

INSTRUCTIONS FOR USE

Puritan® PurSafe Plus® Collection & Transport System



PurSafe
PLUS



Puritan®
Quality since 1919



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IVD

R_x
ONLY



Puritan® PurSafe Plus® Collection & Transport System System (Rx only)

INTENDED USE

Puritan® PurSafe Plus® Collection & Transport System is an enclosed system intended for the collection, inactivation, and preservation of human upper respiratory specimens suspected of containing SARS-CoV-2. Puritan PurSafe Plus Collection & Transport System can be used for collection, transport, and storage of specimens at 2-4°C and 25-30°C. Specimens collected and stored in the PurSafe Plus Collection & Transport System are suitable for use with legally marketed molecular diagnostic devices.

BACKGROUND

Puritan PurSafe Plus Collection & Transport System consists of a vial containing 1 mL of proprietary solution for inactivation, stabilization, and preservation of SARS-CoV-2 RNA in human upper respiratory specimens for prolonged time periods.

SUMMARY & PRINCIPLES

Nucleic acid amplification tests are widely used 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 maintain a consistent sensitivity and specificity, allowing for quick turnaround time for test results. The Puritan MK buffer solution inactivates, stabilizes, and protects nucleic acids of SARS-CoV-2 for up to 4 weeks when stored at 2-4°C and 25-30°C.

All HydraFlock swabs in Puritan PurSafe Plus Collection & Transport Systems are scored and color printed 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 and the cap is screwed tightly onto the vial.

REAGENTS

Approximate formulation:

Guanidine thiocyanate	HEPES
Tris Base	Triton X-100
EDTA	Buffering Agent
	Molecular Grade Water

MATERIALS PROVIDED

Each Puritan PurSafe Plus Collection & Transport System includes the following materials:

- One pre-labeled screw-cap polypropylene vial containing 1 mL of MK buffer solution preservative.
- One scored Sterile HydraFlock® flocked swab.

Puritan PurSafe Plus Collection & Transport System is available in product configurations indicated in the table below.

Item No.	Description	Pack Size
PSP-106	<ul style="list-style-type: none">• Light blue polypropylene screw-cap tube with 1 mL of MK buffer solution• One HydraFlock large tip flocked swab	50 / Box 6x50 / Case
PSP-116	<ul style="list-style-type: none">• Light blue polypropylene screw-cap tube with 1 mL of MK buffer solution• One HydraFlock mini tip flocked swab	50 / Box 6x50 / Case
PSP-120	<ul style="list-style-type: none">• Light blue polypropylene screw-cap tube with 1 mL of MK buffer solution• One HydraFlock ultrafine flocked swab	50 / Box 6x50 / Case
PSP-100	<ul style="list-style-type: none">• Light blue polypropylene screw-cap tube with 1 mL of MK buffer solution	50 / Box 6x50 / Case



MATERIALS NOT PROVIDED

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

LIMITATIONS

1. This product is intended for use by trained and qualified professionals, and not intended in POC or home settings.
2. Performance characteristics of PurSafe Plus have only been validated for SARS-CoV-2 RNA in nasal matrix using the Cepheid Xpert Xpress CoV-2/Flu/RSV Plus assay.
3. The end-user is responsible for establishing appropriate system performance characteristics for other specimen types and tissues. The end-user is responsible for establishing appropriate system compatibility and performance characteristics for all diagnostic assays.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- For prescription use only.
- For single use only.
- 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 the device if the peel pouch seal is damaged.
- Puritan PurSafe Plus preservative does not require any concentration step. Do not pellet because pelleting may lead to loss of established performance.
- Dispose of unused reagents, waste, and specimens according to biohazard waste disposal regulations. Refer to the Safety Data Sheet found on www.puritanmedproducts.com
- Do not use beyond expiry date.
- Do not ingest the medium.
- Do not repack.

SHELF-LIFE STORAGE

For optimum performance, store at 2-4°C or 30-35°C for up to 24 months. Do not use beyond the expiration date listed on the package label. Do not freeze or expose to excessive heat.

DIRECTIONS FOR USE

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 upper respiratory specimen. Using appropriate aseptic technique, remove the vial cap and insert the swab into the vial.
3. Break the swab shaft 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 under the validated specimen storage conditions.

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 color printed breakpoint must not be touched (area from the breakpoint to the tip of the HydraFlock flocked swab).



Processing PurSafe Plus specimens for molecular testing

Puritan MK buffer solution preserves viral nucleic acid present in human upper respiratory specimen for up to 28 days when stored at 2-4°C and 25-30°C. Specimens should be immediately processed for nucleic acid detection when received in the laboratory. In case of delay, please refer to the appropriate specimen storage conditions.

QUALITY CONTROL

Every batch of Puritan PurSafe Plus Collection & Transport System is tested for pH and media appearance (i.e., media volume, media color and media clarity) prior to release.

SYMBOL DEFINITIONS

Consult www.puritanmedproducts.com/symbols-glossary for definition of symbols used in Puritan labeling.

REPORTING OF SERIOUS INCIDENTS

Any serious incident that has occurred in relation to the device, the patient and/or the end user should be reported to the manufacturer and, where applicable, the competent authority of the Member State in which the user/of patient is established.

RESULTS

Accuracy of molecular testing depends on proper specimen collection, integrity of nucleic acid, extraction and PCR amplification.

PERFORMANCE CHARACTERISTICS

NOTE: Performance characteristics of the Puritan PurSafe Plus Collection & Transport System have only been demonstrated for SARS-CoV-2 RNA in nasal specimen.

Limit of Detection (LOD): LOD for Puritan PurSafe Plus Collection & Transport System

Limit of Detection studies were carried out to assess any impact or interference of the Puritan PurSafe Plus Collection & Transport System on the pre-established performance of an FDA-cleared in-vitro diagnostic assay. For this study, Cepheid Xpert Xpress CoV-2/Flu/RSV assay (Cat #: XP3COV2/FLU/RSV-10) with pre-established limit of detection of 64 copies/mL for the nasal swab specimens was used on the Cepheid GeneXpert IV system.

The LOD studies indicate sufficient recovery and detection of SARS-CoV-2 viral RNA to an estimated concentration of 64 genome copies/mL for Puritan PurSafe Plus Collection & Transport System. This is the stated limit of detection for the Cepheid Xpert Xpress CoV-2/Flu/RSV system.

**Table 1.** Results of exploratory LOD study.

ID	Lot	Genome copies/mL	SARS-CoV-2 test result	Cepheid Probe Check
P1	240312	256	Positive	Pass
P2	240312	256	Positive	Pass
P3	240312	128	Positive	Pass
P4	240312	128	Positive	Pass
P5	240312	64	Positive	Pass
P6	240312	64	Positive	Pass
P7	240312	32	Negative	Pass
P8	240312	32	Positive	Pass
P9	240312	16	Negative	Pass
P10	240312	16	Negative	Pass
P11	240312	0	Negative	Pass
P12	240312	0	Negative	Pass

Confirmation of Limit of Detection (LOD)

SARS-CoV-2 Ct values from 20 samples, each at the LOD concentration of 64 genome copies/mL. Samples were drawn randomly from all three Puritan PurSafe Plus Collection & Transport System lots. This study was conducted over 6 days. All samples tested positive for SARS-CoV-2 and less than 2 Ct values separated the highest and lowest values.

**Table 2.** Results of LOD confirmation study.

Rep	Assay Day	SARS-CoV-2 test result	Cepheid Probe Check	Ct Values
1	1	Positive	Pass	36.6
2	1	Positive	Pass	36.7
3	1	Positive	Pass	36.9
4	1	Positive	Pass	37.6
5	1	Positive	Pass	37.6
6	1	Positive	Pass	37.1
7	2	Positive	Pass	36.4
8	2	Positive	Pass	37.0
9	2	Positive	Pass	36.5
10	2	Positive	Pass	36.0
11	3	Positive	Pass	37.1
12	3	Positive	Pass	36.9
13	3	Positive	Pass	36.6
14	3	Positive	Pass	36.6
15	3	Positive	Pass	36.6
16	3	Positive	Pass	37.2
17	3	Positive	Pass	36.3
18	3	Positive	Pass	36.3
19	6	Positive	Pass	36.1
20	6	Positive	Pass	36.9
			Min	36.0
			Max	37.6

**Stability**

Stability studies were conducted to evaluate the preservation of SARS-CoV-2 viral RNA stored in the three lots of PurSafe Plus Collection & Transport System in clinically negative nasal matrix. A concentration of 100 genome copies/μL (concentration 2-3 times the LOD) was used for the stability studies. Two storage temperatures were evaluated, 2-4°C and 25-30°C for 0, 1, 7, and 28 days. The reagent lots used in the study included newly manufactured, middle-aged lots and a lot near or beyond the claimed expiration date. All samples were assayed using the Cepheid Xpert Xpress CoV-2/Flu/RSV plus assay as per manufacturers protocol.

Table 3. Results of Stability Studies.

Temperature	Time (days)	Lot 1 (240312) New		Lot 2 (230207) Mid		Lot 3 (221109) Exp	
		Assay	Ct Values	Assay	Ct Values	Assay	Ct Values
	0	Positive	36.3	Positive	37.1	Positive	35.8
	0	Positive	36.1	Positive	36.2	Positive	35.4
2-4°C	1	Positive	35.6	Positive	36.6	Positive	37.1
	1	Positive	35.3	Positive	35.3	Positive	37.5
	7	Positive	36.4	Positive	36.6	Positive	36.7
	7	Positive	35.9	Positive	36.3	Positive	36.4
	28	Positive	36.2	Positive	36.2	Positive	36.9
	28	Positive	36.1	Positive	36.5	Positive	36.6
25-30°C	1	Positive	33.9	Positive	36.6	Positive	37.4
	1	Positive	37	Positive	36	Positive	36.8
	7	Positive	35.9	Positive	38.3	Positive	37.1
	7	Positive	38.4	Positive	39	Positive	36.2
	28	Positive	37.9	Positive	39.9	Positive	38.3
	28	Positive	37.5	Positive	37.7	Positive	36.8

All internal Cepheid probe checks passed (Table 3). Mean Ct values for all samples across all time points and temperatures were less than 3 Ct units from baseline (Time = 0) values (Table 4).

**Table 4.** Differences in mean Ct values from baseline (Time 0).

Temperature	Time (days)	Lot 1 (240312) New		Lot 2 (230207) Mid		Lot 3 (221109) Exp	
		Mean Ct Values	Difference from baseline (Time 0)	Mean Ct Values	Difference from baseline (Time 0)	Mean Ct Values	Difference from baseline (Time 0)
	0	36.2	–	36.6	–	35.6	–
2–4°C	1	35.5	0.75	36	0.65	37.3	1.7
	7	36.2	0.05	36.5	0.15	36.6	0.95
	28	36.2	0.05	36.4	0.25	36.8	1.15
25–30°C	1	35.5	0.75	36.3	0.3	37.1	1.5
	7	37.2	0.95	38.7	2.05	36.7	1.05
	28	37.7	1.5	38.8	2.2	37.6	1.95

In conclusion, all samples yielded positive detection at 100 genome copies/mL for all lots at storage temperatures of 2–4°C and 25–30°C for up to 28 days.

Inactivation

Uninfected VeroE6 cells were exposed to the PurSafe Plus Buffer to observe possible cytotoxicity. Serial dilutions of each buffer (3 PurSafe Plus Lots) were carried out across a 96-well plate ranging from 1:10 dilution to 1:2160 dilution. Cytotoxicity with the PurSafe Plus buffer was observed at a dilution of 1:10. No cytotoxicity was observed for all other dilutions. Since the Puritan PurSafe Plus buffers showed slight cytotoxicity at 1:10, but the 1:60 dilution had healthy cells, it was determined that a dilution $\geq 1:10$ but $< 1:60$ is adequate to show no cytotoxic effects.

For the subsequent inactivation studies, a 1:60 dilution was used for Puritan PurSafe Plus Collection & Transport System. Study was conducted to evaluate inactivation of SARS CoV-2 using 3 different lots of Puritan PurSafe Plus. The culture fluid from cells infected with SARS-CoV-2 virus (Isolate: USA-WA1/2020; Titer = 1.02×10^8 TCID₅₀/mL) was mixed with the Puritan MK buffer at a ratio of 1:10 for different time periods and evaluated in a cell culture-based assay in 96-well plates. Samples were evaluated for infectivity testing at 0-, 1-, 5- and 30-minutes time points after mixing with the Puritan MK buffer. Each condition was further diluted 1:60 and set up with 4 replicates (n=4). The diluted media and viruses were then added to confluent VeroE6 cells to evaluate viral infectivity. Cytopathic effects (CPE). The CPEs were visually observed over 7-day to determine the outcome of the study.

For VeroE6 cells-only controls no cytopathic effect was observed. The positive control SARS-CoV-2 culture fluid and virus treated with PBS resulted in positive CPE over the course of the assay. No visible CPE was observed over the course of the assay in wells with virus mixed with Puritan MK buffers for any exposure time evaluated in the study. Therefore, the PurSafe Plus buffer was effective at inactivating the SARS-CoV-2 virus upon contact, and after a minimum of 1 minute of exposure.



REFERENCES

1. Sewell, D.L. 1995. Laboratory-associated infection and biosafety. Clin. Microbiol. Rev 8:398-405. American Society for Microbiology. Washington, DC.
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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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