

Single Use Specimen Container (Nasal Swab)

CATALOGUE NUMBER	KIT SIZE (TESTS)
SSCCOV2	50T

Intended Use:

For In Vitro diagnostic use by trained professionals only.

The Single Use Specimen Container is intended for the collection, transportation and storage of nasopharynx (nasal) swab samples for later testing for detection of virus, bacteria, mycoplasma and chlamydia infection.

Test Principle:

Guanidine thiocyanate when added to a specific buffer, has the capacity to inactivate pathogenic microorganisms including viruses, bacteria, mycoplasma and chlamydia and stabilize the total nucleic acid (RNA and DNA) at the appropriate temperature given below, improving the biological safety and reliability of subsequent tests carried out using the samples.

Reagent Composition:

Tris-HCl, guanidine isothiocyanate, EDTA, phenol red indicator.

Kit Components:

Specimen collection tubes containing storage buffer, nasopharyngeal swabs, specimen bags.

Storage and Stability:

The Single Use Specimen Container and its liquid contents are stable up to 12 months when stored at 2 – 30°C.

Sample Collection, Preparation and Stability:

Sample type: The sample type which is compatible with the Single Use Specimen Container is a nasopharyngeal secretion sample.

Sample collection: The secretion sample should be collected by standard swab technique, consistent with local practices and the nature of the clinical examination being undertaken.

Sample storage and transportation: The collected clinical samples should be stored at 2 – 8°C for up to 48 hours, or for longer term storage, frozen at -20°C or below. Samples must be transported in a polystyrene box surrounded by ice packs.

Limitations and Precautions:

- Please read this IFU carefully before use.
- Wear powder-free latex gloves, laboratory coat and safety glasses throughout the collection process and kit use.
- The processing of clinical samples needs to be performed in a Class II biological safety cabinet,
- Proper purification procedures should be carried out before and after the experiment.
- Do not allow the collection container to come into direct contact with the patient at any time.
- The collection of virus specimens should be carried out in strict accordance with the collection procedures.
- Do not use the product beyond the expiry date stated on the kit or if the packaging is damaged.
- Dispose of all samples and reagents properly, thoroughly clean and disinfect all operating surfaces.
- The kit is suitable for swab collection of secretions, but variability in manual collection technique can affect the results of subsequent testing.

Procedure:

- Keeping the tube upright, unscrew the specimen tube cap.
- Collect the sample by swab. For nasal swabbing insert the swab into the nasal palate to the back of the nasal cavity, hold for a moment then rotate slowly during withdrawal.
- Put the swab into the tube and keep the swab tip below the liquid surface.
- Break off the swab shaft and screw the tube cap back on securely, leaving the swab tip still inside the storage buffer.
- Put the specimen tube in the plastic specimen bag and secure the zip-lock seal.






Performance Characteristics:

Appearance: Components intact, clean package, no leakage, no damage and transport buffer is red, transparent and without visible suspended particles.

Net Content: No less than 95% target dispense volume.

pH Value: pH = 7.5 ± 0.2.

Symbols:

REF	Catalogue number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use by Date
	Manufacturer		Do not reuse

