



## **AMPICOLLECT™ Saline NP Swab Kit**

### **INSTRUCTIONS FOR USE**

Catalog #: ENZ-GEN244-0050

50 Units

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**IVD**

For *in vitro* diagnostic use

## **AMPICOLLECT™ Saline NP Swab Kit - Instructions for Use**

### **INTENDED USE**

The AMPICOLLECT™ Saline NP Swab Kit is intended for the collection and transport of clinical specimens from the collection site to the testing laboratory for molecular test for detection of SARS-CoV-2 virus. This kit is to be used by trained and qualified professionals ONLY. This kit is for *in-vitro* diagnostic use ONLY.

### **SUMMARY AND PRINCIPLES**

1. Collection and refrigerated transport of biological specimens is a routine procedure in the diagnosis of infections caused by viruses. The collected samples, using the AMPICOLLECT™ Saline NP Swab Kit, can be stored for up to 48 hours at 2-25°C. The medium contains preservatives that inhibit growth of bacteria and yeasts, maintain cellular integrity and encourage preservation of the virus SARS-CoV-2.
2. After collection, the specimen should be stored at 2-25°C and processed within 48 hours. If delivery and processing exceed 48 hours, specimens should be transported in dry ice. Once in the laboratory, the specimens should be stored frozen at -70°C or colder.

### **PRODUCT DESCRIPTION**

The AMPICOLLECT™ Saline NP Swab Kit which contains sterile components is ready for use and requires no further preparation. The kit includes the following:

CAT. NO.	COMPONENTS per Kit	PACKAGING
ENZ-GEN244-0050	3 mL AMPICOLLECT™ Saline, Normal medium in 16x94 mm screw-cap tube One flexible nasopharyngeal applicator swab with flocked nylon fiber tip with breaking point	50 kits per box

### **KEY COMPONENTS**

1. Sodium Chloride (NaCl)
2. 5-Chloro-2-methyl-4-isothiazolin-3-one (CMIT)
3. 2-Methyl-4-isothiazolin-3-one (MIT)
4. Magnesium Salts

## **REQUIRED MATERIALS BUT NOT PROVIDED**

Materials suitable for isolation, differentiation and culture of viruses.

## **STORAGE**

Store the product in its original packaging at a temperature between 2°C and 25°C until the time of use. DO NOT expose to heat or freeze prior to use. This product is stable for a year from the date of manufacture, when stored as per recommendation.

## **LIMITATIONS**

The AMPICOLLECT™ Saline NP Swab Kits are to be used only with the medium tubes and swabs provided. The use of medium or swabs from other sources could affect the performance of the product. This kit is to be used by trained and qualified professionals ONLY.

## **PERFORMANCE CHARACTERISTICS**

Replicates of saline transport matrix, spiked with SARS-CoV-2 pseudovirus at high (4000cp/mL) and low (2000cp/mL) concentrations were prepared and stored at -20°C, 2-8°C, and room temperature for a span of 14 days. The samples were tested on Days 0, 1, 2, 3, 7, and 14; samples were processed on the GENFLEX platform. Results indicate that SARS-CoV-2 pseudovirus is stable in the saline transport matrix (containing 5-Chloro-2-methyl-4-isothiazolin-3-one (CMIT) / 2-Methyl-4-isothiazolin-3-one (MIT)) as preservatives) for up to 7 days at room temperature, 2-8°C and -20°C.

**Table 1: Duplicate averages for High Copy saline (4000cp/mL)**

Specimen Condition	Platform	Detector	0	1	2	3	7	14
Frozen(-20°C)	GENFLEX	N1	32.79	33.05	32.97	33.30	32.86	34.990
		N2	33.63	33.94	33.14	33.96	33.20	35.34
Refrigerated (2 to 8°C)	GENFLEX	N1	32.79	32.84	32.88	32.68	32.94	35.71
		N2	33.63	33.79	33.31	32.89	33.03	36.63
Room Temperature (18 to 26°C)	GENFLEX	N1	32.79	32.99	33.53	33.34	32.93	36.33
		N2	33.63	33.52	33.94	33.97	32.82	37.16

**Table 2: Duplicate averages for Low Copy saline (2000cp/mL)**

Specimen Condition	Platform	Detector	0	1	2	3	7	14
Frozen (-20°C)	GENFLEX	N1	34.23	34.37	34.05	34.85	34.67	35.990
		N2	34.37	35.07	34.47	35.42	34.81	37.09
Refrigerated (2 to 8°C)	GENFLEX	N1	34.23	34.38	33.98	34.03	33.68	36.5
		N2	34.37	35.12	34.29	34.29	34.03	37.47
Room Temperature (18 to 26°C)	GENFLEX	N1	34.23	34.19	34.16	34.66	34.40	37.41
		N2	34.37	35.03	34.3	34.86	34.14	37.46

## QUALITY CONTROL

Sterility of this product is demonstrated by streaking saline on blood agar plates under sterile conditions. Then the plates are incubated at 37 degrees Celsius. The plates are checked for any growth at 24 hours and 36 hours.

## WARNINGS AND PRECAUTIONS

1. Single-use device for professional in vitro diagnostic use.
2. Do not use beyond the expiry date.
3. Specimen stability for this media was not validated for recovery of viral infectious particles using a culture-based assay.
4. Do not use the AMPICOLLECT™ Saline, Normal medium to pre-wet the applicator swab prior to collecting the sample.
5. Do not re-sterilize or re-pack unused swabs.
6. The medium contains 5-Chloro-2-methyl-4-isothiazolin-3-one (CMIT) / 2-Methyl-4-isothiazolin-3-one (MIT) as preservatives.
7. The kit is not suitable for collecting microorganisms other than SARS-CoV-2.
8. Do not ingest the medium.
9. Use personal protective equipment against biological risk according to published guidelines when collecting specimens.
10. Avoid repeated freezing and thawing of specimens as this may reduce the recovery of viable organisms.
11. Do not use the product if there is evidence for leakage, damage of the product, swab pouch is open, or other signs of deterioration.
12. The use of this product in combination with diagnostic kits or instruments must be validated by the user prior to use.

13. The transport medium has not been reviewed by the FDA.
14. If the user must remove the swab from the tube, use caution and observe adequate precaution to protect the operator and the environment in case of splash.

## **INSTRUCTIONS FOR USE**

1. Cut open the kit package and remove the medium test tube and the pouch containing the swab.
2. Peel open pouch and remove swab. DO NOT touch the swab handle below the breaking point.
3. Collect specimen sample. To reduce risk of contamination, ensure swab applicator only comes in contact with suspected infectious area.
4. After collecting sample, insert swab into the test tube until the breakpoint is level with the test tube opening.
5. Bend the swab shaft at a 180° angle to break it off at the breaking point. Discard the broken upper part of the swab shaft.
6. Securely tighten cap on specimen transport tube.

## **DISPOSAL**

Waste must be disposed of in compliance with local legislation. Take the appropriate precautions for infected material if necessary.

## SYMBOLS USED

Symbol	Meaning
	Manufacturer
	In vitro diagnostic device
	Catalog number
	Batch code (Lot)
	Use by / Expiry date
	Sterilized
	Sterilized using ethylene oxide
	Do not reuse / For single use only
	Do not use if package is damaged
	Keep dry
	Keep away from sunlight



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