Disposable virus sampling swab kits

◎ The sampling swab uses advanced jet implanted nylon fuzz technology. Compared with conventional fiber swabs, the sample is easily penetrated, diluted, and trapped in the fiber. The nylon flocking swab has outstanding sample collection and release capability, and the release rate can reach 90%, which is much higher than that of the conventional fiber swab.

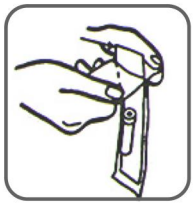
◎ Light red Hank's solutions contains antibiotics that can effectively inhibit the reproduction of bacteria and fungi.

◎ Colorless and transparent preservative solutions can effectively inactivate virus and reduce the degradation of viral nucleic acid.

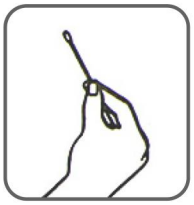
Cat. No.	Preservation solution type	Tube type	Swab type	Specification
ST8001-2	Colorless solution (inactivate)	5ml	Nasal swab	2ml/3ml
ST9001-2	Light red solution (culture medium)	5ml	Nasal swab	2ml/3ml
ST9001-3	Light red solution (culture medium)	5ml	/	2ml/3ml
ST8001-3	Colorless solution (inactivate)	5ml	/	2ml/3ml

Cat. No.	Preservation solution type	Tube type	Swab type	Specification
ST8001-1	Colorless solution (inactivate)	4ml	Pharyngeal swab	2ml/3ml
ST9001-1	Light red solution (culture medium)	4ml	Pharyngeal swab	2ml/3ml

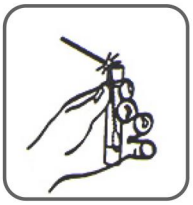
Operating Instruction



1.Open the package, take out the sampling tube and swab. Mark relevant information on the label of the tube or paste the barcode before sampling.



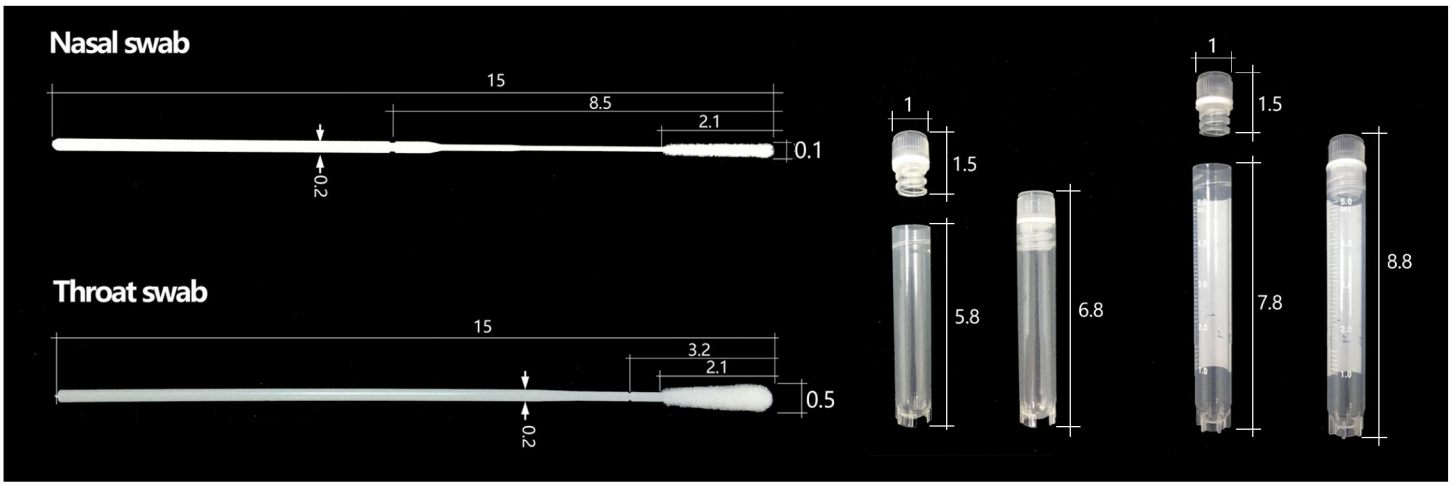
2.Sampling nose or pharynx according to different sampling requirements.



3.After sampling, put the swab into the preservation tube and break the swab stick at the breakpoint.

4.Tighten the tube cover. Specimens should be transported to the laboratory within 48 hours at 2-8℃.

- If it cannot be sent to the laboratory within 48hours, it should be stored at -70 ℃ or below, and the specimens should be sent to the laboratory within 1 week. Avoid repeated freezing and thawing.



BioTeke
BioTeke Corporation(wuxi) Co.,Ltd
4th floor, D5, No.1719,Huishan Avenue,Wuxi,
400-678-8982
www.bioteke.cn

中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号　苏锡药监械出 202000079 号
Certificate NO.: SXYJXC202000079

产品名称：一次性使用病毒采样管
Product(s): Disposable Virus Sampling Tube

规格型号：**ST8001-1、ST8001-2、ST9001-1、ST9001-2**
Model: ST8001-1、ST8001-2、ST9001-1、ST9001-2

产品注册或备案凭证号：苏锡械备 **20200046** 号
Registration certificate(s): SXXB 20200046 号

生产企业：无锡百泰克生物技术有限公司
Manufacturer: BioTeke Corporation (Wuxi) Co., Ltd

生产企业住所：无锡惠山经济开发区惠山大道 1719-5 号四层
Address of manufacturer: 4th floor,D5, No.1719,Huishan Avenue,Wuxi,China

生产许可或备案凭证号：苏锡械生产备 20190009 号
Manufacturing License(s): SXXSCB 20190009

兹证明上述产品已准许在中国生产和销售。
This is to certify that the above products have been registered to be manufactured and sold in China.

证明有效日期至：2022 年 04 月 16 日
This certification valid until: 16 April, 2022

备注：
Remark:

2020 年　4 月 17　日
（出具单位盖章）

FDA Registration Confirmation

This is to confirm that, as the US Agent, we have completed the registration activation confirmation for the **FDA Establishment Registration and Device Listing** with the US Food & Drug Administration for the **Fiscal Year 2020** of

BIOTEKE CORPORATION (WUXI) CO., LTD
4th floor, D5, No.1719, Huishan Avenue Wuxi, Jiangsu, 214174, CHINA

The facility registration and device listing information:

Owner/Operator Number: 10071745		
Device Listing No.	Product Code	Product Name(s)
D396234	NNI	Disposable Virus Sampling Swab Kits

SUNGO Technical Service Inc. will confirm that such registration remains effective upon request and presentation of this attestation until the end of the calendar year stated above, unless said registration is terminated after issuance of this attestation. SUNGO Technical Service Inc. makes no other representations or warranties, nor does this attestation make any representations or warranties to any person or entity other than the named attestation holder, for whose sole benefit it is issued. ***This attestation does not denote endorsement or approval of the attestation-holder's device or establishment by the U.S. Food and Drug Administration.*** *SUNGO Technical Service Inc. assumes no liability to any person or entity in connection with the foregoing.*

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." ***The U.S. Food and Drug Administration does not issue a attestation of registration, nor does the U.S. Food and Drug Administration recognize a attestation of registration, SUNGO Technical Service Inc. is not affiliated with the U.S. Food and Drug Administration.***

Reference Number: 2007US298518
Issue date: Apr.24, 2020

For and on behalf of
SUNGO Technical Service Inc.

Authorized Signature
Only used for the US Agent Signature

SUNGO Technical Service Inc.
6050 W EASTWOOD AVE APT 201
CHICAGO, ILLINOIS 60630, USA
sungo.group@yahoo.com

File No: CE-TCF-001

EC Declaration of Conformity
Regarding In Vitro Diagnostic Directive (98/79/EC)

Manufacturer: BioTeke Corporation（Wuxi）Co., Ltd

Address: 4th floor, D5, No.1719,Huishan Avenue, Wuxi, China 214174

EU REP
SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product
Name:Disposable virus sampling Swab kits
Type :ST8001-1, ST8001-2, ST8001-3,ST9001-1, ST9001-2, ST9001-3

We confirm our product can meet the requirement of In Vitro Diagnostic Directive and the following harmonized standards.

EN ISO 14971:2012
EN ISO 18113-1:2011
EN ISO 18113-3:2011
EN ISO 15223-1:2016

Signature:

Date: 2020.3.30

BIOTEKE CORPORATION (WUXI) CO., LTD 无锡百泰克生物技术有限公司 3202061932606

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.

Sungo global service

Authorized Signature (S)

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

SUNGO Europe B.V.
T.a.v. de heer Luo
Olympisch Stadion 24
1076 DE Amsterdam

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
T.I. van Langeveld - Baas

medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-20201166

Bijlagen
-

Uw aanvraag
2 april 2020

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum: 17 april 2020
Betreft: aanmelding In-vitro diagnostica

Geachte heer Luo,

Op 2 april 2020 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam BioTeke Corporation (Wuxi) Co., Ltd met Europees gemachtigde SUNGO Europe B.V. onderstaand product als in-vitro diagnosticum op de Europese markt te brengen.

Het product staat geregistreerd als in-vitro diagnosticum onder nummer:

Disposable virus sampling Swab kits
(geen merknaam) (NL-CA002-2020-50243)

Hiermee heeft u voldaan aan uw verplichting op grond van artikel 4, BIVD.

In alle verdere correspondentie betreffende bovenvermeld product verzoek ik u dit nummer te vermelden. Aan dit nummer kunnen geen verdere rechten ontleend worden, het dient alleen om de notificatie administratief te vergemakkelijken.

De registratie van in-vitro diagnostica als medisch hulpmiddel op grond van de Classificatiecriteria (Bijlage II) bij Richtlijn 98/79/EG betreffende medische hulpmiddelen voor in-vitro diagnostiek is onderhevig aan mogelijke revisies van Europese regelgeving inzake de classificatie van medische hulpmiddelen en aan voortschrijdend wetenschappelijk inzicht (zie artikel artikel 10, eerste lid van Richtlijn 98/79/EG).

Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, BioTeke Corporation (Wuxi) Co., Ltd de CE-conformiteitsmarkering heeft aangebracht op het desbetreffende product alvorens het in een EU-lidstaat in de handel te brengen. Zodoende garandeert SUNGO Europe B.V. dat het in-vitro diagnosticum voldoet aan de essentiële eisen zoals opgenomen in bijlage I bij Richtlijn 98/79/EG (en in het daarmee corresponderende onderdeel 1 bij het besluit)

Volledigheidshalve wijzen wij u erop dat een in-vitro diagnosticum moet voldoen aan de eisen uit het BIVD. Het BIVD is gebaseerd op Richtlijn voor in-vitro diagnostiek, 98/79/EG. Met name wijzen wij u op de Nederlandse-taaleis zoals deze in Nederland geldt, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Marketing Surveillance- en vigilantiesysteem.

Tot slot merk ik op dat met uw notificatie - de administratieve notificatie als fabrikant - en deze brief geen sprake is van een oordeel over de status of kwalificatie van uw product: notificering betekent niet dat daadwerkelijk sprake is van een in-vitro diagnosticum in de zin van de onderhavige wet- en regelgeving. In voorkomende gevallen kan de Inspectie Gezondheidszorg en Jeugd (IGJ), belast met het toezicht op de naleving van het bij of krachtens de wet bepaalde, een standpunt innemen over de status van een product, waarbij het volgens vaste jurisprudentie uiteindelijk aan de nationale rechter is om te bepalen of een product onder de definitie van in-vitro diagnosticum valt.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec,

Dr. M.J. van de Velde

Dhr. M.J. van de Velde

【Product Name】 Disposable Virus Sampling swab kits

【Product Model】 ST9001-1, ST9001-2, ST9001-3

【Package】 ST9001-1: 2/3 ml solution , 4ml tube volume (sampling throat swab included)
ST9001-2: 2/3 ml solution , 5ml tube volume (sampling nasal swab included)
ST9001-3: 2/3 ml solution , 5ml tube volume (without swab)
Light red solution (culture medium)

【Intended Use】

For sampling clinical samples. Not intended for microbial identification and drug sensitivity test.

【Main Components】

Hanks, gentamicin, Polymyxin

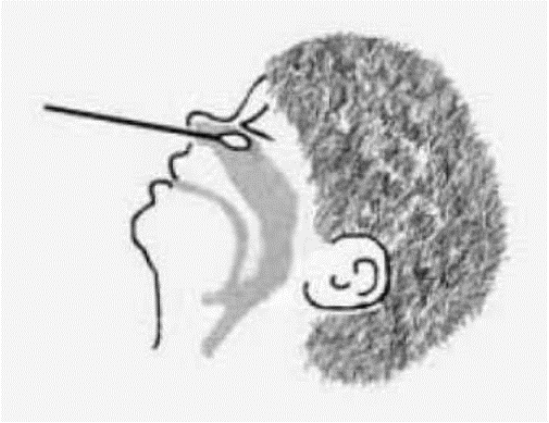
【Storage Condition and Validity】

Storage condition: 5-25℃

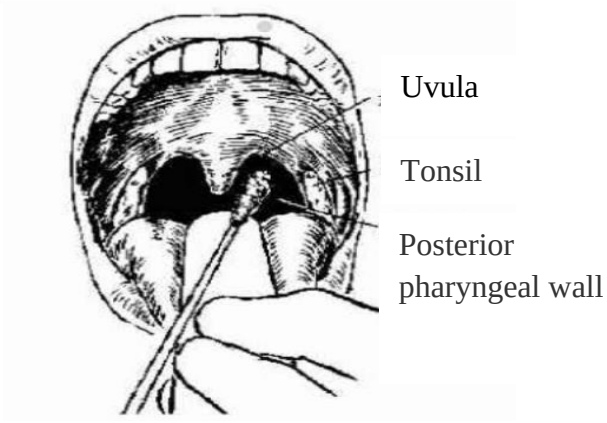
Validity: 12 months

【Instructions】

1. Open the package, take out the sampling tube and swab. Mark relevant information on the label of the tube or paste the barcode before sampling.
2. Sampling nose or pharynx according to different sampling requirements.
3. After sampling, put the swab into the preservation tube and break the swab stick at the breakpoint.
4. Tighten the tube cover. Specimens should be transported to the laboratory within 48 hours at 2-8℃.
5. If it cannot be sent to the laboratory within 48 hours, it should be stored at -70 ℃ or below, and the specimens should be sent to the laboratory within 1 week. Avoid repeated freezing and thawing.



(Nasal swab sampling)



(Throat swab sampling)

【Limitations】

This product is used for collection, transportation and storage of clinical virus sample only.

【Performance Index】

Appearance: The sampling solution inside tube is light red and precipitation-free liquid.

pH value: 7.8-8.2 at 25℃

Loading amount: no less than labeled amount

Stability: the characters of this product should remain stable when exceeding by one month the validity

【Attention】

1. The storage solution should not be in direct contact with the human body.
2. Do not immerse swab in sampling solution before sampling.
3. This is disposable product. It is used for collection, transportation and storage of clinical virus sample only. Please do not use otherwise.
4. Do not use this product after expiry date or when the package is in damaged condition.
5. Virus specimen collection should be performed by professionals in strict accordance with sampling procedures. The specimen testing should be performed in laboratories meeting safety requirements.
6. Please transfer specimen to relative laboratory within 2 working days after specimen collection. The storage temperature is 2-8℃; If the specimen cannot be sent to laboratory within 48 hours, please store it under -70℃ or below, and ensure that the collected specimen is sent to relative laboratory within one week. And please avoid repeated freezing and thawing.

【References】

1. Standard Operating Procedure of National Influenza Center
2. Wilhelm Kirch. WHO Influenza Surveillance Program WHO Influenza Surveillance Progra m[M]. Springer Netherlands, 2008.
3. Specimen Collection and Detection Technique Scheme for Hand-foot-mouth Disease (HFMD)

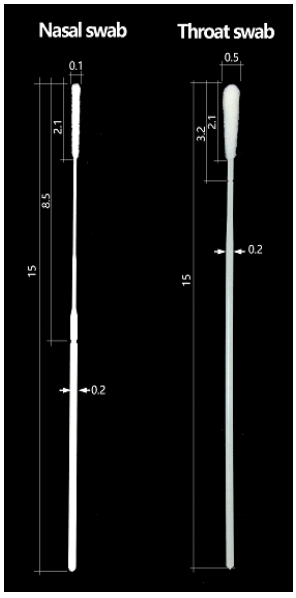
【Manufacturer】

Manufacturer: BioTeke Corporation (Wuxi) Co., Ltd.

Registered Address: 4th Floor, D5, No.1719,Huishan Avenue, Wuxi city, Jiangsu, China

Factory Address: 4th Floor, D5, No.1719,Huishan Avenue, Wuxi city, Jiangsu, China

Postcode: 214174



【Product Name】 Disposable Virus Sampling swab kits

【Product Model】 ST8001-1, ST8001-2, ST8001-3

【Package】 ST8001-1: 2/3 ml solution , 4ml tube volume (sampling throat swab included)
ST8001-2: 2/3 ml solution , 5ml tube volume (sampling nasal swab included)
ST8001-3: 2/3 ml solution , 5ml tube volume (without swab)
Colorless solution (inactivate)

【Intended Use】

For sampling clinical samples. Not intended for microbial identification and drug sensitivity test.

【Main Components】

Guanidinium isothiocyanate, Tris, EDTA

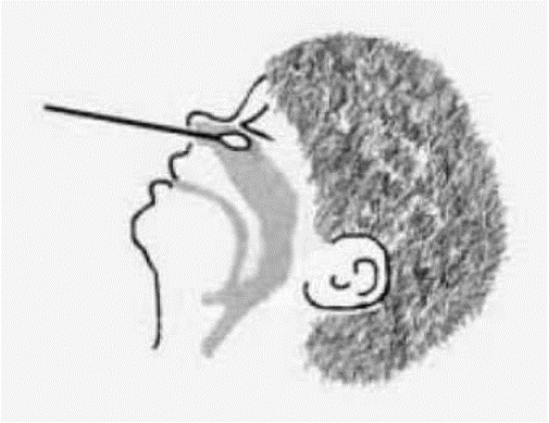
【Storage Condition and Validity】

Storage condition: 5-25℃

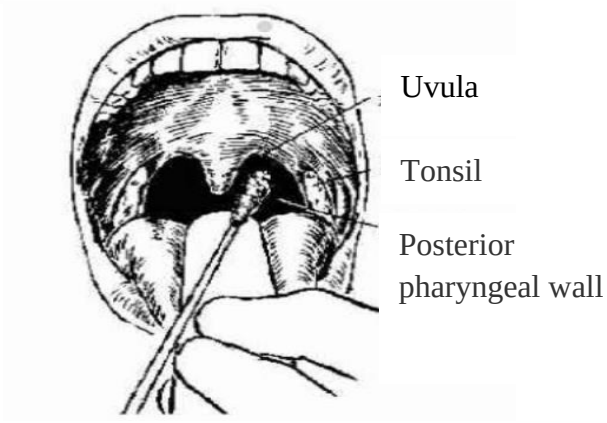
Validity: 12 months

【Instructions】

1. Open the package, take out the sampling tube and swab. Mark relevant information on the label of the tube or paste the barcode before sampling.
2. Sampling nose or pharynx according to different sampling requirements.
3. After sampling, put the swab into the preservation tube and break the swab stick at the breakpoint.
4. Tighten the tube cover. Specimens should be transported to the laboratory within 48 hours at 2-8℃.
5. If it cannot be sent to the laboratory within 48 hours, it should be stored at -70 ℃ or below, and the specimens should be sent to the laboratory within 1 week. Avoid repeated freezing and thawing.



Nasal swab sampling



Throat swab sampling

【Limitations】

This product is used for collection, transportation and storage of clinical virus sample only.

【Performance Index】

Appearance: The sampling solution inside tube is colorless, transparent and precipitation-free liquid.

pH value: 7.8-8.2 at 25℃

Loading amount: no less than labeled amount

Stability: the characters of this product should remain stable when exceeding by one month the validity

【Attention】

1. The storage solution should not be in direct contact with the human body.
2. Do not immerse swab in sampling solution before sampling.
3. This is disposable product. It is used for collection, transportation and storage of clinical virus sample only. Please do not use otherwise.
4. Do not use this product after expiry date or when the package is in damaged condition.
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6. Please transfer specimen to relative laboratory within 2 working days after specimen collection. The storage temperature is 2-8℃; If the specimen cannot be sent to laboratory within 48 hours, please store it under -70℃ or below, and ensure that the collected specimen is sent to relative laboratory within one week. And please avoid repeated freezing and thawing.

【References】

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【Manufacturer】

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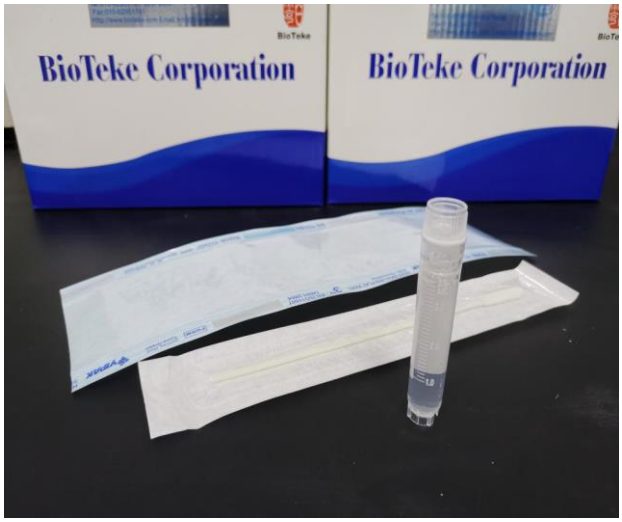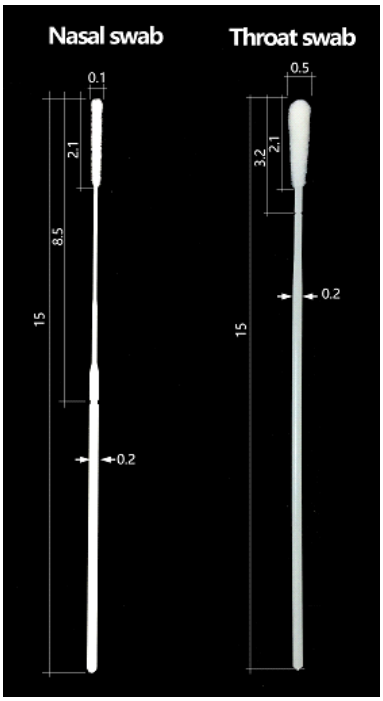
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