

VSMO 1

DISPOSABLE SAMPLING TUBE (NON-INACTIVATED)

1. GENERAL DESCRIPTION

1.1 PRODUCT NAME

Disposable sampling tube (non- inactivated)

1.2 COMPONENTS

Hanks' Balanced Salts Sucrose
Penicillin
Gentamicin Streptomycin sulfate
Amphotericin B
Nonessential Amino Acid
Phenol Red

1.3 SPECIFICATIONS

10ml/ tube and one Collecting Swab: Pkg of 1, Pkg of 10, Pkg of 20, Pkg of 50, Pkg of 100, Pkg of 200, Pkg of 300, Pkg of 500.

1.4 PRINCIPLES

Disposable sampling tube (Non- inactivated) consists of modified Hanks' balanced salt solution supplemented with bovine serum albumin, sucrose and nonessential amino acid. Phenol red is used to indicate pH. Three antibiotics are incorporated in the medium to inhibit growth of competing bacteria and yeast. The medium is isotonic and non-toxic to mammalian host cells. The presence of sucrose acts as a cryoprotectant which aids in the preservation of

viruses and chlamydiae if specimens are frozen (-70 °C) for prolonged storage. It can be stored for 48 hours in room temperature.

2. THE INTENDED USE

Disposable sampling tube (Non- inactivated) is intended for the collection and transport of clinical specimens containing viruses from the collection site to the testing laboratory. This kit can be processed using standard clinical laboratory operating procedures for viral cultural or detection.

3. CLASSIFICATION AND CONFORMITY ASSESMENT ROUTE

3.1 CLASSIFICATION

Others of Annex II of IVDD

3.2 CONFORMITY ASSESMENT ROUTE

EN ISO13485:2012/AC:2016 & IVDD 98/79/EC Annex III

4. PERFORMANCE

4.1 APPEARANCE

The medium in the tube is light orange-red liquid

4.2 LOADING CAPACITY

Not less than indicated quantity

4.3 PH VALUE

7.4±0.2 @25° C

4.4 ASEPSIS

The medium should be asepsis

4.5 GROWTH EXPERIMENT

In a sterile environment, the quality control bacteria Escherichia coli, Staphylococcus aureus and candida albicans were inoculated in the culture medium and cultured in an incubator at 36 ± 1 °c for 18-24 h. The growth of the quality control bacteria was inhibited.

4.6 STABILITY

5-25 °c sealed storage, valid for 24 months.

5. STORE

Store at room temperature for 48 hours after collection: Store specimens at 2-8 °C for up to 72 hours after collection: if a delay in testing or shipping is expected, store specimens at -70 °C or below.

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