

1 Intended use of the Device

The CANSWAB™ Nasopharyngeal Swab is a single-use device that is designed to collect upper respiratory specimens from patients with signs and symptoms of COVID-19 respiratory infection. The CANSWAB™ is individually packaged at an ISO 13485/MDSAP certified medical device facility. The swabs are packaged in a clear film material with a porous medical grade paper backing. The swabs are then sterilized using 100% Ethylene Oxide at a facility certified to ISO 11135:2014. The sterilization cycle is validated to a Sterility Assurance Level (SAL) of 10^{-6} .

2 Directions for use

This NP swab is used to collect samples for COVID-19 diagnostics purposes. Instructions as found on labelling are the following:

1. Keep out of direct sunlight.
2. Remove carefully from packaging, avoid touching the swab tip.
3. Collect specimen according to standard clinic/hospital procedures.
4. Transfer swab and sample to vial, snap at breakpoint before sealing.

Recommended for use with 10cm sample vials. If swab must be shortened, use sharp cutting device and trim thinnest portion of shaft near collection tip.

General instructions for specimen collection are detailed below, based on the protocol by the Winnipeg Regional Health Authority Acute Care Infection Prevention & Control Manual.

1. Assemble all supplies such as gloves, facial protection, swab and transport medium and check expiry date of transport medium.
2. Perform hand hygiene and don appropriate personal protective equipment.
3. Have patient sit in a chair or lie on a bed – elevate the head of the bed so their head can be tilted back.
4. Remove any mucous from the patient's nose, with a tissue or cotton tipped swab prior to collecting the NP swab.
5. Measure the distance from the corner of the nose to the front of the ear.
6. Tilt the patient's head back slightly (about 70°) to straighten the passage from the front of the nose to the nasopharynx making insertion of the swab easier. Gently insert the shaft ONLY half of the measured length into the nostril (if resistance is encountered, try the other nostril, as the patient may have a deviated septum). Note: insertion of the swab usually induces a cough.
7. Rotate the swab several times to dislodge the columnar epithelial cells, and then remove the swab.
8. Cut the shaft of the swab short enough to fit into the VTM bottle. When placing the lid on the bottle, make sure the entire shaft of the swab is inside the bottle. Failure to do so will result in the transport media leaking and the sample being discarded.
9. Ensure the lid of the bottle is screwed on tight (can use paraffin to wrap the neck of the bottle to prevent leakage if available).