GeneBio Systems, Inc.™

USER MANUAL

SkinnyTube™ 10X Dx™ Viral Transport Medium Tubes and Kits

For collecting nasal swab samples

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SKINNYTUBE

SkinnyTube™ 10X Dx™ Viral Transport Medium Tubes and Kits

INTENDED USE

SkinnyTube™ 10X Dx™ Viral Transport Medium System is designed for the collection and transport of clinical specimen for the preservation and recovery of viral agents for diagnostic testing, with a gain of around 10 times concentration of collected swab samples, relative to the traditional transport medium tube.

SUMMARY

The ready-to-use system combines a disposable ***SkinnyTube™*** transport tube filled with non-inactivating viral transport medium (VTM) and a Puritan® PurFlock Ultra® Flocked Sterile nasal swab for efficient collection and safe transport. The VTM is stable from 2°C to 4°C with a neutral pH maintained by a buffer solution comprised of antimicrobial agents in addition to sources of protein and sucrose to support virus preservation for up to 48 hours.

PRINCIPLES

The internal compartment results in up to 10X increased diagnostic sensitivity (10X Dx™) by reducing sample dilution while introducing a secondary self-containment system to ensure maximum leakage prevention and safe transport.

PRODUCT DESCRIPTION

Table 1: Product Description

Cat No.	Product Description		Package Contents
	Tube	Swab	
SKT-031A	One SkinnyTube™ 10X Dx™ screw-cap cylindrical contour tube filled with 0.3 ml VTM	One Puritan® PurFlock Ultra® Sterile Flocked Nasal Swab	50 Kits/Package
SKT-061A	One SkinnyTube™ 5X Dx™ screw-cap cylindrical contour tube filled with 0.6 ml VTM	One Puritan® PurFlock Ultra® Sterile Flocked Nasal Swab	50 Kits/Package
SKT-032A	One SkinnyTube™ 10X Dx™ screw-cap cylindrical contour tube filled with 0.3 ml VTM	NA	100 Tubes/Package
SKT-062A	One SkinnyTube™ 5X Dx™ screw-cap cylindrical contour tube filled with 0.6 ml VTM	NA	100 Tubes/Package
SKT-031B	One SkinnyTube™ 10X Dx™ screw-cap, cylindrical top/spiky bottom tube filled with 0.3 ml VTM	One Puritan® PurFlock Ultra® Sterile Flocked Nasal Swab	50 Kits/Package

SKT-061B	One SkinnyTube™ 5X Dx™ screw-cap, cylindrical top/spiky bottom tube filled with 0.6 ml VTM	One Puritan® PurFlock Ultra® Sterile Flocked Nasal Swab	50 Kits/Package
SKT-032B	One SkinnyTube™ 10X Dx™ screw-cap, cylindrical top/spiky bottom tube filled with 0.3 ml VTM	NA	100 Tubes/Package
SKT-062B	One SkinnyTube™ 5X Dx™ screw-cap, cylindrical top/spiky bottom tube filled with 0.6 ml VTM	NA	100 Tubes/Package

TECHNICAL DESCRIPTION

Designed for compatibility with the Puritan® PurFlock Ultra® Sterile Flocked Nasal Swab with a break point at 30 mm.

Dimensions:

1. Tube: 9.0 cm (height) by 5.5 cm (circumference)
2. Swab: 153.4 mm handle (length) with 3.429 mm tip (diameter)

Specifications:

1. Tube: Polypropylene tube, silicone inner cap, and high-density polyethylene plastic (HDPE) cap (red)
2. Swab: Polystyrene handle and flocked polyester tip

Compatible Swab Types: Nasal; we recommend the Puritan Nasal swab (see Table 1).

TRANSPORT MEDIUM

The non-inactivating viral transport medium included in these products is a universal transport medium formulated for virus preservation (Table 2). The key ingredients include:

Table 2: Transport Medium Composition

Hank's Balanced Salts	L-Glutamic Acid
Bovine Serum Albumin	Phenol Red
Gelatin	Colistin
Sucrose	Amphotericin B
L-Cysteine	Vancomycin
HEPES	pH: 7.3 ± 0.2

REQUIRED MATERIALS NOT PROVIDED

Reagents and instruments required for the isolation and identification of viruses.

STORAGE

For reliable results, the kit must be stored in its original packaging between 2°C and 25°C prior to use. Improper storage will result in a loss of efficacy.

LIMITATIONS

1. Validation was conducted solely with the Puritan® PurFlock Ultra® Sterile Flocked Nasal Swab. The usage of this product with compatible swabs from other sources could impact the performance of the product and accuracy of the results.
2. The ***SkinnyTube™ 10X Dx™*** Viral ***Transport Medium System Kit*** is intended to be used with the tube and swab provided in the kit.
3. Follow recommended guidelines for specimen collection to ensure reliable results.
4. Repeated freeze-thaw cycles may impact the integrity of the sample.
5. Extreme temperature fluctuations and prolonged transit time may impact results.
6. ***SkinnyTube™ 10X Dx™ Viral Transport Medium System*** kits are intended to be used with the medium tubes and swabs provided in the kit.
7. The use of tubes, medium or swabs from any other source could affect the performance of the product.
8. Sensitivity gain may vary from 10X depending on current lab protocol and specific ***SkinnyTube™*** in use.
9. Condition, timing, and volume of specimen collected for clinical investigation are significant variables in obtaining reliable results. Follow recommended guidelines for specimen collection.

PRECAUTIONS

1. Intended solely for professional in vitro diagnostic testing.
2. Read user manual and package insert in full before use.
3. Follow standard aseptic microbiological techniques.
4. Prevent premoistening of tip before use.
5. Do not use if the package or contents are damaged.
6. Do not use if the medium has changed colour due to contamination (i.e., yellow or cloudy).
7. Do not use if the integrity of the tube is compromised (i.e., cracked or dented)
8. Do not reuse swabs or tube.
9. Practice necessary caution when handling human specimens.

INSTRUCTIONS FOR USE

SkinnyTube™ Kit

1. Open package containing the Puritan® swab and ***SkinnyTube***™ tube filled with VTM.
2. Open the sterile swab pouch and collect the specimen without bending the nasal swab as directed by Puritan®.
3. Unscrew the tube's cap aseptically and insert swab containing the sample into the media in the inner compartment without touching any other surfaces to prevent contamination.
4. Snap swab at the breakpoint highlighted by the black line using the edge of the tube and appropriately discard of the upper portion of the used swab into a medical waste container.
5. Align and lower the plunger with the opening of the inner compartment to seal off the medium tube and screw the cap back on to properly seal the tube.
6. Label the tube containing the specimen using appropriate identifications.
7. Follow local institutional procedures and send the ***SkinnyTube***™ tube sample to the laboratory for analysis.

LABORATORY PROCEDURES

To ensure adequate sample collection, it is recommended that laboratory technicians utilize a P200 pipette with ***SkinnyTube***™. Temperature conditions for storage and transport following collection should be maintained between 2°C and 8°C. If processing is delayed for longer than 72 hours, specimens must be frozen at -70°C or below.

DISPOSAL PROTOCOL

Dispose of product waste according to protocols outlined by local legislation relating to appropriate precautions for biohazard disposal.

QUALITY CONTROL

Designed and manufactured with a quality management system designed in compliance with ISO 13485 and the requirements of the Canadian Medical Devices Regulations. Each lot of ***SkinnyTube***™ undergoes testing for batch-to-batch manufacturing variability while the VTM is tested for bacterial and fungal contamination and medium pH.

PERFORMANCE CHARACTERISTICS

To investigate on the notion of raised analyte concentration in the novel tube compared to that of the conventional tube, the ***SkinnyTube***™ with 0.3 ml of Hanks-balanced salt-based medium was compared to the conventional tube with 3 ml of Hanks-balanced salt based medium.

A total of 36 swabs were tested. Each of the 36 swabs was dipped into a spiked mock sample containing a SARS-CoV-2 RNA (COVID-19 viral RNA). Then each of 18 dipped swabs was placed into a separate ***SkinnyTube***™ (novel tube); each of the other 18 swabs were placed into a separate conventional tube. 100uL of the transport medium from each of the 36 tubes was removed, heated, and then tested in a duplex SARS-CoV-2 quantitative reverse transcription polymerase chain reaction (RT-qPCR).

A duplex SARS-CoV-2 RT-qPCR tested 2 regions (N1 and N2 regions of the N gene) of the viral SARS-CoV-2 RNA to further validate the assay results. The cycle threshold (Ct) values from the RT-qPCR are listed below in Figure 1. The results showed that the average Ct value for N1 Region for the novel tube was 29.6 or was 3.1 less than that for the conventional tube (average Ct 32.7). Since Ct is a direct reflection of the analyte concentration, this difference corresponds to 8.5-fold more viral RNA analyte concentration in the novel tube than that for the conventional tube. The difference of average Ct value for N2 Region between the two groups of tubes was 4.7 (average Ct 35.5-30.9), corresponding to 25-fold viral RNA analyte concentration in the novel tube than that for the conventional tube. This > 10-fold increase in the viral RNA analyte concentration for N2 test was probably because when the assay result was near 37, the errors in Ct were inherently greater.

The N2 Region assay data showed that 5 of 18 (28%) samples were not even detectable (Ct<45 or 43 as criterion) in the conventional tube group, whereas all 18 samples in the novel tubes were detected. This suggests that the novel tubes are particularly more useful in the detection of low concentration (low positives near cut-off of an assay) samples (see the low panel of Figure 1).

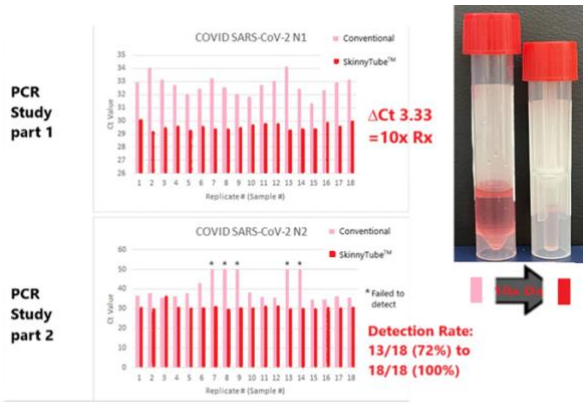

Figure 1 Comparing samples from SkinnyTube and Conventional Tube

Figure 1: Transport Medium Composition

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