Directions for Use

ClearTip Swab™ Contoured

REF **YM202, YM205**

Indications for Use

The Yukon Medical ClearTip™ Swab – Contoured is designed for specimen collection performed by a clinician in a wide variety of healthcare environments, including hospitals, clinics, long-term care facilities, retail pharmacies, urgent care, and community-based testing sites. Yukon Medical ClearTip™ Swabs (Contoured and Contoured Mini) are indicated for point-of-care use or with standard transport media and collection tubes for collection, transfer, and/or transport of clinical specimens.

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.
- 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.
- 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 – Self-Collection

1. Practice good hand hygiene before, during, and after the collection procedure. Use appropriate personal protective equipment (PPE) per your facility's guidelines.
2. Prepare any kit components according to the manufacturer's instructions.
3. Peel open the Swab pouch using the peel tabs.
4. Remove the Swab from the packaging, being careful to grip the Handle behind the annular Ring.
5. Avoid touching the Specimen Collection Head throughout the procedure by keeping all fingers on the Handle, behind the Ring.
6. Collect the nasal specimen.
    a. If the patient has nasal congestion, ask them to clear their nose into a tissue.
    b. Insert the Swab into a nostril. Advance the Swab as far as the annular Ring.
    c. Leave the Swab in place for 5 seconds, and then rotate it five times (or according to assay kit manufacturer's instructions).
    d. Remove the Swab.
    e. If required by your facility or a particular assay kit, repeat steps b through d in the other nostril.
7. Immediately place the Swab into the specimen tube or container as specified by your facility or kit manufacturer.
8. If the specimen is being collected and then transported, carefully close the specimen tube cap tightly and follow facility protocols for labeling and transporting the specimen tube.
9. Ensure good hand hygiene after completing the procedure, including thoroughly washing your hands with soapy water.

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

Manufactured by:
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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*	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 indentified.

Manufacturer 5.1.1	Indicates the medical device manufacturer, as defined in EU Directives 90/385/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 I***SO 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

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