

Single Use Specimen Container

Instruction for Use

Product:

Single Use Specimen Container

Cat No	Model	Specification
CP01030011	G01	50T
CP01170011	G02	50T
CP01240011	G03	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 samples for later testing for detection of virus, bacteria, mycoplasma and chlamydia infection.

Test Principle:

G01: 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 & DNA) at the appropriate temperature given below, improving the biological safety and reliability of subsequent tests carried out using the samples.

G02: Provide a stable transportation and preservation environment for samples, and improve the biological safety and reliability of subsequent tests carried out using the samples.

G03: Hank's Buffer solution helps to establish a neutral environment, pH 7.2-7.4 (phenol red is red), which contributes increasing the survival time and infection stability of the virus. Bovine serum albumin (BSA) is a protein stabilizer, which protects capsid protein of virus, making it difficult to decompose and ensuring the integrity of the virus. Multiple antibiotics can suppress bacteria. If the specimen is contaminated by bacteria, the color of the preservation solution will change from red to yellow.

Reagent Composition:

G01: Tris-HCl, Guanidine isothiocyanate and EDTA

G02: NaCl

G03: Hank's buffer, BSA, Amino acid, Antibiotics

Non-sterile.

Accessories:

nasopharyngeal swab

oropharyngeal swab

specimen bag

Storage and Stability:

The Single Use Specimen Container and its liquid contents are stable up to 12 months when stored at 0 – 40°C.

Sample Collection, Preparation and Stability:

Sample type: The sample type which is compatible with the Single Use Specimen Container is a nasopharyngeal or oropharyngeal 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 1 month, 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 manual carefully before use.
- Wear powder-free latex gloves properly throughout the collection and 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.
- Do not touch the solution directly anytime.

Procedure:












- Keeping the tube upright, unscrew the tube cap.
- Collect sample by swab.
- 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.
- Put the tube into specimen bag and seal the bag.

Performance Characteristics:

Appearance: Components intact, clean package, no leakage, no damage, labels legible.

Net Content: No less than 95% stated content.

pH Value: G01: pH = 6.85 ± 1.0, G03: pH = 7.4 ± 0.2.

	Catalogue number		Temperature limit
	Consult instructions for use		Batch code
	In vitro diagnostic medical device		Use-by date
	Manufacturer		Do not re-use
	This way up		Keep dry
	Fragile, handle with care		