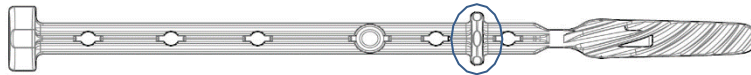


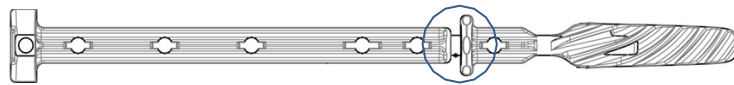
Directions for Use
ClearTip Swab™ Contoured Mini & Contoured Mini NB
REF YM201, YM203

Intended Use

The ClearTip™ Swabs Contoured Mini and Contoured Mini NB are individually packaged, sterile, ready to use devices for collection, transfer, and/or transport of clinical specimens. The Swabs are available with and without a Break Point.



ClearTip Contoured Mini NB (YM201). Circled feature is the Ring (Depth Indicator). Picture shown is YM201 (without Break Point).



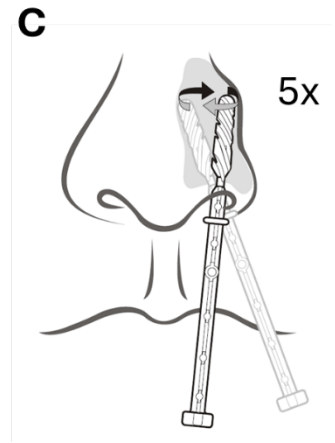
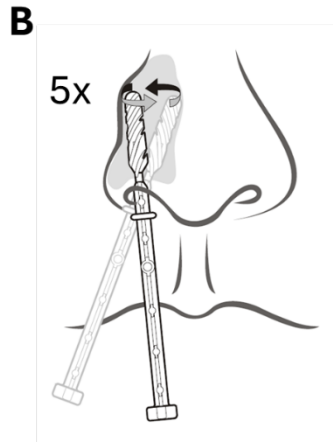
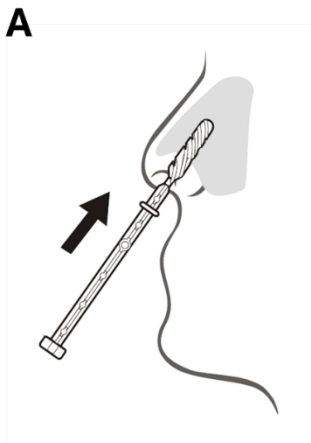
ClearTip Contoured Mini (YM203). Circled feature is the Ring (Depth Indicator) with the adjacent Break Point. Picture shown is YM203 (with Break Point).

Precautions

- Carefully follow the instructions for use.
- 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.
- Visually locate the Ring (Depth Indicator) before use.
- Do not use if the expiration date has been exceeded.
- Do not spray the package with cleaning agents as damage to labeling may occur.
- If the specimen is collected by the patient, ensure that good hand hygiene is used before and after the collection procedure and that the swab and any collection materials are stored, used, and disposed of properly.
- If the specimen is collected by a health care professional, ensure that Universal Precautions and all facility prevention and control steps are followed including:
 - Use aseptic techniques as defined by facility protocols.
 - Practice good hand hygiene before and after the procedure and before and after the patient encounter.
 - Wear 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.
- 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.
- Follow state, local and institutional guidelines for the handling and disposal of tubes, swabs, and all biohazard waste.

Directions For Use – Specimen Self-Collection

1. Wash your hands thoroughly using warm, soapy water.
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 Ring (Depth Indicator).
5. Avoid touching the Specimen Collection Head throughout the procedure by keeping all fingers on the Handle, behind the Ring (Depth Indicator).



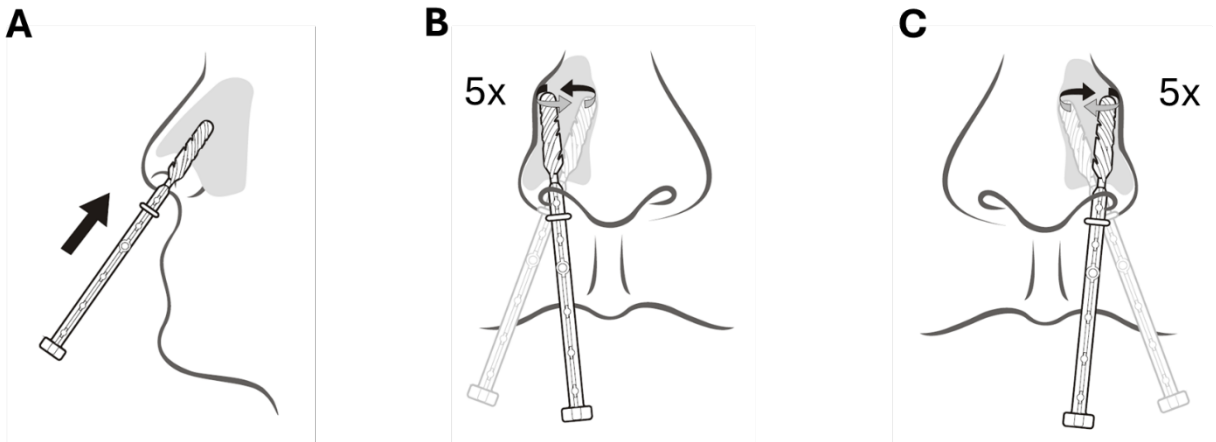
- A. Carefully insert the Specimen Collection Head of the Swab into a nostril up to the Ring (Depth Indicator).
- B. Swab the inside of your nose with moderate pressure against as much of the wall of your nostril as possible. Using a large circular path to swab at least 5 times, then remove the Swab from your nose.
Note: Simply twirling the Swab against one part of the inside of the nose or just leaving the swab in the nose for 10 seconds is not proper technique and may result in an insufficient sample.
- C. Using the same Swab, carefully insert the Swab into the second nostril up to the Ring (Depth Indicator). Repeat as before: swab the inside of your nose with moderate pressure against as much of the wall of the nostril as possible in a large circular path at least 5 times and remove the Swab from your nose.

Note: You must collect the sample from both nostrils!

7. Remove the Swab from your nose and immediately place it into the specimen tube or container as specified by the particular kit that is being used.
8. Follow the manufacturer's instructions for the next steps, including any shipping or disposal steps.
9. Ensure good hand hygiene after completing the procedure, including thoroughly washing your hands with soapy water.

Directions For Use – Clinician Specimen 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 Ring (Depth Indicator).
5. Avoid touching the Specimen Collection Head throughout the procedure by keeping all fingers on the Handle, behind the Ring (Depth Indicator).
6. Collect the nasal specimen. If the patient has nasal congestion, ask them to clear their nose into a tissue first.



- A. Carefully insert the Specimen Collection Head of the Swab into a nostril up to the Ring (Depth Indicator).
- B. Swab the inside of the patient's nose with moderate pressure against as much of the wall of the nostril as possible. Using a large circular path to swab at least 5 times, then remove the Swab from their nose.

Note: Simply twirling the Swab against one part of the inside of the nose or just leaving the Swab in the nose for 10 seconds is not proper technique and may result in an insufficient sample.

- C. Using the same Swab, carefully insert the Swab into the second nostril up to the Ring (Depth Indicator). Repeat as before: swab the inside of the patient's nose with moderate pressure against as much of the wall of the nostril as possible. Using a large circular path to swab at least 5 times, then remove the Swab from their nose.

Note: You must collect the sample from both nostrils!

7. Remove the Swab from the patient's nose and process according to facility guidelines, including breaking the Swab at the break point (if applicable).
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. Send the sample to the laboratory.
10. 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. 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.



Manufactured by:
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 Durham, NC 27703

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 trademark or registered
 trademark of Yukon
 Medical, LLC.

Symbol	Symbol Title	Explanatory Text	Standard	Standard Reference
	Catalog Number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.1.6 FDA Recognition # 5-117 ISO 7000 Reference #2493 FDA Recognition # 5-103
	Do Not Re-Use	Indicates the medical device is for single use only and cannot be re-used.	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.4.2 FDA Recognition # 5-117 ISO 7000 Reference #1051 FDA Recognition # 5-103
	Do Not Use if Package is Damaged.	Indicates medical device should not be used if the package has been damaged or opened.	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.2.8 FDA Recognition # 5-117 ISO 7000 Reference #2606 FDA Recognition # 5-103
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions.	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.4.4 FDA Recognition # 5-117 ISO 7000 Reference #0434A FDA Recognition # 5-103
	Sterilized using Irradiation	Indicates a medical device that has been sterilized using irradiation.	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.2.4 FDA Recognition # 5-117 ISO 7000 Reference #2502 FDA Recognition # 5-103
	Manufacturer	Indicates the medical device manufacturer.	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.1.1 FDA Recognition # 5-117 ISO 7000 Reference #3082 FDA Recognition # 5-103