

Indications for Use

The Yukon Medical ClearTip Swab™ Ultra Thin is an individually wrapped, single-use, sterile swab intended to collect upper respiratory specimens. The swab is indicated for *in vitro* analysis and detection purposes.

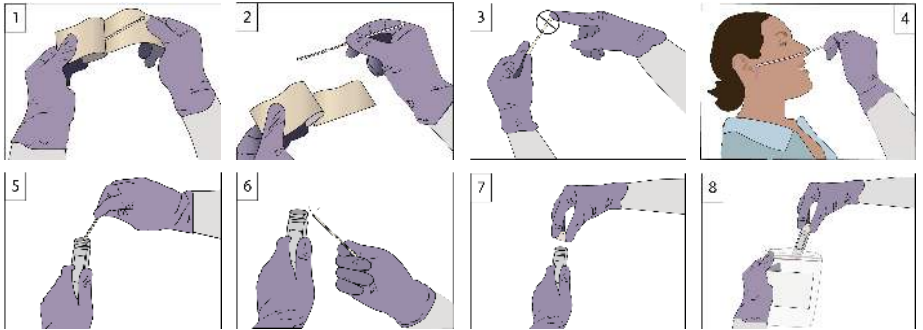
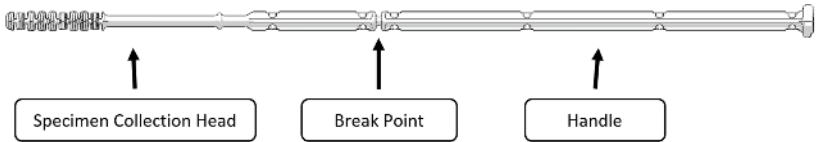
Precautions

- For single use only. Re-use creates an unacceptable risk of infection and/or inaccurate results.
- Do not re-pack or re-sterilize.
- Do not use if the package is open or damaged.
- Do not use if the expiration date has been exceeded.
- Do not spray the package with cleaning agents as damage to labeling may occur.
- Device should be used and handled by trained personnel only. Follow the directions for use provided below.
- Ensure that Universal Precautions and all facility infection prevention and control steps are followed including:
 - a) Use aseptic techniques as defined by facility protocols.
 - b) Practice good hand hygiene before and after the procedure and before and after the patient encounter.
 - c) Don appropriate personal protective equipment (PPE), including mask and eye protection (for example, face shield), gloves, and gown.
- Do not apply excessive force when collecting swab samples from patients as the device may break.
- All clinical specimens may contain infectious bloodborne microorganisms (including human immunodeficiency virus and hepatitis viruses) and should be handled with care.
 - a) Special precautions should be taken when handling specimens that may have come into contact with blood and other bodily fluids. Follow all laboratory and biosafety guidelines when handling clinical specimens, including PPE requirements.
 - b) Follow state, local and institutional guidelines for the handling and disposal of tubes, swabs, and all biohazard waste.

Storage

Store between 15 and 40°C.

Directions For Use



1. Peel open Swab pouch using the peel tabs.
2. Remove the Swab from the packaging, being careful to grip the Handle behind the Break Point.
3. Avoid touching the patient side of Swab (Specimen Collection Head) throughout the procedure by keeping all fingers on the Handle, behind the Break Point.
4. Collect the clinical specimen.
 - a. If the patient has nasal congestion, ask them to clear their nose into a tissue.
 - b. Tilt their head back slightly, supporting it if necessary.
 - c. Insert the Specimen Collection Head of the Swab into the nostril - parallel to the palate - until resistance is met by contact with Nasopharynx.
 - d. Leave the Swab in place for 3 seconds, and then gently rotate it for 10-15 seconds.
 - e. Remove the Swab. Repeat the process on the other nostril with the same Swab.
5. Immediately place the Swab into a sterile specimen tube containing the appropriate medium (for example, CDC Viral Transport Medium (VTM)).
6. Place the Break Point of the Swab at the edge of the specimen tube opening, then bend the Swab until the shaft breaks. The Specimen Collection Head will drop into the specimen tube and the Handle can be appropriately discarded.
7. Carefully close the specimen tube cap tightly.
8. Follow facility protocols for labeling and transporting the specimen tube.

Limitations

Successful specimen collection depends on many factors, including collection and handling technique, specimen conditions, and timing. Best results are achieved when specimens are processed shortly after the time of collection. If delays are anticipated, swab specimens should be stored in a suitable transport medium until processed.

References

1. Isenberg, H.D. 1998. Collection, Transport and Manipulation of Clinical Specimens. In *Essential Procedures for Clinical Microbiology*. American Society for Microbiology, Washington, DC.
2. NEJM Procedure: Collection of Nasopharyngeal Specimens with the Swab Technique, <https://www.youtube.com/watch?v=DVJNwefmHJE>. Accessed 11 July 2020.
3. Centers for Disease Control and Prevention. (2020). Preparation of Viral Transport Medium. SOP#: DSR-052-03. <https://www.cdc.gov/coronavirus/2019-ncov/downloads/Viral-Transport-Medium.pdf>. Accessed 11 July 2020.

Rx Only



STERILE EO



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Catalog Number REF 5.1.6	Indicates the manufacturer's catalogue number so that the medical device can be identified.
Sterilized using ethylene oxide STERILE EO 5.2.3	Indicates a medical device that has been sterilized using ethylene oxide.
For prescription use only Rx Only CFR 801.109 ¹	Caution: Federal Law restricts this device to sale by or on the order of a physician.
Caution 5.4.4	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.

Do not use if package is damaged 5.2.8	Indicates a medical device that should not be used if the package has been damaged or opened.
Do not re-use 5.4.2	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
Use-by date 5.1.4	Indicates the date after which the medical device is not to be used.
Batch Code LOT 5.1.5	Indicates the manufacturer's batch code so that the batch or lot can be identified.

Manufacturer 5.1.1	Indicates the medical device manufacturer, as defined in EU Directives 90/269/EEC, 93/42/EEC and 98/79/EC
Date of manufacture 5.1.3	Indicates the date when the medical device was manufactured.

All symbols in this table are from ISO 15223-1:2016 - Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1 General requirements, except if specifically noted

¹This symbol is from CFR 801.109 - Code of Federal Regulations Title 21 Chapter I Subchapter H Part 801 Section 109 Prescription Devices