



FLONIC ENGINEERING SDN BHD (600567-T)

Lot 2168-AL121-F, Jalan Subang, Bt 13, Kg Baru, Sg Buloh, 47000 Shah Alam, Selangor Darul Ehsan.

Phone: 03-6157 6623 Fax: 03-6157 6613



DISPOSABLE VIRUS SPECIMEN COLLECTION (STORAGE) TUBE

Manufactured by Shandong Chengwu Medical Products Factory

ABOUT US

Shandong Chengwu Medical Products Factory was established in 1998. It is located in the Developmental Zone to the south of Chengwu county, with convenient transportation and beautiful environment. There are more than 400 employees with a management team made up of the senior and intermediate professionals. Covering an area of over 42,000 square meters, owning 100,000 grade purification workshop up to the standard of GMP with an area of more than 20,000 square meters and a domestic advanced physics and chemistry laboratory with full sets of biological testing equipment. Its sales and service network has spread throughout all of China, Exports more than 20 countries.

We mainly produce disposable vacuum blood collection tubes, disposable venous blood specimen collection needles, disposable blood collection micro tube, disposable lancet, disposable infusion set and other medical supplies. Our products have been approved by Shandong Provincial Drug Administration, and they are in line with the medical device access qualification.



认证证书



CERTIFICATE



认证证书



CERTIFICATE

POSI CERTIFICATE

This is to certify that the Quality Management System of

Shandong Chengwu Medical Products Factory

Business License Number: 91371723732624230U

Registered Address: Southern end of Quancheng Road, Chengwu
County, 274200 Heze City, Shandong Province, P.R.China

Audit Address: Southern end of Quancheng Road, Chengwu
County, 274200 Heze City, Shandong Province, P.R.China

applicable to

Manufacture and Distribution of Vacuum Blood Collection
Tube, Disposable Blood Collection Needles, Disposable
Lancet, Disposable capillary tube; Manufacture and
Distribution of Non Vacuum Blood Collection Tube, Needle
Holder, Micro Blood Collection Tube, Urine Container, Petri
Dish, Pasteur Pipette, Pipette Tips, Stool Container, Test
Tube, Infusion Set, Scalp Vein Set (export only); Distribution
of Urine Bag, Centrifuge Tube, I.V. Cannula, Disposable
Syringes, Infusion Set With Burette (export only)

has been assessed and registered by POSI against the provisions of
ISO13485:2016

This registration is subject to the company maintaining a quality management system,
to the above standard, which will be monitored by POSI.

Please consult the website: www.posicert.com

The certificate information is also available on the CNCA official website: <http://cx.cnca.cn>.



General Manager

Certificate Registration No: 381190057R0M

Initial issue date: 2019.11.29

Issue date: 2019.11.29

Valid until: 2022.11.28

Shanghai POSI Certification Co., Ltd.

Room 1002A, No.1500, Century Avenue, Pudong New Area, Shanghai, China. Email: info@posicert.com





REGISTRATION NO. 04720Q10000336

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that the quality management system of

Shandong Chengwu Medical Products Factory

Registered Address: Southern End of Quancheng Road, Chengwu County, 274200 Heze
City, Shandong Province, P.R. China

Manufacturing Address: Southern End of Quancheng Road, Chengwu County

Has been assessed and conformed to the following standard(s)

YY/T 0287-2017 idt ISO 13485:2016

The certificate is valid for the following scope:

The development, production and service of disposable virus specimen collection tube.

Date of issue: July 13, 2020

Date of expiry: July 12, 2023

General Manager:

BEIJING HUA GUANG CERTIFICATION
OF MEDICAL DEVICES CO., LTD.

Note: This certificate will not be continuously valid until the organization has been approved in the annual surveillance audit. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (<http://www.cnca.gov.cn>) or the website of CMD (<http://www.cmdc.com.cn>). Address: 5th floor of Zhong Lian building, No. jia88, An Ding Men Wai street, Dongcheng district, Beijing, 100011, P.R. China Telephone: 010-62351993



CE Notification Confirmation

This is to confirm that, according to the council directive 98/79/EC, SUNGO Europe B.V. performed the notification duties and responsibilities as the European authorized representative of:

Shandong Chengwu Medical Products Factory
Southern End of Quancheng Road, Chengwu County,
274200 Heze City, Shandong Province, P.R.China.

The Manufacturer has provided SUNGO Europe B.V. with the EC Declaration of Conformity confirming that the In Vitro Diagnostic Medical Device (IVDD), as stipulated here below, is fulfilling the applicable requirements of the European Council Directive 98/79/EC.

According to 98/79/EC, the European Databank on Medical Devices (EUDAMED) is established as of May 1 2011. The Netherlands Competent Authority is notified of the manufacturer's In Vitro Diagnostic Medical Device and has allocated registration number.

Disposable Virus Specimen Collection Tube

Not in List A and List B according to Annex II of 98/79/EC

GMDN CODE : 63232

CIBG Number: NL-CA002-2020-50479

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This document should be used together with the competence authority notification letter and the Declaration of Conformity issued by the Manufacturer. This document will become to be invalid once the notification status is changed or the EAR agreement is terminated.

Reference Number: EUCAN00195
Issue date: May, 06, 2020

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
ec.rep@sungogroup.com

For and on behalf of
SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE Amsterdam, Netherlands



Authorized Signature
Only used for the EU Representative Signature



报告编号:SHC20040092-01E

Material Safety Data Sheet

Report No: SHC20040092-01E

Suppliers' name: Shandong Chengwu Medical Products Factory

Address: Southern End of Quancheng Road, Chengwu County,
274200 Heze City, Shandong Province, P.R.China

Product Name: Disposable Virus Specimen Collection Tube

Compile date: Apr 15th, 2020

Edit: ICAS Testing Technology Service(Shanghai) Co., Ltd

Edit:

Audit:



1 / 7

英格尔检测技术服务(上海)有限公司
ICAS TESTING TECHNOLOGY SERVICE (SHANGHAI) CO., LTD

NCA0133116

Hotline:400-182-9001 Tel:0086 21-51682918 www.icas.org.cn Add:155 Pingbei Rd,Minhang District,Shanghai 上海市闵行区颛北路155号

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: 鲁菏食药监械出 20200012 号
Certificate NO.: 鲁菏食药监械出 20200012 号

产品名称: 见附件
Product(s): See Attachment

规格型号: 见附件
Model: See Attachment

生产企业: 山东省成武县医用制品厂
Manufacturer: Shandong Chengwu Medical Products Factory

生产企业住所: 山东省菏泽市成武县经济开发区泉城路南段(医疗器械产业园)
Address of manufacturer: Southern End of Quancheng Road, Chengwu County,
274200 Heze City, Shandong Province, P.R.China

生产许可(备案)或医疗器械出口备案凭证号: 见附件
Exportation Registration certificate(s): See Attachment

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

证明有效日期至: 2022年3月9日
This certification valid until: March 9, 2022

备注: /
Remark: /





NO.2020102505



货物运输条件鉴定书

Certification

for Safe Transport of Chemical Goods

非限制性货物

样品名称： 一次性使用病毒采样管

Sample Name: disposable virus specimen collection tube

委托单位： 山东省成武县医用制品厂

生产单位： 山东省成武县医用制品厂



上海化工院检测有限公司

Shanghai Research Institute of Chemical Industry Testing Co., Ltd



NO.2020072840



货物运输条件鉴定书

Certification

for Safe Transport of Chemical Goods

非限制性货物

样品名称： 一次性使用病毒采样管

Sample Name: Disposable Virus Specimen Collection Tube

委托单位： 山东省成武县医用制品厂

生产单位： 山东省成武县医用制品厂



上海化工院检测有限公司

Shanghai Research Institute of Chemical Industry Testing Co., Ltd



Disposable Virus Specimen Collection (Storage) Tube

I. Application Scope

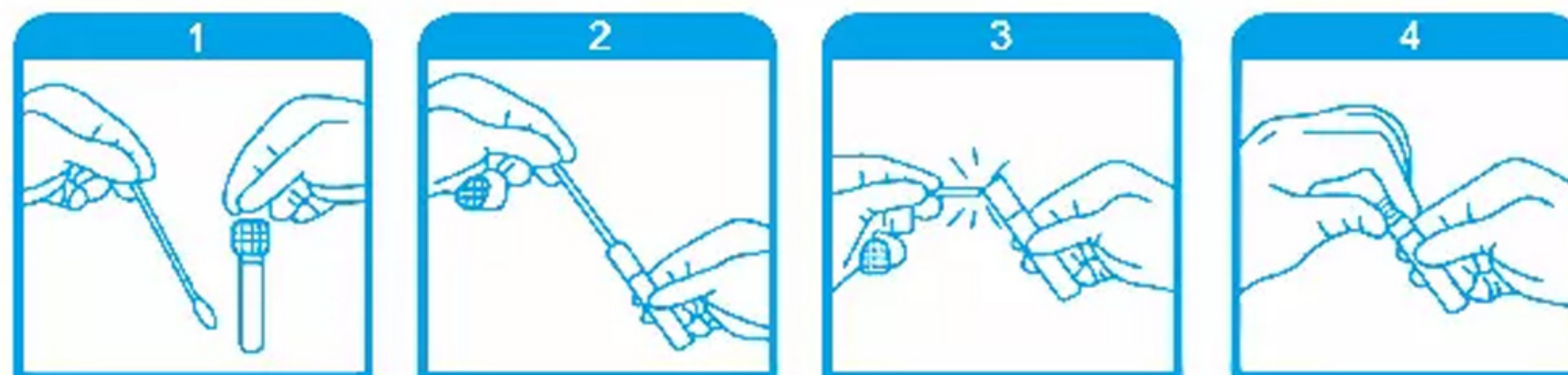
It is used for the collection, storage and transportation of virus specimens, such as influenza virus, avian influenza virus, coronavirus and measles virus. It is also suitable for the collection, storage and transportation of microbial specimens between viruses and bacteria, such as chlamydia and mycoplasma.

II. Product Features

1. The flocking swab is used for collecting specimen, and the total specimen amount and release amount are large. If the specimen is few, the flocking swab is more advantageous.
2. The flocking swab can be broken to make the subject more comfortable. It's more conducive to the specimen being placed in the preservation solution.
3. Internal preset microbeads facilitate elution of specimen and release more microorganisms into the medium.
4. The osmotic pressure of the preservation solution is more conducive to the preservation of microorganisms.
5. The reasonable PH value of the preservation solution can optimize the preservation environment of microorganisms.

III. Product Composition

The product is mainly composed of storage tube, storage solution, microbeads and swabs. The reasonable and stable osmotic pressure and reasonable PH of the storage solution lay a foundation for the storage and transportation of the specimen.



IV. Product Usage

1. Take out the flocked swab and get sampling with it from right body parts.
2. Remove the tube cap, put the swab into the transport medium.
3. Bend the swab at a 180 degrees angle to break at the appropriate point.
4. Tighten the cap, shake it several times and complete the sampling.

V. Pay Attention

1. This product is only used for collecting, storage and transportation of IVD specimen for one-time use.
2. If it is expired, damaged or contaminated with bacteria, please discard it.
3. Failure to reach the specified temperature or direct sunlight for a long time after specimen collection, it will affect the final result.
4. This product is only used by well-trained medical personnel and laboratory personnel.
5. After use, it should be disposed according to relevant requirements and procedures, and discarded in the designated clinical waste collector as required.
6. It is recommended to wear protective equipment to ensure user safety when using this product.

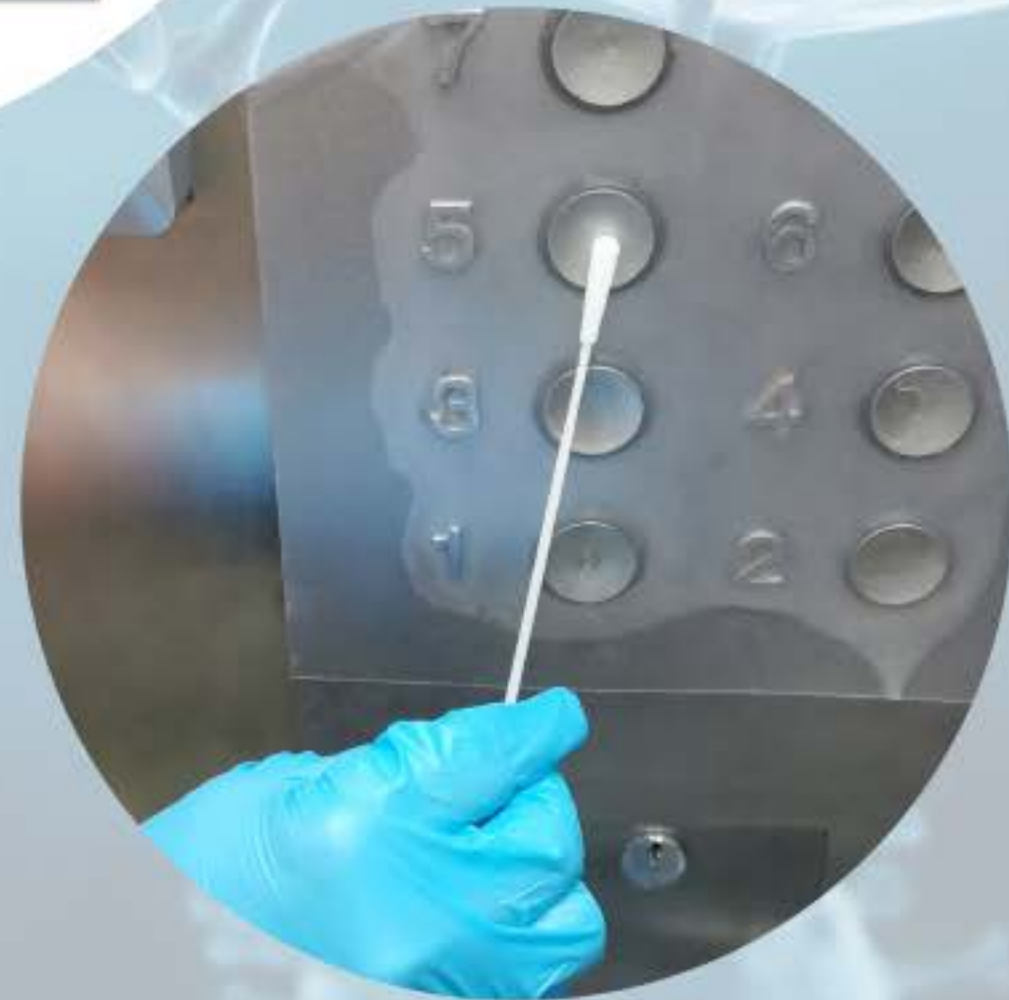


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Application





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PRODUCTS

DISPLAY





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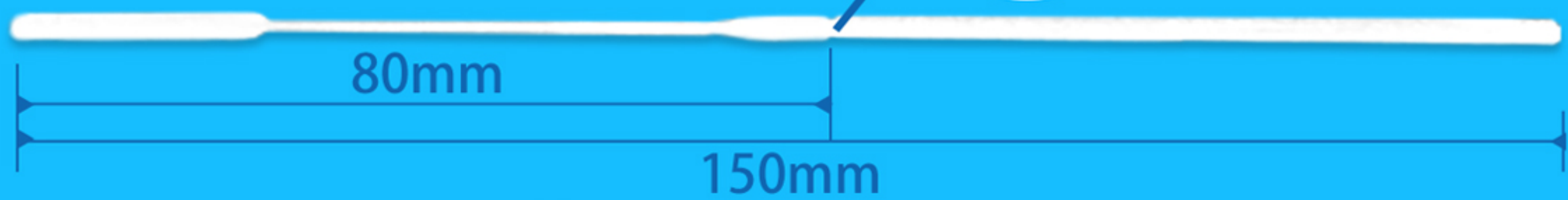
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Liquid Volume: 3ml
Tube Volume:10ml

Material:PP
Liquid Volume: 3ml
Tube Volume:10ml

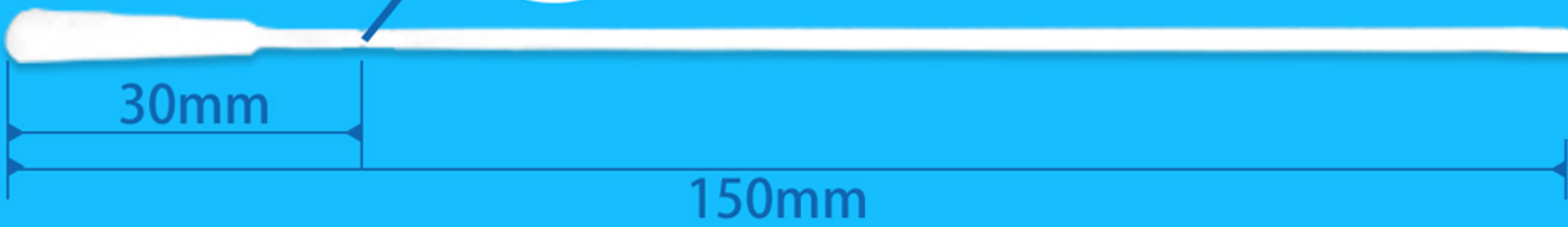
Material:PET
Liquid Volume: 3ml
Tube Volume:10ml

Material:PET
Liquid Volume: 3ml
Tube Volume:10ml

Nasal Swabs



Oral Swabs





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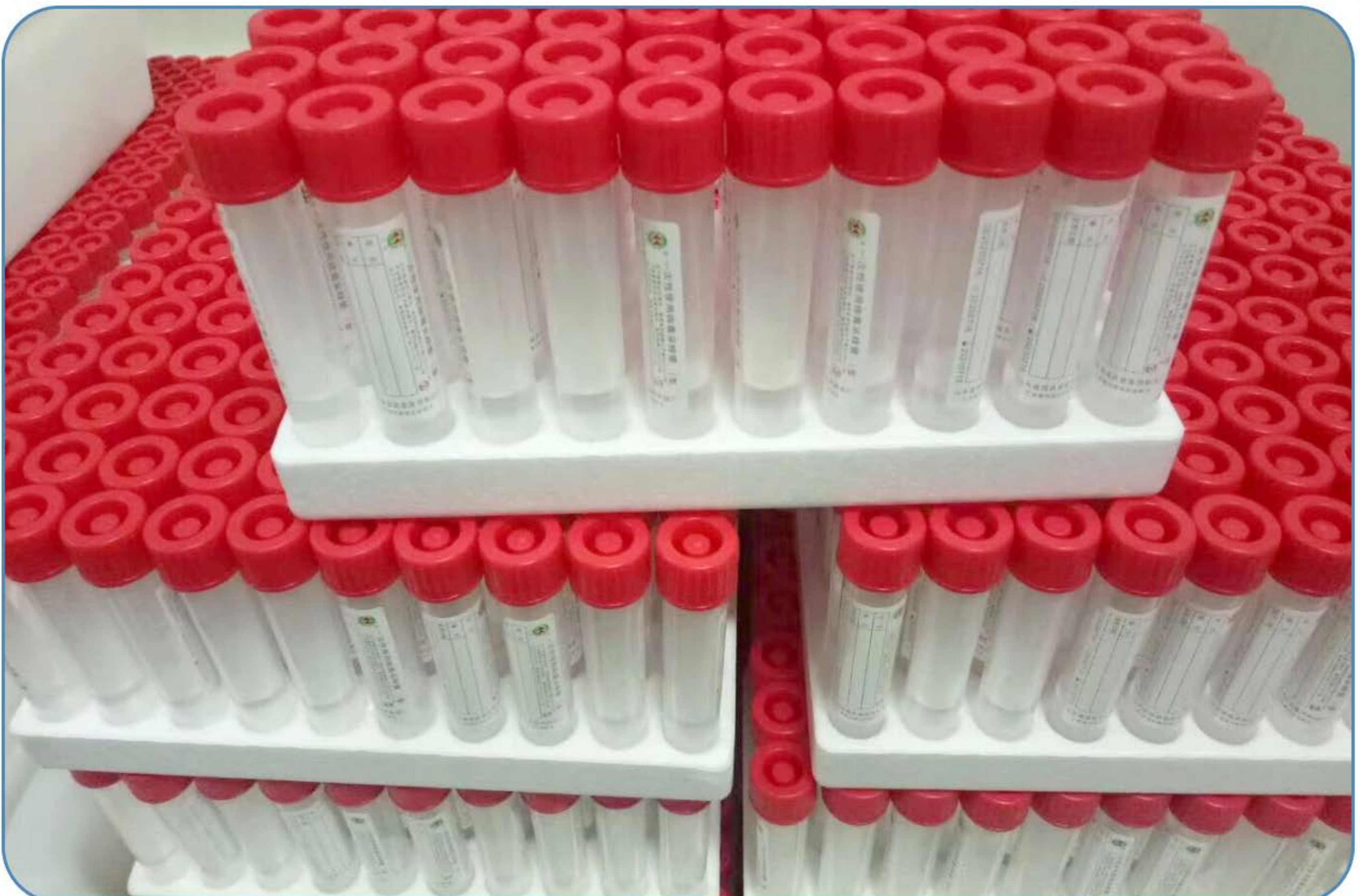
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