August 2023

PAXgene® Saliva Collectors (25) Handbook

For collection, stabilization, transportation, and storage of 2 mL human saliva

For molecular biology applications only. This product is not intended for the diagnosis, prevention, or treatment of a disease.

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Contents

Intended Use and Product Use Limitations

The PAXgene Saliva Collectors are intended for non-invasive collection, storage, and transport of human saliva and stabilization of DNA for preparation of DNA from Saliva for use with molecular test methods.

In addition, the collector stabilizes SARS-CoV-2 (severe acute respiratory syndrome coronavirus type 2)-derived RNA copy numbers and can be used for preparation of RNA from SARS-CoV-2 particles.

The PAXgene Saliva Collectors are intended for molecular biology applications. This product is not intended for the diagnosis, prevention, or treatment of a disease.

It is the user's responsibility to validate the performance of the PAXgene Saliva Collectors for any particular use since the performance characteristics of this product have not been fully established.

Introduction

The PAXgene Saliva Collectors are part of a comprehensive pre-analytical workflow for human saliva collection, stabilization, transport, and storage through nucleic acid extraction and analyses (Figure 1).

The collection device contains a stabilizing solution that stabilizes the DNA levels in human saliva samples by protecting DNA from degradation and inhibiting bacterial growth over storage time. It is compatible with existing QIAGEN technologies for manual or automated DNA extraction. In addition, SARS-CoV-2 RNA genome is stabilized and can be isolated and quantified.

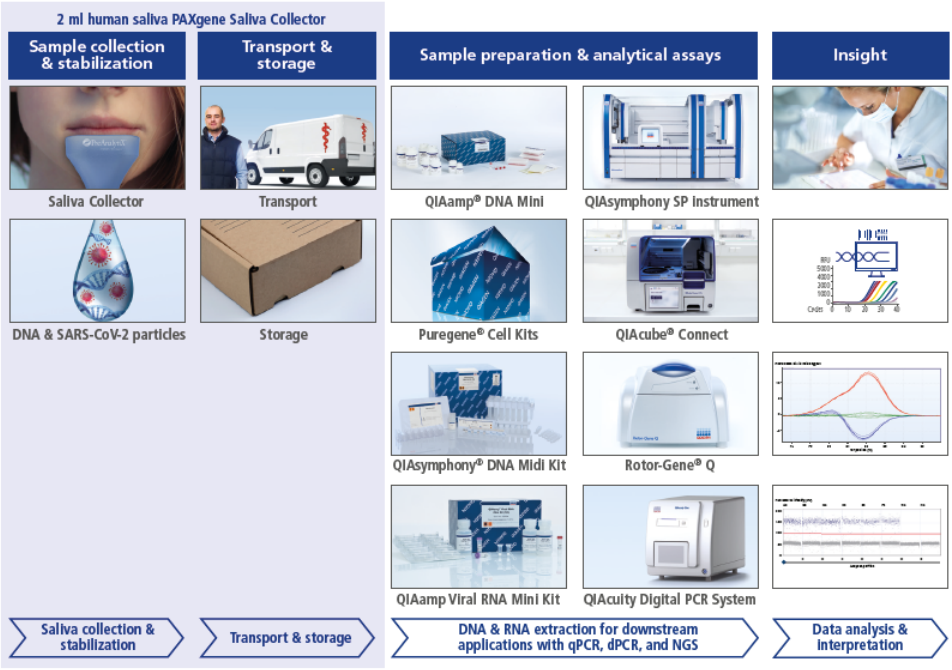


Figure 1. PAXgene Saliva workflow. Saliva collected into PAXgene Saliva Collectors can be used to process DNA with QIAGEN manual and automated extraction methods such as the QIAamp® DNA Mini and Puregene® Cell Kits or the QIAsymphony® DNA Midi Kit on the QIAsymphony SP instrument and the QIAamp DNA Mini Kit on the QIAcube® (Classic and Connect). SARS-CoV-2 RNA can be isolated with the QIAamp Viral RNA Mini Kit. Obtained nucleic acids can be used for molecular test methods including qPCR, dPCR, and NGS.

PreAnalytiX developed the PAXgene Saliva workflow to minimize post-collection changes caused by preanalytical variables and to standardize the preanalytical steps from saliva collection until nucleic acid is available for molecular analyses.

Principle and procedure

The PAXgene Saliva Collector is a plastic device with a funnel attached to a collection tube that enables collection of 2.0 mL human saliva. The inner tube contains 1.0 mL of stabilizing solution that is only released upon unscrewing the funnel (Figure 2). It

has bacteriostatic properties that inhibit bacterial growth over storage time. It is free of crosslinking or nucleic-acid–modifying substances.

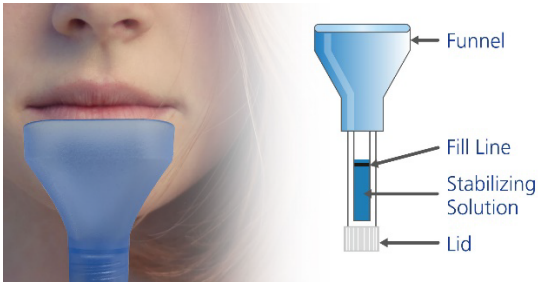


Figure 2. PAXgene Saliva Collector.

In contrast to invasive specimen collection, saliva collection with the PAXgene Saliva Collector does not require trained and educated professionals or dedicated facilities to collect the saliva sample. With clear instruction and verified collection device safety claims, saliva specimens can be easily self-collected with the PAXgene Saliva Collector by most people at home or out of a doctor's office.

After collection, stabilized saliva samples collected into the PAXgene Saliva Collector can be shipped in the blister box at ambient temperatures.

Saliva collected and stabilized with the PAXgene Saliva Collector can be stored for DNA isolation for at least 24 months at temperatures up to 25°C (study ongoing). In addition, PAXgene Saliva can be frozen long term at –20°C or –80°C when transferred into a suitable cryovial.

SARS-CoV-2-derived RNA copy numbers are stabilized in saliva collected into PAXgene Saliva Collector for up to 4 days (96 h) at 37°C.

For the latest results on storage at ambient or frozen temperature, see the relevant technical notes at the resource section of **www.qiagen.com** and **www.preanalytix.com**.

DNA purification

DNA can be purified from saliva collected and stabilized with the PAXgene Saliva Collector using QIAGEN manual and automated extraction methods. The broad range of existing, proven QIAGEN DNA extraction solutions offer the highest flexibility with regard to throughput and sample input volume.

Automated extractions kits include the QIAsymphony DNA Midi Kit on the QIAsymphony SP instrument and the QIAamp DNA Mini Kit on the QIAcube (Classic and Connect). Manual extraction kits include the QIAamp DNA Mini and Puregene Cell Kits.

Total DNA purified from PAXgene Saliva Collector with the QIAGEN DNA purification kits has A_{260}/A_{280} ratios of 1.7–1.9, and absorbance scans show a symmetrical peak at 260 nm, confirming the high purity of DNA. Contamination is minimized, and purified DNA is ready to use in downstream applications with no detectable PCR inhibition.

Protocols and supplementary protocols for QIAamp, Puregene, and QIAsymphony kits are available at the Resources section on **www.qiagen.com** and **www.preanalytix.com**.

RNA purification from SARS-CoV-2

The genome of SARS-CoV-2 consists of RNA and can be isolated from saliva collected and stabilized with the PAXgene Saliva Collectors with the QIAamp Viral RNA Mini Kit for quantification with the QuantiTect Probe RT-PCR and the SARS-CoV-2 N1+N2 Assay Kits on QIAGEN Rotor-Gene Q.

Materials Provided

Kit contents

PAXgene Saliva Collectors		(25)
Catalog no.		769040
Number of collection devices		25
Component name	**Description**	**Quantity**
PAXgene Saliva Collector	Single blister boxes	25
Product sheet	Provided in each blister	1

Safety information

When working with chemicals, always wear a suitable lab coat, disposable gloves, and protective goggles. For more information, please consult the appropriate safety data sheets (SDSs). These are available online in convenient and compact PDF format at **www.qiagen.com/safety**, where you can find, view, and print the SDS for each QIAGEN kit and kit component.

All chemicals and biological materials are potentially hazardous. Specimens and samples are potentially infectious and must be treated as biohazardous materials.

Discard sample and assay waste according to your local safety procedures.

Storage and Handling

The PAXgene Saliva Collectors (25) box is shipped at ambient temperature. Store the PAXgene Saliva Collector device at room temperature (15–30°C). Do not store at temperatures below 15°C. When stored properly, the PAXgene Saliva Collectors are stable until the expiration date printed on the label.

Quality Control

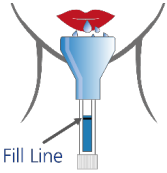
In accordance with QIAGEN's ISO-certified Quality Management System, each lot of PAXgene Saliva Collectors are tested against predetermined specifications to ensure consistent product quality.

Protocol: Saliva Collection and Stabilization with the PAXgene Saliva Collectors

Important points before starting

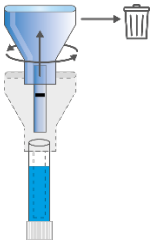
- Do not rotate and do not unscrew the funnel before use to avoid unintentional release of the stabilizing solution into the collection tube.
- Do not ingest the stabilizing solution. If skin comes in contact with stabilizing solution, wash area with soap and water. If eyes come into contact with stabilizing solution, rinse with water for at least 15 minutes and consult a physician.
- In case precipitate occurs, equilibrate at room temperature and invert until the precipitate disappears (see "Storage and Handling" on page 12); note that this will not impact the procedure.
- Make sure that the packaging is intact. If not, do not use the device. Never reuse a device.
- Rinse mouth 30 minutes prior collection to remove any food or other foreign particles in sample.
- Do not drink, eat, smoke, chew gum, or brush teeth within 30 minutes prior to sample collection.

Procedure



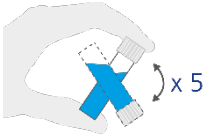
1. Spit gently into funnel. To encourage saliva production, massage cheeks for 15–30 s, or increase salivation by raising the tongue tip against the palate or lower jaw.
   Note: If the saliva is sticky and hard to flow shake tube gently to assist saliva flow.

2. Keep spitting until liquid saliva (excluding bubbles) fills up outer part of the tube and reaches fill line.
   Note: Saliva collection will take approximately 5–10 min.



3. Hold tube upright and slowly unscrew funnel. This release stabilizing solution from inner part of the tube. Shake carefully to ensure fluids transfer completely into the tube. Discard the funnel.
   Note: Unscrewing the funnel before the saliva sample collection is completed will lead to unintentional release of the stabilizing solution into the collection tube.

4. Keep the tube in upright, remove the lid from the bottom of the tube, place over the opening, and screw the lid on tightly to close.



5. Ensure that the tube is sealed, then invert the tube 5 times to mix the saliva and stabilizing solution.

Troubleshooting Guide

This troubleshooting guide may be helpful in solving any problems that may arise. For more information, see also the Frequently Asked Questions page at our Technical Support Center: **www.qiagen.com/FAQ/FAQList.aspx**. The scientists in QIAGEN Technical Services are always happy to answer any questions you may have about either the information and/or protocols in this handbook or sample and assay technologies (for contact information, visit **www.qiagen.com**).

	Comments and suggestions
General handling	
a) After a few minutes, the saliva level is still not reaching the fill line	It takes up to 5–10 min to complete collection of 2 mL saliva.
b) Saliva flow is very slow and insufficient	Massaging of cheeks with both hands for 15–30 s can increase saliva flow.
c) Fill line is no longer visible	Saliva bubbles can form during collection and impair visibility of fill line. Wait until bubbles disappear and fill line is visible again, then continue with saliva collection.
d) Funnel was unscrewed before completing saliva collection	Unscrewing of funnel releases the stabilization solution into the collection tube and the fill line does not indicate correct volume of saliva anymore. Saliva collection should be repeated with a new PAXgene Saliva Collector.
e) Stabilization solution was spilled	Contents of the tube may cause irritation to the eyes, respiratory system, and skin. Please refer to the PAXgene Saliva Collector Handbook, accessible under the Resources tab of the product webpage on **www.preanalytix.com** or **www.qiagen.com**, for more details. Additional information can be found in the Safety Data Sheet, also accessible under the Resources tab.
f) Saliva collection was stopped before reaching the fill line	The PAXgene Saliva Collector is robust against underfilling. However, only a complete fill ensures optimal results. Reduced volume of saliva will lead to lower nucleic acid yield, which might negatively impact subsequent molecular analyses.
g) Activities such as eating or drinking were performed within 30 min prior to collection	Eating, drinking, smoking, chewing gum, or kissing affect the saliva sample's composition and DNA content. These activities should be strictly avoided 30 min before saliva collection. Otherwise, saliva collection should be repeated with a new PAXgene Saliva Collector.
h) Precipitates formed in stabilizing solution	Precipitates can occur due to low temperatures and do not impair functionality of PAXgene Saliva Collector. Collector can be equilibrated at room temperature and inverted regularly until precipitates disappear.

Contact Information

For technical assistance and more information, please see our Technical Support Center at **www.qiagen.com/Support**, call 00800-22-44-6000, or contact one of the QIAGEN Technical Service Departments or local distributors (see back cover or visit **www.qiagen.com**).

Ordering Information

Product	Contents	Cat. no.
PAXgene Saliva Collectors (25)	25 PAXgene Saliva Collectors in single blister box for 2 mL human saliva collection	769040
Related products		
QIAamp DNA Mini Kit (50)	For 50 DNA preps: 50 QIAamp Mini Spin Columns, QIAGEN Proteinase K, reagents, buffers, collection tubes (2 mL)	51304
QIAamp DNA Mini Kit (250)	For 250 DNA preps: 250 QIAamp Mini Spin Columns, QIAGEN Proteinase K, reagents, buffers, collection tubes (2 mL)	51306
QIAamp DNA Mini QIAcube Kit (240)	For 240 DNA minipreps: QIAamp Mini Rotor Adapters (preloaded with spin columns and elution tubes), Proteinase K and buffers	Please inquire
QIAamp Viral RNA Mini Kit (50)	For 50 RNA preps: 50 QIAamp Mini Spin Columns, carrier RNA, collection tubes (2 mL), RNase-free buffers	52904
QIAamp Viral RNA Mini Kit (250)	For 250 RNA preps: 250 QIAamp Mini Spin Columns, carrier RNA, collection tubes (2 mL), RNase-free buffers	52906
QIAamp Viral RNA Mini QIAcube Kit (240)	For 240 viral RNA minipreps: QIAamp Mini Rotor Adapters (preloaded with spin columns and elution tubes); carrier RNA and RNase-free reagents and buffers	52926
QIAsymphony DNA Midi Kit (96)	For 96 preps of 1000 µL each: includes 2 reagent cartridges and enzyme racks and accessories	931255
Rotor-Gene Q 5plex HRM Platform	Real-time PCR cycler and High Resolution Melt analyzer with 5 channels (green, yellow, orange, red, crimson) plus HRM channel, laptop computer, software, accessories: includes 1 year warranty on parts and labor, installation and training not included	9001580

Product	Contents	Cat. no.
Puregene Cell Kit (8×10^8)	For (8×10^8) cells: RNase A solution and reagents	158403
Puregene Cell Kit (6.7×10^9)	For (6.7×10^9) cells: reagents	158046
QuantiTect Probe RT-PCR Kit (200)	For 200 × 50 µL reactions: 3 × 1.7 mL 2x QuantiTect Probe RT-PCR Master Mix, 100 µL QuantiTect RT Mix, 2 × 2 mL RNase-free water	204443
SARS-CoV-2 N1+N2 Assay Kit (600)	For 600 × 20 µL reactions: 1 × 600 µL SARS-CoV-2 N1+N2 assay, 20x concentrate	222015
SARS-CoV-2 N1+N2 Assay Kit (2400)	For 2400 × 20 µL reactions: 4 × 600 µL SARS-CoV-2 N1+N2 assay, 20x concentrate	222017
QIAcuity Digital PCR System	For nanoplate-based digital PCR applications	Please inquire
QIAcube Connect	Instrument, connectivity package, 1 year warranty on parts and labor	9002864
Starter Pack, QIAcube	Reagent bottle racks (3); 200 µL filter-tips (1024); 1000 µL filter-tips (1024); 30 mL reagent bottles (12); rotor adapters (240); rotor adapter holder	990395
Rotor Adapters (10 x 24)	For 240 preps: 240 Disposable Rotor Adapters; for use with the QIAcube Connect	990394

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

Document Revision History

Date	Changes
08/2021	Initial release
08/2023	Updated street address, SARS-CoV-2 derived RNA stabilization temperature, Puregene brand name, and catalog numbers.

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