CE

Xebios Diagnostics

PRODUCT DATA SHEET

MSC-96000 Flocked Sampling Swab for Nasopharyngeal (Nose) for Clinical Diagnostics (FSSN)

Product Description

MSC-96000 is a flocked swab of sampling for Nasopharyngeal clinical diagnostic, it utilizes state of the art “spray on technology” so that the flocking process by means of an electro-static charge perpendicularly attaches millions of nylon microfibers on the medical grade handle tip. The flocked swab is ideal for collecting large amount of cells and rapid elution of the specimens that instantly releases the cells into the transport tip.

Product Data

Article Number	95-1020	Brand Name	MRC
Article Name	Flocked Sampling Swab for Nasopharyngeal (Nose)	Instrument classification	Class I
Place of Origin	Guangdong, China	Packing	Sterilization packaging
Model Number	MSC-96000	Feature	Flocked technology
Material	Nylon & ABS	Color	White
Certificate	CE FDA ISO13485	Application	Laboratory
Properties	Nasopharyngeal specimen collection		
Usage	Nasopharyngeal specimen collection		

Product Performance Details

1. **Ergonomic and anatomic design,** perpendicular nylon fiber acts like a soft brush thus improves patient comfort and efficiency in cell specimen collection.
2. **Improved sample collection,** sprayed-on fibers statically charged and attached to the applicator tip in a uniform perpendicular manner and by means of strong capillary action cell specimens are rapidly absorbed.
3. **Superior sample elution,** with an open fiber structure it instantly dislodges the specimen cells into the liquid medium, unlike traditional wound swabs when the specimen is entrapped in the mattress core.
4. **Increased assay sensitivity**, flocked swabs are proven to elute >95% of the original sample rapidly thus easily resulting in improved assay sensitivity.
5. **Quantitative volume transfer,** measurable and consistent uptake and transfer from patient to the test tube has no internal mattress core to disperse and entrap the precious sample like traditional fiber wound swabs.
6. **Certified free of inhibitors and interference,** collection swabs are certified DNASE, RNASE-free and human DNA- free. They are also free of any PCR inhibitors, certificate of analysis available for each lot of manufacture.

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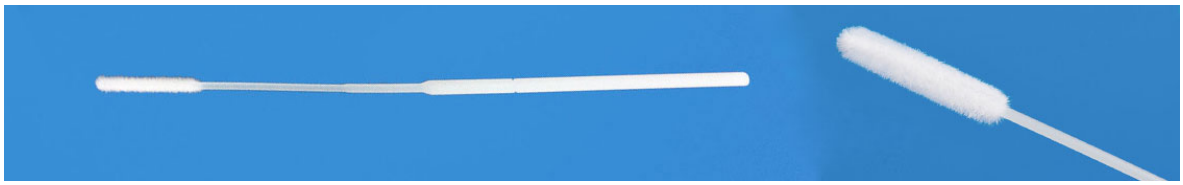
Product Specifications

MSC-96000 Flocked Sampling Swab for Nasopharyngeal Clinical Diagnostic							
							
Item No.	Dimensions of flocked tip			Dimensions of ABS handle			
	Width	Thickness	Length	Diameter 1	Diameter 2	Breakpoint	Total length
MSC-96000	3 mm	3 mm	16 mm	2,5 mm	Taper to 1,1 mm	82 mm	150 mm

Packaging Details

Base Unit	100 single packed paper-plastic bags/bag	Case Dimensions	460 *310 *270 mm
Case	50 bags/case	Weight	7,3 KGS

Method

After taking the nasopharyngeal swap break the handle tip and insert the sampling swap into the virus transportation medium (VTM; for example **GLY-Medium, Xebios Article Number 60-2025**). Close the tube of the VTM tightly.

Handling and Storage of Samples

The tubes with the virus transportation medium and the swap should contain 3ml of medium. Higher volumes should not be used for swaps because of the increased dilution effect.

The laryngopharyngeal swap should be taken as soon as possible after the appearance of symptoms. The chance for a successful sampling is the best within the first three days of the appearance of the symptoms and decreases rapidly in case of viral infections after 5 days. To prevent the spreading of viral infectious diseases swapping can also be useful before the appearance of symptoms.

All swap samples should be handed over to the analyzing laboratory as soon as possible after the swap sample was taken, because a decrease of infectivity will take place in the course of the time. Samples with labile viruses and low titers are those that show the strongest loss of infectivity in case of delayed transport. In case that immediate shipment is not possible store the samples in the refrigerator (2°C to 8°C) or on ice or with a cooling pad. The loss of viability is lower at low temperatures. However, do not freeze the samples.

Precautions

- For professional use only.
- All samples, microbiological cultures and inoculated products should be considered as infectious and should be treated accordingly. Aseptically working techniques and usual precautions for the handling of analyzed group of viruses or bacteria should be followed during the whole analytic procedure

- Additional information on precautions can be taken from local legislation if necessary.
- Interpretation of the test results should be carried out under consideration of the anamnesis of the patient, the source of the sample the colonial and microscopical morphology and, if necessary, the results of other accompanying tests.

Safety information

This product should only be used by trained personal. This includes the disposal of used or unused reagents or any other contaminated disposable material according to applicable procedures for infectious or potentially infectious materials. Every laboratory is solely responsible for disposal of laboratory waste according its nature and its level of hazardousness.

This preparation does not contain any substances presenting a health hazard within the meaning of the Dangerous Substances Directive 67/548/EEC (see safety data sheet ready to use media).

Labelling (Legend of Symbols)

Symbol	Meaning	Symbol	Meaning
	Shelf life	REF	Article number
LOT	Lot number		Storage temperature range
IVD	*In vitro* Diagnostic Medical Device		Store protected from light
	Manufacturer	CE	CE-Label

Copy of CE Certificate

EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

TÜVRheinland

Registration No.: DD 60126640 0001
Report No.: 17062799 002

Manufacturer: Miraclean Technology Co., Ltd.
No. 18, Rongshuxia Industrial Zone
Tongle Community, Longgang District
Shenzhen
518116 Guangdong
China

Products: Aspects of manufacture concerned with securing and maintaining sterile conditions:
- Sterile Disposable Sampling Swabs
- Sterile Disposable Medical Swabs

Expiry Date: 2023-03-11

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2018-03-22
Date: 2018-03-22

Notified Body
X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.