA
- Medium-throughput processing of 24–72 samples in parallel

PAXgene 96 Blood RNA Kit (RUO)

- Manual RNA purification
- High-throughput processing of 96 samples in parallel

96-well manual

* For Research Use Only. Not for use in diagnostic procedures.

Read about typical RNA yields from PAXgene Blood RNA Tubes processed with dedicated PAXgene Blood RNA Kits.

PAXgene Blood RNA and miRNA product selection guide (RUO, IVD)

Multiple processing options

Depending on your requirements, the PAXgene Blood RNA and miRNA Systems provide pure RNA and miRNA from both manual and automated protocols.

Analyte	Throughput	Protocol and instrument	Average time per run	Number of samples processed	Kit to use
RNA (>200 nt*)	Low	Manual	90 min for 12 samples	1–12	PAXgene Blood RNA Kit (IVD)
		Automated on QIAcube	151 min for 12 samples		
RNA/miRNA (all sizes, optimized for small RNA)	Medium	Automated on QIAsymphony	2.5 h for 24 samples	24–72	QIAsymphony PAXgene Blood RNA Kit (RUO)
RNA/miRNA (all sizes, optimized for small RNA)	Low	Manual	90 min for 12 samples	1–12	PAXgene Blood miRNA Kit (RUO)
		Automated on QIAcube	125 min for 12 samples		
RNA (>200 nt*)	High	Manual	3.5 h for 96 samples	96	PAXgene 96 Blood RNA Kit (RUO)

IVD = in vitro diagnostic; RUO = for Research Use Only, not for use in diagnostic procedures
* nt = nucleotides

See the PreAnalytiX website www.preanalytix.com or contact QIAGEN technical services or your local QIAGEN distributor to discuss how to process your PAXgene Blood RNA Tubes.

Ordering Information

IVD products	Contents	Cat. no.
PAXgene Blood RNA Tubes (100)	100 PAXgene Blood RNA Tubes	762165
PAXgene Blood RNA Kit (50)	50 PAXgene Spin Columns, 50 PAXgene Shredder Spin Columns, Processing Tubes, RNase-Free DNase I, RNase-Free Reagents and Buffers. To be used in conjunction with PAXgene Blood RNA Tubes.	762164 (North America) 762174* (Other countries)
RUO products		
QIAsymphony PAXgene Blood RNA Kit (96)†	For 96 preps: 2 Reagent Cartridges, Enzyme Racks, Accessories and RNase-Free Buffers. To be used in conjunction with PAXgene Blood RNA Tubes.	762535
PAXgene 96 Blood RNA Kit (4)†	4 PAXgene 96 RNA Plates, 4 PAXgene 96 Filter Plates, Buffers, Proteinase K, RNase-free DNase Sets, AirPore Tape Sheets and Collection Vessels. To be used in conjunction with PAXgene Blood RNA Tubes.	762331
PAXgene Blood miRNA Kit (50)†	For 50 RNA preps: PAXgene Spin Columns, PAXgene Shredder Spin Columns, Processing Tubes, Microcentrifuge Tubes, RNase-Free DNase, RNase-free Reagents and Buffers. To be used in conjunction with PAXgene Blood RNA Tubes.	763134
Accessories		
BD Vacutainer Push Button Blood Collection Set	21G ¾ inch (0.8 x 19 mm) needle, 12 inch (305 mm) tubing with luer adapter, 50/box, 200/case	367344
BD Vacutainer Safety-Lok Blood Collection Set	21 G, ¾ inch (8.8 x 19 mm) needle, 12 inch (305 mm) tubing with luer adapter, 50/box, 200/case	367286 (CE) 367281 (US)
BD Vacutainer One-Use Holder	Case only for 14 mm and 16 mm diameter, 2000/case	364815
BD Vacutainer Plus Serum Tubes	13 x 75 mm x 4.0 mL draw with red BD Hemogard closure and paper label, 100/box, 1000/case	368975 (CE) 367812 (US)

* Not available in all countries, please inquire.

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For up-to-date licensing information and product-specific disclaimers, see the respective PreAnalytiX or QIAGEN kit handbook or user manual. PreAnalytiX and QIAGEN kit handbooks and user manuals are available at www.preanalytix.com and www.qiagen.com or can be requested from PreAnalytiX technical services.

BLOOD · TISSUE · BONE MARROW
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Discover more about the PAXgene RNA Systems at: **www.preanalytix.com**

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