

YUGOMED®

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2024  
-  
2025

**YUGOMED®**  
BIOLOGICAL TECHNOLOGY

# Company Introduction

Hangzhou Yiguoren Biotechnology Co., Ltd. (also as YUGOMED®) was established in March 2014, integrating the development, registration, production, sales, and trade of sterile medical devices. We are committed to providing a wide range of medical consumable products to meet the needs of hospitals, clinics, and other medical facilities. As a leading medical consumables company, we aim to provide reliable, safe and quality standard compliant products to the healthcare industry. Our product line covers multiple areas including disposable sterile sampling swabs, transport medium kit, disposable virus sampling tube, TCT liquid-based thin layer cell detection consumables, HPV consumables, wound retractor, pathological technology services and supporting products, etc. Our products are produced in strict accordance with international quality standards and certification to ensure their quality and reliability. We work with reliable suppliers and manufacturers to adopt advanced production processes and technologies to ensure that each product meets the highest quality requirements. Committed to promoting the development and progress of the medical industry. We continue to invest in R&D and innovation, introducing new technologies and products to meet the changing market demands. The company's products have obtained China NMPA, MDR CE, US FDA, ISO13485:2016, TUV qualification, with the exclusive right of registered trademark and sales right of multinational products, the products are exported to 120 countries such as Europe, America, Asia, the Middle East, and won the unanimous praise and recognition of the majority of customers. If you have any questions or interest in our products or services, please feel free to contact us. We look forward to working with you and providing you with high quality medical consumables products and solutions.



# Enterprise Certificate

**EU Certificate**

**Production Quality Assurance  
REGULATION (EU) 2017/745 on Medical Devices  
Annex XI Part A**

Registration No.: DZ 2313780-1  
 Manufacturer: Hangzhou Yigouren Biotechnology Co., Ltd.  
 Room 201, Building 5, No. 360,  
 Tianshushanxi Road, Yuhang Street, Yuhang District,  
 Hangzhou,  
 311100 Zhejiang  
 P.R. China  
 EUDAMED Single  
 Registration No.: CN-MF-00003616  
 Products: A1101 - SAMPLE COLLECTION NEUTRAL SWABS  
 A1102 - SAMPLE COLLECTION SWABS WITH TRANSPORT  
 MEDIUM  
 The scope of certification is limited to the aspects relating to  
 establishing, securing and maintaining sterile conditions  
 Authorized representative: BioDomi GmbH  
 Schokoladenring, 13 65795 Hattersheim am Main, Germany

The Notified Body hereby declares that the requirements of Annex XI, Part A of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a production quality assurance system which is subject to periodic surveillance, defined by Annex XI, Part A, Section 7 of the aforementioned regulation. If class III devices or class IIb devices are covered by this certificate, an EU type-examination certificate in accordance with Annex X of the aforementioned regulation is required before placing them on the market.

Report No.: 190157799-110  
 Effective date: 2024-09-20  
 Expiry date: 2026-09-24  
 Issue date: 2024-09-20

The certificate can be validated on <https://www.tuvsouth.com>

TÜV Rheinland LGA Products GmbH  
 Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland  
 Precisely Right.

CE MDR

**Certificate**

**Quality Management System  
EN ISO 13485:2016  
EN ISO 13485:2016/AC:2018  
EN ISO 13485:2016/A11:2021**

Registration No.: SX 2313780-1  
 Certificate Holder: Hangzhou Yigouren Biotechnology Co., Ltd.  
 Room 201, Building 5, No. 360,  
 Tianshushanxi Road, Yuhang Street, Yuhang District,  
 Hangzhou,  
 311100 Zhejiang  
 P.R. China  
 Scope: Design and Development, Manufacture and Distribution of  
 Disposable Samples Collection Swabs, Disposable Cervical  
 Sampler Brush, Disposable Wound Incision Protector, Virus  
 Collection and Preservation Tubes, Sample Preservation  
 Solution, Transportation Tube With Medium and sampling  
 Swabs, Cell Preservation Solution, Nucleic Acid Extraction  
 Reagent, Collection Swabs with Transport Medium,  
 Microscope Slides, Cover Glass, Plastic Consumables for  
 Medical Laboratories

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 190157799-110  
 Effective date: 2024-09-25  
 Expiry date: 2027-09-24  
 Issue date: 2024-09-20  
 Replaces certificate SX 2313780-1 issued 2023-09-15

The certificate can be validated on <https://www.tuvsouth.com>

TÜV Rheinland LGA Products GmbH  
 Tillystraße 2 · 90431 Nürnberg · Germany

Dakks  
 Deutsche  
 Akkreditierungsorganisation  
 D-12205 Berlin

TÜV Rheinland  
 Precisely Right.

ISO 13485: 2016

File No: YGR/CE-006-06 Rev. No:

**EU DECLARATION OF CONFORMITY**

According to Art. 17 of the In Vitro Diagnostic Reagents Regulation (EU) 2017/746

<b>Manufacturer:</b> 制造商	Hangzhou Yigouren Biotechnology Co., Ltd. Room 201, Building 5, No. 360, Tianshushanxi Road, Yuhang Street, Yuhang District, Hangzhou, 311100 Zhejiang, P.R. China.
<b>Trademark:</b>	<b>YUGOMED®</b>
<b>European Representative:</b>	BioDomi GmbH Schokoladenring, 13 65795 Hattersheim am Main, Germany
<b>SRN:</b>	DE-AR-000016611
<b>Trade name:</b>	Cell Preservation Solution
<b>Product Name:</b>	Cell Preservation Solution
<b>Model:</b>	A, B, C, D
<b>Specification:</b>	2 ml/ bottle, 3ml/ bottle, 5ml/ bottle, 7ml/ bottle, 10ml/ bottle, 15ml/ bottle, 16ml/ bottle, 20ml/ bottle, 500ml/ bottle, 1L/ bottle; 5L/ barrel, 25L/ barrel. Or customized according to customer requirements
<b>Intended use:</b>	It is used to preserve and transport cells taken from the human body and maintain the cell preservation environment.
<b>Classification acc. to IVDR Ax. VIII:</b>	Class A, rule 5 of IVDR Annex VIII
<b>Applied Standard &amp; Common Specification:</b>	EN ISO 13485:2016
<b>Conformity assessment procedure</b>	Annex II of IVDR (EU) 2017/746

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the In Vitro Diagnostic Reagents Regulation (EU) 2017/746. All supporting documentations are retained under the premises of the manufacturer.

Wu Shuangqian  
General Manager  
Hangzhou, 25. 05. 2023

DOC Cell Preservation Solution

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: 浙杭食药监械出20230711号  
 Certificate NO.: 浙杭食药监械出20230711号  
 产品名称: 一次性使用无菌采样拭子等产品, 见附件(共3页)  
 Product(s): Disposable Sterile Swabs, etc. See Attachment (3 pages)  
 规格型号: 见附件(共3页)  
 Model: See Attachment (3 pages)  
 产品注册或备案凭证号: 见附件(共3页)  
 Registration certificate(s): See Attachment (3 pages)  
 生产企业: 杭州医国仁生物科技有限公司  
 Manufacturer: Hangzhou Yigouren Biotechnology Co., Ltd.  
 生产企业住所: 浙江省杭州市余杭区余杭街道天目山西路360号5幢201室  
 Address of manufacturer: Room 201, Building 5, No. 360, Tianshushanxi  
 Road, Yuhang Street, Yuhang District, Hangzhou, 311100Zhejiang,  
 P.R. China  
 生产许可或备案凭证号: 浙药监械生产许20140130号  
 Manufacturing License(s): 浙药监械生产许20140130号  
 兹证明上述产品已准许在中国生产和销售。该产品出口不受限制, 出口医疗器械的企业应当保证其出口的医疗器械符合进口国(地区)的要求。  
 This is to certify that the above products have been registered to be manufactured and sold in China. The exportation of the product(s) is not restricted. The exporter should assure that exporting medical devices meeting requirements of the importing country (region).  
 证明有效日期至: 2025年01月01日  
 This certification valid until: 2025-01-01  
 备注: null  
 Remark: null

Zhejiang Medical Products Administration  
 (浙江省药品监督管理局)  
 2024年12月05日  
 医疗(体外诊断试剂)专用章  
 3201002254515

Certificate Of Free Sale

# Content

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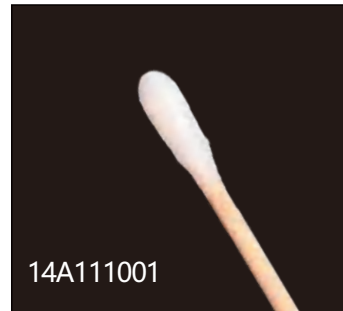
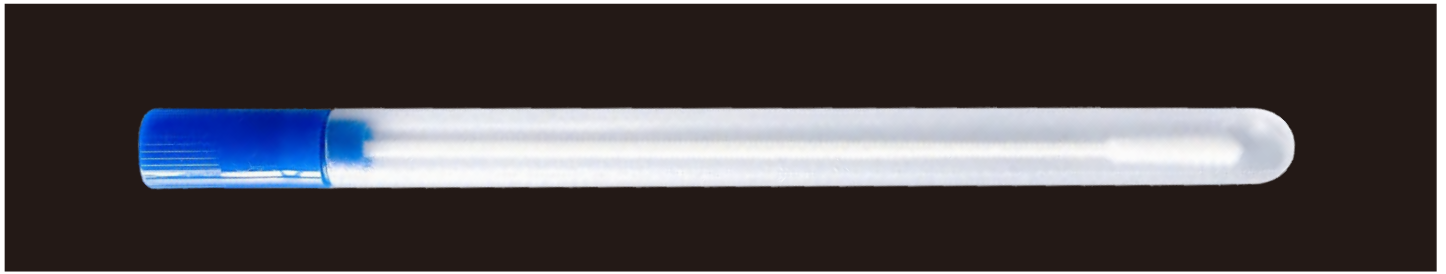
Collection Swabs With Transport Medium

06

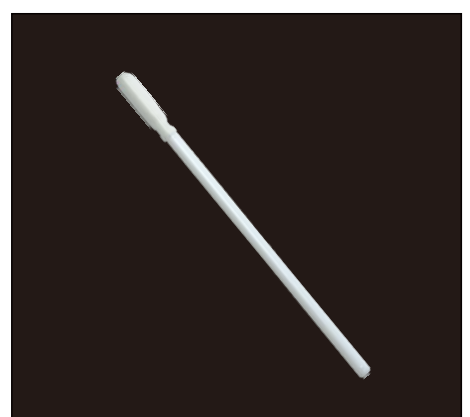
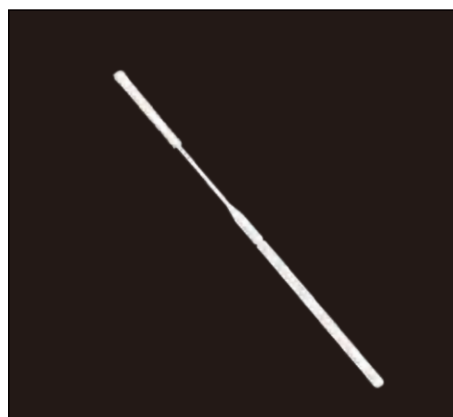
Wound Retractor

# Disposable Sterile Swabs

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Type	Ref Code	Material	Breakpoint	Total Length	Sterilization Method
A1-53	14A153003	PA66 Flocking tip +ABS rod	48mm	175mm	EO
A1-53	14A153001	PA66 Flocking tip +ABS rod	30mm	175mm	EO
A1-53	14A153005	PA66 Flocking tip +ABS rod	48mm	175mm	EO
A1-53	14A153006	PA66 Flocking tip +ABS rod	80mm	175mm	EO
A1-11	14A111001	Absorbent cotton tip Wooden rod	80mm	175mm	EO
A1-53	14A132001	Viscose tip + PS rod	anywhere	175mm	EO



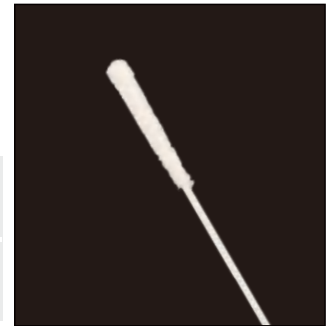
Type	Ref Code	Material	Breakpoint	Total Length	Sterilization Method
A2-41	14A241001	Absorbent cotton tip Stainless steel rod	/	90mm	EO
A2-53	14A253001	PA66 Flocking tip +ABS rod	50mm	90mm	EO
A2-24	14A224001	Foam tip + PP rod	/	80mm	EO

# Disposable Sterile Swabs

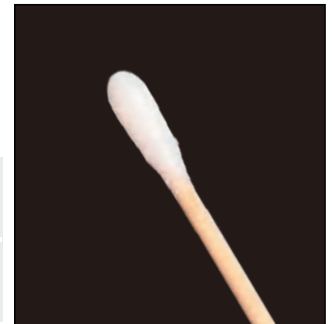
YUGOMED®



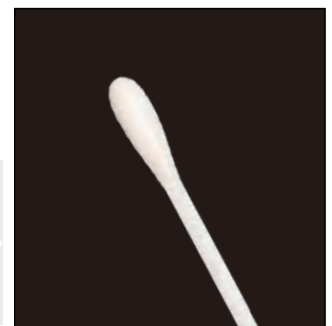
Type	Ref Code	Material	Breakpoint	Total Length
B1-53	14B153006	PA66 Flocking tip + ABS rod	80mm	150mm



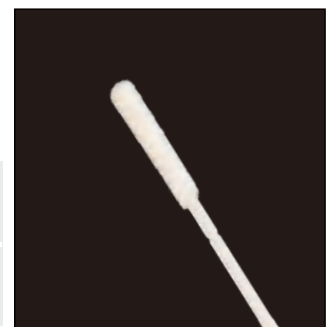
Type	Ref Code	Material	Breakpoint	Total Length
B1-11	14B111001	Absorbent cotton tip Wooden rod	/	150mm



Type	Ref Code	Material	Breakpoint	Total Length
B1-32	14B132001	Viscose/Rayon tip + PS rod	anywhere	150mm



Type	Ref Code	Material	Breakpoint	Total Length
B1-53	14B153003	PA66 Flocking tip + ABS rod	30mm	150mm



Type	Ref Code	Material	Breakpoint	Total Length
B1-53	14B153007	PA66 Flocking tip + ABS rod	40mm	170mm



# Disposable Sterile Swabs

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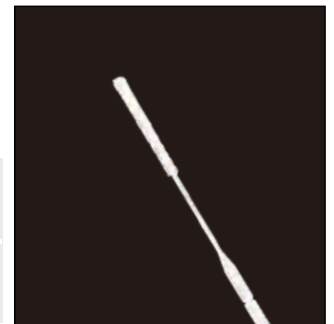
Type	Ref Code	Material	Breakpoint	Total Length
B2-24	14B224001	Foam tip + PP rod	/	80mm



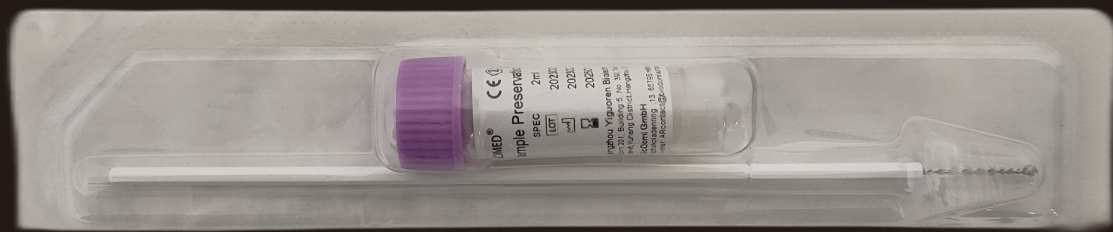
Type	Ref Code	Material	Breakpoint	Total Length
B2-23	14B223001	PA66 Flocking tip + P P rod	/	80mm



Type	Ref Code	Material	Breakpoint	Total Length
B2-53	14B253001	PA66 Flocking tip + ABS rod	50mm	90mm



# Disposable Sampling Kit



Type	Ref Code	Material	Sample Preservation Type	Sterilization Method
BT1-21	17BT12106	(stainless steel and nylon bristle) tip + PP rod	NaC1 solution	Irradiation
BT1-31	17BT13106	(stainless steel and nylon bristle) tip + PS rod	NaC1 solution	Irradiation
BT2-21	17BT22106	(stainless steel and nylon bristle) tip + PP rod	lysis Solution	Irradiation
BT2-31	17BT23106	(stainless steel and nylon bristle) tip + PS rod	lysis Solution	Irradiation
BT3-21	17BT32106	(stainless steel and nylon bristle) tip + PP rod	Liquid Medium	Irradiation
BT3-31	17BT33106	(stainless steel and nylon bristle) tip + PS rod	Liquid Medium	Irradiation

# Disposable Sterile Swabs

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Type	Ref Code	Material	Size	Sterilization Method
C1-24	14C124001	PP rod + PE tip + PP casing	1.Rod length $\geq$ 150mm 2.Tip length $\geq$ 20mm	EO
Customization according to customer requirements				



Type	Ref Code	Material	Size	Sterilization Method
C1-24	14C124002	PP rod + PE tip + PP casing	1.Rod length $\geq$ 150mm 2.Tip length $\geq$ 20mm	EO
Customization according to customer requirements				



Type	Ref Code	Material	Size	Sterilization Method
C1-24	14C124003	PP rod + PE tip + PP casing	1.Rod length $\geq$ 150mm 2.Tip length $\geq$ 20mm	EO
Customization according to customer requirements				





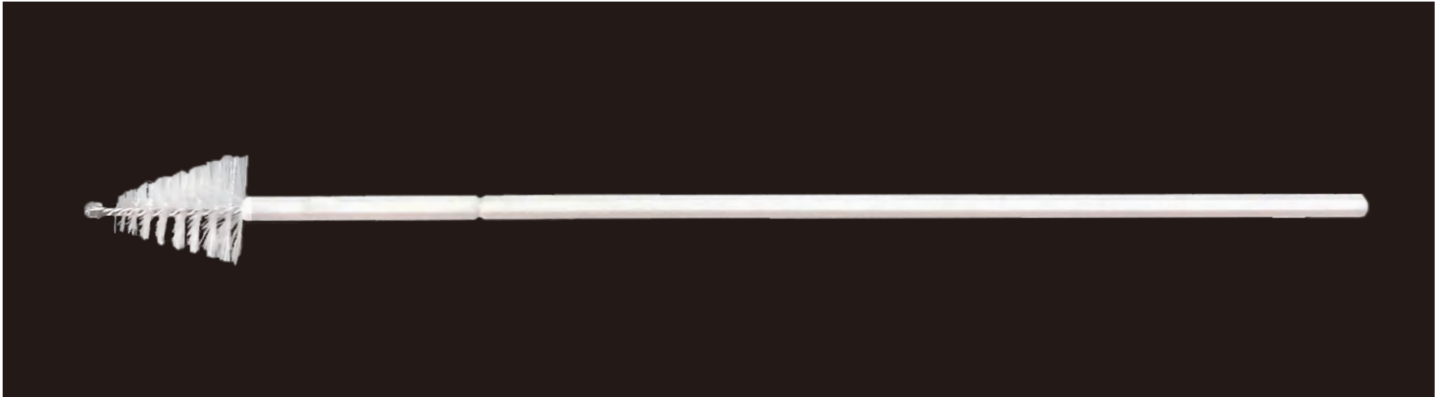
Type	Ref Code	Material	Size	Sterilization Method
C1-24	14C124004	PP rod + PE tip + PP casing	1.Rod length $\geq$ 150mm 2.Tip length $\geq$ 20mm	EO

Customization according to customer requirements



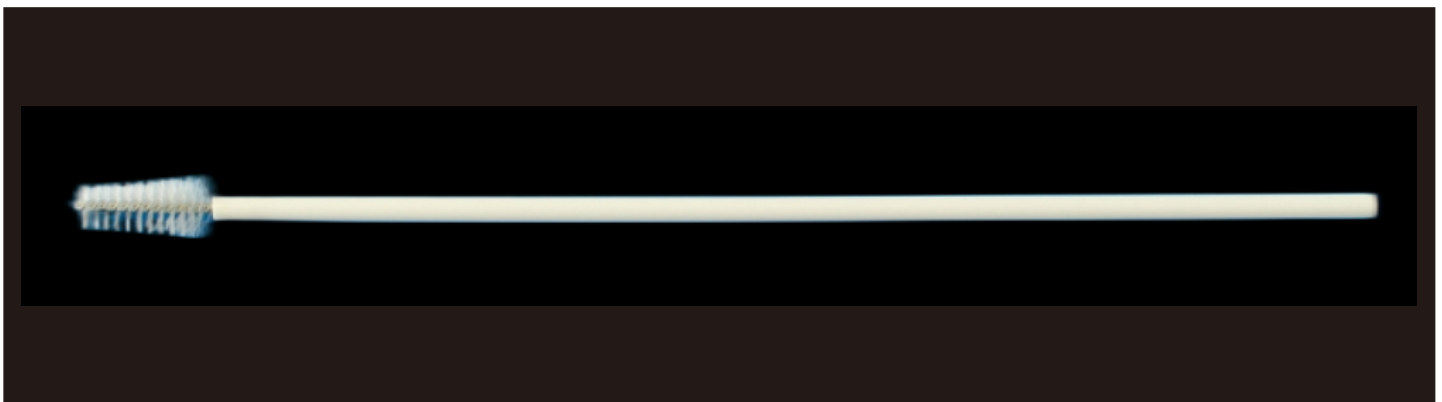
Type	Ref Code	Material	Size	Sterilization Method
C1-24	14C124005	PP rod + PE tip + PP casing	1.Rod length $\geq$ 150mm 2.Tip length $\geq$ 20mm	EO

Customization according to customer requirements



Type	Ref Code	Material	Size	Sterilization Method
C2-2/43	14C243001	PP rod + stainless steel + PA6 rod	1.Rod length $\geq 120\text{mm}$ 2.Tip length $\geq 15\text{mm}$	EO

1.Rod length, tip hardness and tip length can be customized according to customer requirements  
2.Distance from tip of brush head to breakpoint  $D:40\text{mm} \leq D \leq 100\text{mm}$



Type	Ref Code	Material	Size	Sterilization Method
C2-2/43	14C243002	PP rod + stainless steel + PA6 rod	1.Rod length $\geq 120\text{mm}$ 2.Tip length $\geq 15\text{mm}$	EO

Rod length, tip hardness and tip length can be customized according to customer requirements



Type	Ref Code	Material	Size	Sterilization Method
C2-2/43	14C243003	PP rod + stainless steel + PA6 rod	1.Rod length $\geq 120\text{mm}$ 2.Tip length $\geq 15\text{mm}$	EO

1.Rod length, tip hardness and tip length can be customized according to customer requirements  
2.Distance from tip of brush head to breakpoint  $D:40\text{mm} \leq D \leq 100\text{mm}$



Type	Ref Code	Material	Size	Sterilization Method
C2-2/43	14C243004	PP rod + stainless steel + PA6 rod	1.Rod length $\geq 120\text{mm}$ 2.Tip length $\geq 15\text{mm}$	EO

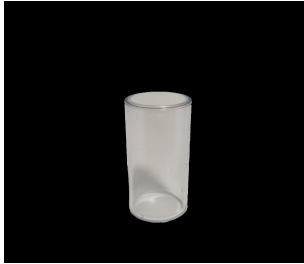
Rod length, tip hardness and tip length can be customized according to customer requirements

# Cytology Test Kit

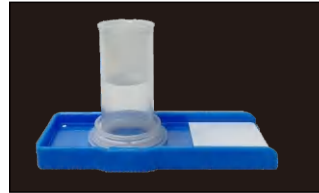
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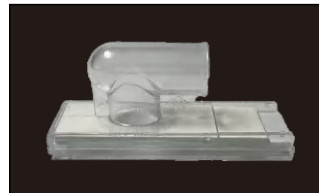
Product Name	Specification	Application Scope
Cell Filter Cytology	ZP30-1	Membrane for LBC



Product Name	Specification	Application Scope
Cell Filter Cytology	ZP30-2	Thinprep for LBC



Product Name	Specification	Application Scope
Cell Filter Cytology	ZP11	Sedimentation for LBC



Product Name	Specification	Application Scope
Cell Filter Cytology	ZP25	Centrifuging for LBC



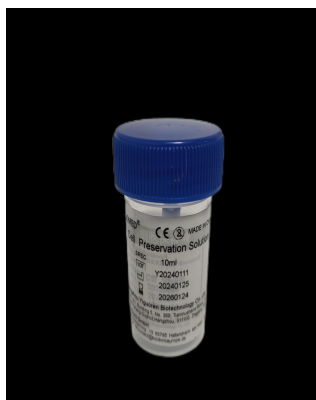
Product Name	Specification	Application Scope
Adhesion Microscope Slides	QP01	Centrifuge use
Adhesion Microscope Slides	QP02	LBC thin-layer use

# Cytology Smear Slide Processor



# Cytology Test Kit

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Product Name	Specification	Application Scope
Cell Preservation Solution	Type A, 10ml/bottle	Sputum
Cell Preservation Solution	Type B, 10ml/bottle	Saliva
Cell Preservation Solution	Type C, 10ml/bottle	Gynecology and general samples
Cell Preservation Solution	Type D, 20ml/bottle	FNA, Body fluid, Urine
Customization according to customer requirements		

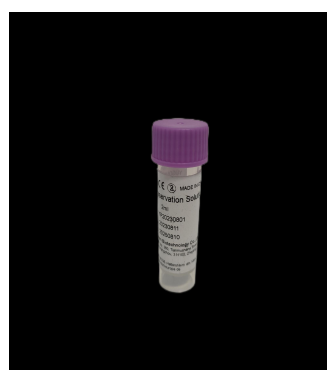


Product Name	Specification	Application Scope
Cell Preservation Solution	Type A, 15ml/bottle	Sputum
Cell Preservation Solution	Type B, 15ml/bottle	Saliva
Cell Preservation Solution	Type C, 15ml/bottle	Gynecology and general samples
Cell Preservation Solution	Type D, 15ml/bottle	FNA, Body fluid, Urine
Customization according to customer requirements		



Product Name	Specification	Application Scope
Cell Preservation Solution	Type A, 20ml/bottle	Sputum
Cell Preservation Solution	Type B, 20ml/bottle	Saliva
Cell Preservation Solution	Type C, 20ml/bottle	Gynecology and general samples
Cell Preservation Solution	Type D, 20ml/bottle	FNA, Body fluid, Urine
Customization according to customer requirements		

# HPV PCR TEST KIT



Product Name	Specification	Application Scope
Sample Preservation Solution	2ml/bottle	Used for preservation of tissue and cytopathology analysis samples DNA/ RNA PCR use
Sample Preservation Solution	3ml/bottle	
Sample Preservation Solution	10ml/bottle	



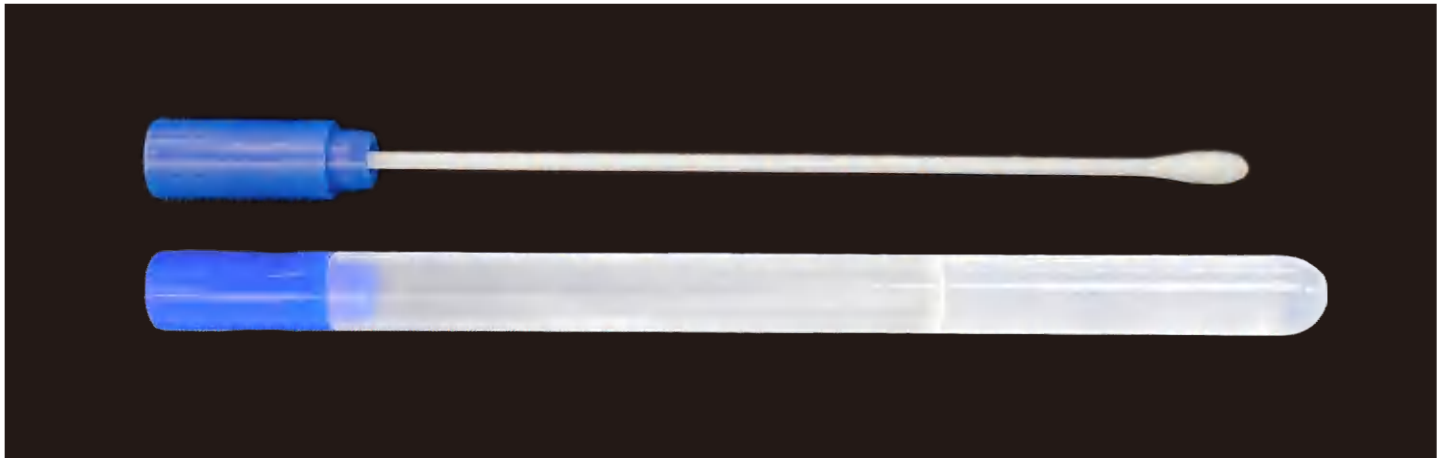
Type	State	Remark
Amies11	Gel	Without Charcoal
Cary-Blair11	Gel	Without Charcoal



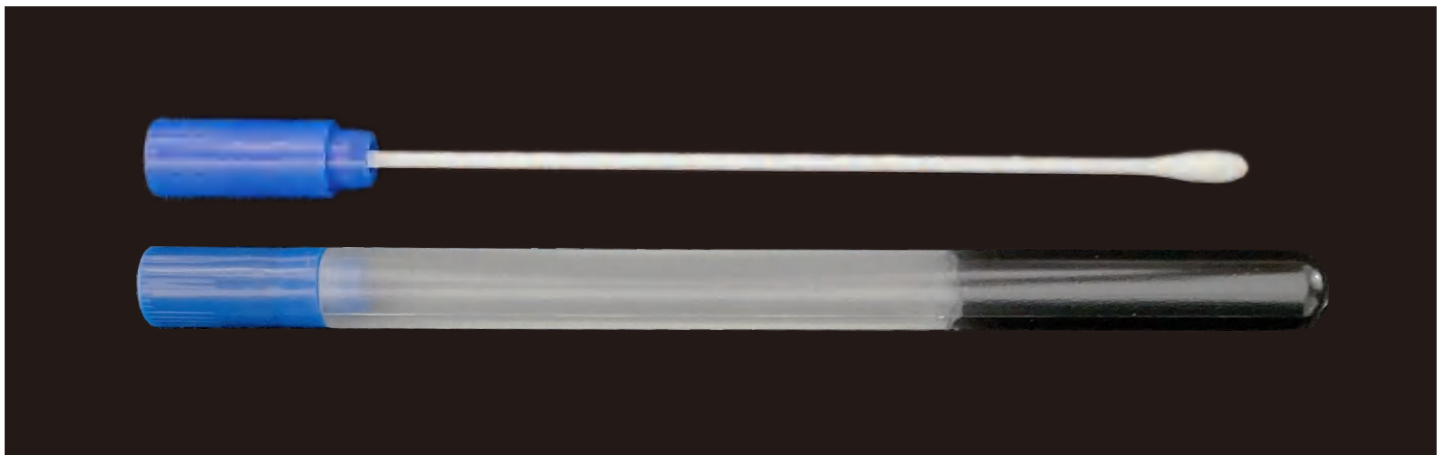
Type	State	Remark
Amies21	Gel	With Charcoal
Cary-Blair21	Gel	With Charcoal
Stuart21	Gel	With Charcoal



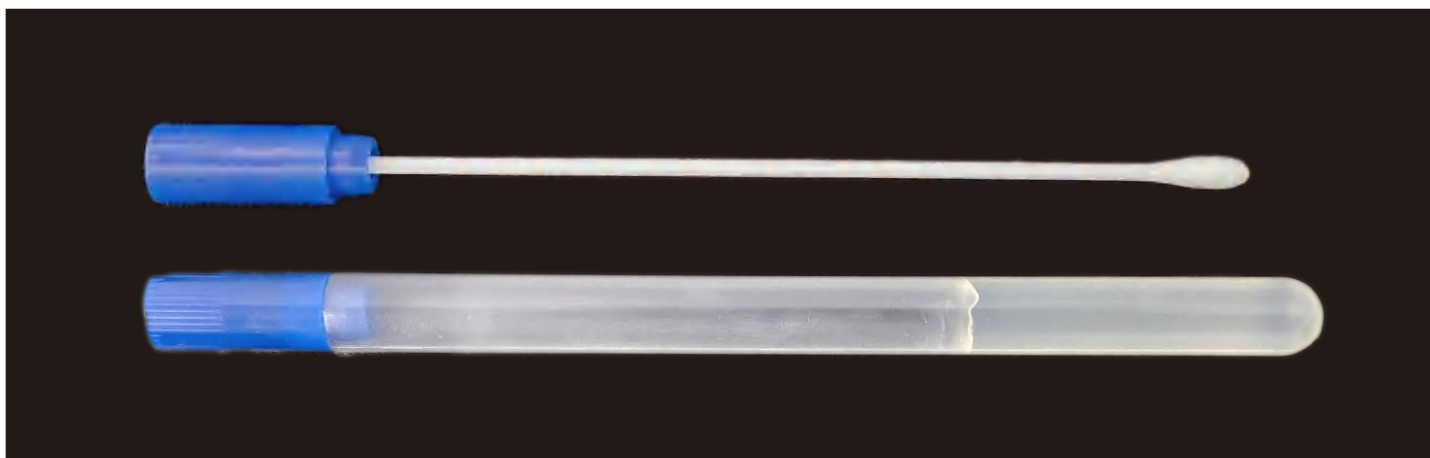
Type	State	Remark
Stuart11	Gel	Without Charcoal, lightyellow in color



Type	State	Remark
Amies12	Gel	Without Charcoal
Cary-Blair12	Gel	Without Charcoal



Type	State	Remark
Amies22	Gel	With Charcoal
Cary-Blair22	Gel	With Charcoal
Stuart22	Gel	With Charcoal



Type	State	Remark
Stuart12	Gel	Without Charcoal, lightyellow in color



Type	State	Remark
Amies12-L	Liquid	With sterile swab
Cary-Blair12-L	Liquid	With sterile swab
Stuart12-L	Liquid	With sterile swab
Amies11-L	Liquid	No sterile swab
Cary-Blair11-L	Liquid	No sterile swab
Stuart11-L	Liquid	No sterile swab





Type	Outer ring diameter	Inner ring diameter	Protection sleeve diameter	Height
B-φ60	60mm	70mm	60mm	150mm
B-φ70	70mm	80mm	70mm	150mm
B-φ80	80mm	90mm	80mm	150mm
B-φ100	110mm	110mm	100mm	200mm
B-φ120	120mm	130mm	120mm	200mm
B-φ150	150mm	160mm	150mm	230mm
B-φ200	200mm	210mm	200mm	230mm
B-φ250	250mm	260mm	250mm	230mm
B-φ280	280mm	290mm	280mm	250mm



Type	Outer ring diameter	Inner ring diameter	Protection sleeve diameter	Height
D-φ15	40mm	30mm	15mm	20mm
D-φ25	50mm	40mm	25mm	25mm
D-φ35-1	70mm	70mm	35mm	25mm
D-φ35-2	70mm	70mm	35mm	40mm
D-φ40	70mm	60mm	40mm	40mm
D-φ45	80mm	70mm	45mm	30mm

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HANGZHOU YIGUOREN BIOTECHNOLOGY CO., LTD.  
Add: No.360, Tianmushan West Road, Yuhang Ave, Hangzhou, Zhejiang, China.  
Contact: Jeffrey  
Email: ygrxs02@yiguoren.com  
Tel: +86-19528841107