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### **ADMINISTRATIVE INFORMATION**

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### **DEVICE NAME**

**Classification Name:** Culture Media, Non-Propagating Transport  
**Trade/Proprietary Name:** BioTeke Sterile Disposable Virus Sampling  
Swab Kit

**ESTABLISHMENT REGISTRATION NUMBER:** 3016837106

### **DEVICE CLASSIFICATION AND PRODUCT CODE**

As shown in (21 CFR 866.2390), Transport Culture Medium devices consist of a semisolid, usually non-nutrient, medium that is intended to maintain the viability of suspected pathogens contained in patient specimens while in transit from the specimen collection area to the laboratory. These devices are classified as Class I. Culture Media, Non-Propagating Transport have been assigned Product Code JSM.

### **INTENDED USE**

The BioTeke Sterile Disposable Virus Sampling Kit is intended for collection and transport of clinical specimens to the laboratory for standard diagnostic/identification techniques. The BioTeke Sterile Disposable Virus Sampling Kit consists of a sterile swab and culture-based media that can be used for respiratory viral diagnostic assays including, Influenza, Respiratory Syncytial Virus (RSV) A and B, Parainfluenza, Adenovirus, and Rhinovirus.

## DEVICE DESCRIPTION

### Design Characteristics

The BioTeke Sterile Disposable Virus Sampling Swab Kit is a specimen collection and transport kit designed to collect a throat or nasal sample from the patient (utilizing the provided Specimen Collection Swab) and subsequently transferring the swab containing the patient's microbial sample into the provide 10mL polymer tube containing 3mL of VTM (Virus Transport Media) for purposes of transferring the swab and associated collected microorganisms into a transport container designed to preserve the sample during transport to the laboratory prior to laboratory analysis. The Specimen Collection Swab is designed with a break point (notched area on the shaft) to allow for the top of the VTM tube to close when the inoculated Specimen Collection Swab is placed into the BioTeke VTM tube.

The Bioteke Sterile Disposable Virus Sampling Swab Kit consists of the following: One (1) Specimen Collection Swab (sterile and individually packaged)  
One (1) Virus Transport Media (10mL polymer tube containing 3mL of sterile VTM)

The Specimen Collection Swab measured 150mm with a breakpoint location (from the tip) at 80mm, a head length at 20mm and a head width of 3mm. The width of the shaft for the Specimen Collection Swab measures 2.5mm. The 10mL polymer tubes are filled with 3mL of Virus Transport Media (VTM) and secured with a leak-proof polymer cap.

### Material Composition

The single use Specimen Collection Swab is constructed of flocked polyester with an acrylonitrile-butadiene-styrene (ABS) shaft.

The 10mL polymer tubes are aseptically filled with 3mL of VTM (Virus Transport Media) that consists of 1X modified Hank's buffered salt solution consisting of the following:

NaCl	MgSO <sub>4</sub> .7H <sub>2</sub> O
KCl	MgCl <sub>2</sub> .6H <sub>2</sub> O
CaCl <sub>2</sub>	Na <sub>2</sub> HPO <sub>4</sub> .12H <sub>2</sub> O
KH <sub>2</sub> PO <sub>4</sub>	Sodium bicarbonate
Glucose	Phenol Red sodium salt
Gentamicin	Polymyxin B

### EQUIVALENCE TO MARKETED PRODUCT

The BioTeke Sterile Disposable Virus Sampling Swab Kit shares indications and design principles with the following predicate devices: Puritan UTM-RT Collection and Transport System (K113249) and the Copan MSwab™ Collection, Preservation and Transport System (K121039); a Class I medical devices that were cleared for marketing in the United States under K113249 and K121039, respectively.

The BioTeke Sterile Disposable Virus Sampling Swab Kit device is substantially equivalent to the Puritan UTM-RT Collection and Transport System (K113249) predicate device in the following respects:

	Subject Device	Predicate Device
Criteria	<b>BioTeke Sterile Disposable Virus Sampling Swab Kit</b>	<b>Puritan UTM-RT Collection and Transport System (K113249)</b>
Intended Use	The BioTeke Sterile Disposable Virus Sampling Kit is intended for collection and transport of clinical specimens to the laboratory for standard diagnostic / identification techniques. The BioTeke Sterile Disposable Virus Sampling Kit consists of a sterile swab and culture-based media that can be used for respiratory viral diagnostic assays including, Influenza, Respiratory Syncytial Virus (RSV) A and B, Parainfluenza, Adenovirus, and Rhinovirus	Puritan UTM - RT Collection and Transport System is intended for the collection and transport of clinical samples containing viruses, chlamydiae, mycoplasmas and ureaplasmas from the collection site to the testing laboratory. The specimen transported in the Puritan UTM - RT can be used in the laboratory to perform viral, chlamydial, mycoplasmal and ureaplasma culture
Individual Contents	1 sterile individually wrapped specimen collection swab and  1 polymer tube containing 3 mL viral transport media	1 sterile individually wrapped specimen collection swab and  1 viral transport media polymer tube containing 1mL or 3mL universal transport media
Swab	Flocked polyester with acrylonitrile-butadiene-styrene (ABS) shaft	Flocked polyester with polystyrene shaft
Swab Breakpoint	80mm	80mm and 100mm
Single Use Components	Yes	Yes
Transport Media Volume	3mL	1mL or 3mL
Contents of Viral Transport Media	Hank's Balanced Salt Solution Gentamicin Polymyxin B Phenol Red Sodium Salt	Hank's Balanced Salt Solution L-Glutamic Acid Bovine Serum Albumin Phenol Red Gelatin Colistin Sucrose Amphotericin B L-Cysteine Vancomycin HEPES
Device Classification Name	Culture Media, Non- propagating Transport	Culture Media, Non-propagating Transport
Regulation (CFR Section)	866.2390	866.2390
Product Code	JSM	JSM
Class	1	1

## PERFORMANCE TESTING

### Non-Clinical Testing

Performance testing was conducted on BioTeke Sterile Disposable Virus Sampling Swab Kit. Virus recovery testing demonstrated that the BioTeke Sterile Disposable Virus Sampling Swab Kit meets the requirements of CSLI-M40-A2.

Mechanical testing was performed on the BioTeke Sterile Disposable Virus Sampling Swab Kit which determined the BioTeke Sterile Disposable Virus Sampling Swab Kit to be substantially equivalent to the predicate device.

Biocompatibility studies were conducted per ISO 10993-1 to demonstrate safety of the Bioteke Sterile Disposable Virus Sampling Swab Kit material. The biocompatibility studies demonstrated that the Specimen Collection Swab component of the BioTeke Sterile Disposable Virus Sampling Swab Kit materials are safe for its intended use.

### Virus Viability over Time

The ability of BioTeke Sterile Disposable Virus Sampling Kit to maintain viability of respiratory viruses was assessed by virus culture after storage at room temperature for 0h, 24h, 48h, 72h, and 120h. The results demonstrate that the viruses influenza, RSV A, RSV B, parainfluenza, adenovirus and rhinovirus stored at 23-25°C were maintained within 0.25 log (PFU/mL) of the input concentration of virus for 48 hours as described in the table below.

Virus Viability over Time				
Organism	pfu/ml T=0	pfu/ml T=24	pfu/ml T=48	T=48 hours Log reduction
Influenza A	85.7	64.0	54.0	- 0.20
RSV A	105.0	85.3	63.3	- 0.22
RSV B	106.7	84.7	64.3	- 0.22
Parainfluenza	167.3	141.7	104.0	- 0.21
Adenovirus	194.7	163.0	117.0	- 0.22
Rhinovirus	137.5	108.5	89	- 0.21

### Conclusion

Based on the test principle, design and performance characteristics of the device, the BioTeke Sterile Disposable Virus Sampling Kit is substantially equivalent to the predicate.