Talis One Nasal Mid-Turbinate Collection Kit Package Insert

For Use Under an Emergency Use Authorization (EUA) Only

For *in vitro* diagnostic use

For prescription use only

This document does not provide the full instructions for use (IFU). For the complete IFU, please visit: https://talisbio.com/ifu/talis-one-covid-19-test To request a printed copy (free of charge), please email: care@talisbio.com.

Description

The Talis One Nasal Mid-Turbinate Collection Kit is a component of the Talis One COVID-19 Test System, for use by clinicians to collect nasal mid-turbinate swab specimens.

The Talis One COVID-19 Test System has not been FDA cleared or approved. It has been authorized by the FDA under an EUA for use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate, or waived complexity tests.

The Talis One Nasal Mid-Turbinate Collection Kit, as a component of the Talis One COVID-19 Test System, is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

The Talis One COVID-19 Test System has been authorized only for the detection of RNA from SARS-CoV-2 virus and diagnosis of SARS-CoV-2 virus infection, using the Talis One COVID-19 Test System with nasal mid-turbinate swab specimens.

Materials Provided

25 Nasal Mid-Turbinate Collection Kits

Each kit contains:

Component	Quantity	Description
Swab	**1**	**Individually wrapped, sterile flocked swab for nasal mid-turbinate swab specimen collection.**
Collection Medium Tube	**1**	**A specimen tube containing 3 mL collection medium.**

Each package contains:

Component	Quantity	Description
Talis One Nasal Mid-Turbinate Collection Kit Package Insert	**1**	**Package Insert**
Talis One Nasal Mid-Turbinate Collection Kit	**25**	**One flocked Swab and one tube containing collection medium.**

Warnings and Precautions

- Wear protective gloves and eye protection at all times when handling collection medium contained in the Collection Medium Tubes—direct contact with skin, eyes, or mucous membranes will cause irritation.
- If collection medium is spilled and makes contact with skin, immediately wash affected area with water and soap and rinse thoroughly.
- Specimens may possess communicable organisms which may be infectious. Use standard precautions when handling specimens and used test materials.
- Do not allow bleach to come into contact with the contents of the Talis One Collection Medium Tubes or control preparation tubes as toxic fumes can develop when the content of the tubes mixes with bleach.
- **WARNING:** Collection medium contained in Collection Medium Tubes is harmful if swallowed or inhaled, may cause skin irritation, and may cause serious eye irritation. Avoid direct skin/mucous membrane contact with or ingestion of collection medium provided with the Talis One Nasal Mid-Turbinate Collection Kits and Talis One COVID-19 Control Medium and Label Pack. If ingested contact Poison Control at 1(800) 222-1222.

  Classifications:

  Acute toxicity, Category 4.
  Skin corrosion/irritation, Category 2.
  Serious eye damage/irritation, Category 2A.

Hazard Statements:

Harmful if swallowed.
Causes skin irritation.
Causes serious eye irritation.

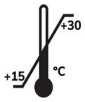
Important information regarding the safe handling, transporting, and disposing of this product is contained in the Safety Data Sheets. Safety Data Sheets are available from Talis Biomedical Corporation. Inquire directly.

- Avoid spilling contents of the Collection Medium Tube (collection tube). If a spill occurs, immediately blot dry and decontaminate impacted surfaces with CaviWipes or an alcohol-based cleaner (**do not use bleach**), then restart the collection procedure with a

new kit. Failure to use a new kit may invalidate the test results.

- Do not allow swab tip to touch anything except the nose.
- If precipitate is observed in the collection tube, do not use.
- If kit pouch is damaged, do not use.
- Dispose of all packaging materials in a safe manner in accordance with your institution's guidelines.
- Handle and dispose of all used kit materials and unused reagent according to your institution's safety guidelines for hazardous materials, in compliance with applicable government regulations.
- Personal protective equipment (PPE), including a lab coat, mask (surgical, dental, medical procedure, isolation, or laser mask), eye protection, and gloves must be worn at all times when collecting specimens.

Kit Storage Requirements



Nasal Mid-Turbinate Collection Kits should be stored at room temperature within the range of 15°-30°C.

Nasal Mid-Turbinate Swab Specimen Performance

The Test System performance characteristics, including Clinical and Analytical Performance of the nasal mid-turbinate swab specimen, are provided in the Talis One COVID-19 Test System Instructions For Use.

Nasal Mid-Turbinate Swab Specimen Collection by Clinician

The following procedure is intended only for collection of patient nasal mid-turbinate swab specimens by a clinician.

IMPORTANT: Personal protective equipment (PPE), including a lab coat, mask (surgical, dental, medical procedure, isolation, or laser mask), eye protection, and gloves must be worn at all times when collecting specimens.

***Before* collection of each new specimen:**

- Disinfect work surfaces with CaviWipes or an alcohol-based cleaner. **Do not use bleach**.
- Put on a new pair of gloves and protective eyewear.
- Check patient for nasal obstructions and clear as needed.

Specimen Collection Procedure (Clinician):

1. Open the Talis One Nasal Mid-Turbinate Collection Kit pouch, remove the contents and inspect components for signs of damage. (Each kit pouch contains one capped Collection Medium Tube and one swab wrapped in its own paper pouch.)
2. Print patient name, ID/Date of Birth, and collection date in the fields provided on the collection tube, or apply printed label.
3. Open the paper swab pouch carefully at the shaft end without touching the soft swab tip. Leave the swab in the partially-opened pouch until ready to use. (The swab tip should not touch any surface, including gloves.)
4. Remove cap from the collection tube and put aside (open side up), then place the open tube on a tube holder.

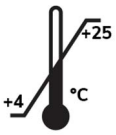
IMPORTANT: If liquid from the collection tube spills or swab tip touches any surface other than the nostril, restart the collection procedure with a new kit. The spillage should be immediately blotted dry and the surface should be decontaminated with CaviWipes or an alcohol-based cleaner. **Do not use bleach.**

5. Carefully remove the swab from the partially-opened pouch—ensure that the tip does not touch any surfaces—and hold at the breakpoint. Failure to hold at the breakpoint may cause the swab to break during specimen collection.
6. Tilt patient head back slightly (~70^{o}) and carefully insert the swab into either of the patient's nostrils while rotating the swab until resistance is met at turbinates (less than 1 inch into the nasal cavity).

   ***Note**: Swab should be inserted in a horizontal direction, approximately parallel to the palate.*
7. Rotate swab against nasal wall for 3-5 seconds.
8. Remove the swab from the nostril, then repeat steps 6 and 7 in the other nostril using the same swab.
9. Insert the swab into the collection tube until the entire swab tip is visible below the liquid level.
10. Break the swab at the breakpoint against the lip of the collection tube, then discard the swab shaft and tightly screw the cap onto the tube.
11. Hold the collection tube by the cap and swirl tube 6 times.
12. Disinfect the collection tube and store upright, then discard used gloves into appropriate waste receptacle.

Prior to collecting any additional specimens from additional patients, ensure that the work area has been decontaminated and that fresh gloves are used.

Specimen Handling and Storage



Specimens should be tested immediately or no later than 30 days from collection. Keep specimens at 4–25° Celsius.

IMPORTANT: Clinician should label the collection tube with the sample identification information, including date and time of the collection, as required.

Limitations

- *For in vitro* diagnostic use.
- For prescription use only.
- For Use Under an Emergency Use Authorization (EUA) Only.
- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories;
- This product is for use with a test authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate, or waived complexity tests.
- The Talis One COVID-19 Test System is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
- Use this collection kit only with the Talis One COVID-19 Test System. Performance has not been established with other products.

Ordering, Contact Information, and Technical Assistance

Corporate Headquarters
Talis Biomedical Corporation **230 Constitution Drive** **Menlo Park, CA 94025** **USA**
Telephone: +1 (855) 956-3594
Technical Support: support@talisbio.com
Customer Service: care@talisbio.com

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℞ ONLY **For prescription use only**

IVD **For *In Vitro* Diagnostic Use**

Symbol Definitions

Following are symbols and associated definitions used in Talis One labeling.

Symbol	Meaning	Symbol	Meaning
IVD	*in vitro* diagnostic medical device		Use by date
Rx ONLY	Prescription use only		Do not reuse
LOT	Batch code		Temperature limitation
REF	Catalog number		Humidity limitation
SN	Serial number		Consult instructions for use
	Health hazards		Manufacturer
	Caution		Date of manufacture
	Warning		Contains sufficient for <n> tests
	Biological risks		Maximum altitude
	Pinch point	CONTROL −	Negative control
		CONTROL +	Positive control