



Puritan® PurSafe® Collection and Transport System

Intended Use

Puritan PurSafe Collection and Transport System is intended for the collection and transport of specimens to be analyzed by nucleic acids amplification tests. The preservative comprised within the kit stabilizes and preserves DNA and RNA for prolonged time periods and is compatible with commercial nucleic acid extraction and amplification platforms.

Summary and Principles

Nucleic acid amplification tests are widely used in research laboratories in a variety of fields. Although such assays may be different in principles and scope, a reliable and stable specimen is essential for all such assays and will help improve the sensitivity and specificity, allowing for rapid turnaround time. The Puritan DNA/RNA preservative stabilizes and protects nucleic acids in tissues and cells for up to 30 days at room temperature.

Precautions

For Research Use Only

Not for Use in Diagnostic Procedures

- For single use only.
- For use by trained qualified personnel.
- Read and follow the instructions in this package insert carefully and use aseptic techniques.
- Refer to the recommendations of the Center for Disease Control and Prevention's *Biosafety in Microbiological and Biomedical Laboratories*.^{1, 2, 3, 4}
- Not suitable for any other application than intended use.
- Do not use if the peel pouch is damaged or open.
- Dispose of unused reagents, waste and specimens according to biohazard waste disposal regulations.
- Do not use beyond expiry date.

Storage

For optimum performance, store at 2-25°C (36-77°F). Avoid freezing and excessive heat.

Materials Supplied

Each Puritan PurSafe Collection and Transport System pouch is provided with the following materials:

- One pre-labeled screw-cap polypropylene vial containing 1 or 2 mL of Puritan DNA/RNA preservative.
- One scored sterile HydraFlock® flocked swab with a standard tip.

All HydraFlock swabs in Puritan PurSafe Collection and Transport Systems are scored for ease of use. This allows the swab to break at the scored point and remain inside the vial containing transport preservative. Self centering screw cap is designed to guide and capture the swab handle.

Materials not provided

Appropriate material for molecular testing according to recommended protocols as per laboratory reference manuals.

Directions for Use

Puritan PurSafe Collection and Transport System is available in product configurations indicated in the table below:

Item Number	Puritan PurSafe Product Descriptions	Sample Sites	Pack Size
VL 1201 SAFE	<ul style="list-style-type: none"> • Light blue polypropylene screw-cap tube with 1 mL of DNA/RNA preservative 	N/A	50 / Box 6x50 / Case
VL 1201 SAFE-H	<ul style="list-style-type: none"> • Light blue polypropylene screw-cap tube with 1 mL of DNA/RNA preservative • One sterile standard HydraFlock flocked swab 	Nose, throat, vagina, rectum, and wounds	50 / Box 6x50 / Case
VL 1202 SAFE	<ul style="list-style-type: none"> • Light blue polypropylene screw-cap tube with 2 mL of DNA/RNA preservative 	N/A	50 / Box 6x50 / Case
VL 1202 SAFE-H	<ul style="list-style-type: none"> • Light blue polypropylene screw-cap tube with 2 mL of DNA/RNA preservative • One sterile standard HydraFlock flocked swab 	Nose, throat, vagina, rectum, and wounds	50 / Box 6x50 / Case

Specimen collection using Pur Safe:

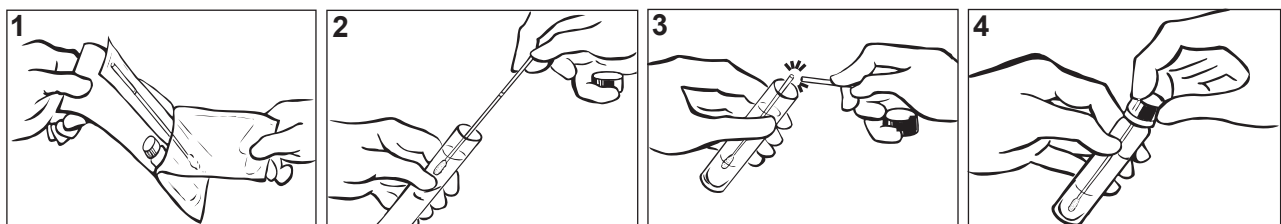
[1] Peel open pouch and remove vial of preservative and the HydraFlock swab. *Do not touch the swab tip.*

[2] Use the swab to collect the sample. Using appropriate aseptic technique, remove the vial cap and insert the swab into the vial.

[3] Break the swab handle at the score point.

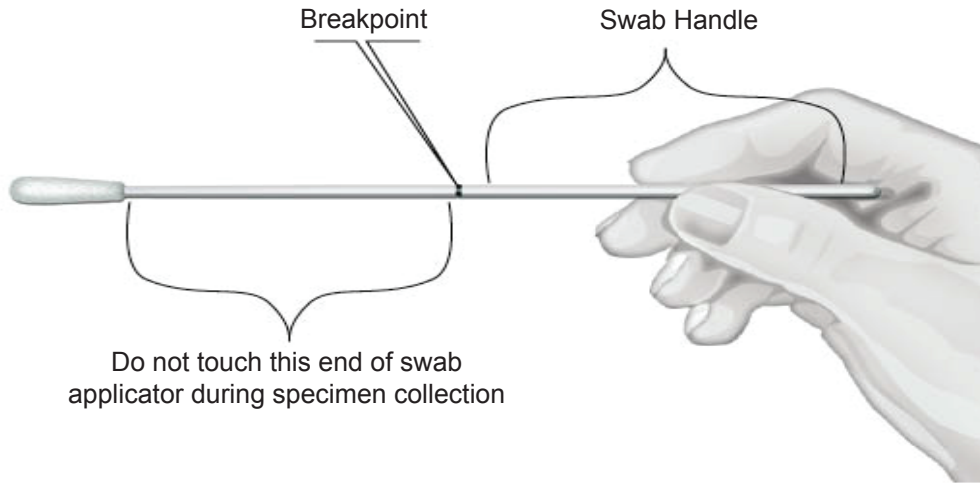
[4] Replace the vial cap, securing tightly. Record sample information in the space provided on the vial label. Transport the specimen to the laboratory.

* Small tissue samples can be added directly to vial. To allow rapid penetration of the DNA/RNA preservative into tissue lightly macerate tissue in vial.



Specimens are considered biohazardous and appropriate protective clothing should be worn when collecting and handling potential infectious specimens. Care should be taken to avoid splashes and aerosols when breaking the swab handle into the vial containing preservative. When collecting specimen with swab applicator, the area below the breakpoint must not be touched (area from the breakpoint to the tip of the HydraFlock flocced swab).

Figure 1. Collection swab showing breakpoint indication line and proper hand placement



Processing PurSafe specimens for molecular testing

Specimens received in the laboratory for nucleic acid detection should be processed when received in the laboratory. In case of delay, please refer to the appropriate specimen storage conditions. Puritan DNA/RNA preservative preserves nucleic acids for up to 30 days at room temperature. Specimens preserved in Puritan DNA/RNA preservative should be extracted and purified before amplification.

Quality Control

Every batch of Puritan PurSafe Collection and Transport System is tested prior to release for pH.

Performance Characteristics

RNA Preservation

Sterile HydraFlock® swabs were immersed in liquid suspensions of E. coli and allowed to absorb for 15-20 seconds then placed in vials containing Puritan DNA/RNA preservative. Tissue samples were added directly to vial and light macerated. 100-200µl of media was processed for total RNA isolation using standard RNA isolation kits. An automated nucleic acid electrophoresis system was used to assess the quality and quantity of RNA. Quantitative real-time PCR was used to confirm Eukaryote RNA (cDNA) integrity.

Organism	Preservative	Analyte Type	Ref Number	Storage	Detection Limit
<i>Rattus norvegicus</i>	Puritan DNA/RNA Preservative	Eukaryote, liver biopsy	--	1-30 days, room temperature and 4°C	RNA, 0.5-1.5 ng/mL
<i>Escherichia coli</i>	Puritan DNA/RNA Preservative	Gram Negative bacteria	PTA-5669	1-30 days, room temperature and 4°C	RNA, 0.5-1.5 ng/mL

References

1. Sewell, D.L. 1995. Laboratory-associated infection and biosafety. Clin. Microbiol. Rev 8:398–405. American Society for Microbiology. Washington, DC.
2. Code of Federal Regulations, title 42, part 72. Interstate shipment of etiologic agents.
3. Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risk related exposure to biological agents at work. Official Journal of the European Communities. L 262/21–45.
4. Centers for Disease Control and Prevention. 2009. Biosafety in Microbiological and Biomedical Laboratories, 5th ed. U.S. Department of Health and Human Services, HHS Publication No. (CDC) 21-1112, rev. December 2009.



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