# STATEMENT

We, **Zybio Inc.**, having a registered office at Floor 1 to Floor 5, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, Chongqing, China assign **Sanmedico SRL** having a registered office at A. Corobceanu street 7A, apt. 9, Chisiinau MD-2012, Moldova, as **Authorized Representative** in correspondence with the conditions of directive 98/79/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Digitally signed by Dolgopol Iulian
Date: 2026.03.20 10:35:28 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Place: Chongqing , China

Date: Feb 17 , 2023

Zybio Inc.

Floor 1 to Floor 5, Building 30, No.6 of Taikang Road,
Block C of Jianqiao Industrial Park, Dadukou District, Chongqing, China 400082
Tel: +86 (0)23 6865 5509 Fax: +86 (0)23 6869 9779 Email: info@zybio.com Website: www.zybio.com

By Royal Charter

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

持有证书 ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:
兹证明

Zybio Inc.
No.45, Shilin Avenue
Tiaodeng Town
Dadukou District
Chongqing
400082
China

中元汇吉生物技术股份有限公司
91500104327817661O
中国
重庆市
大渡口区跳磴镇
石林大道45号
邮编：400082

Holds Certificate No:
持有证书

**MD 782925**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:
并运行符合 ISO 13485:2016 & EN ISO 13485:2016 要求的质量管理体系，认证范围如下：

Please see scope page.

For and on behalf of BSI:
BSI代表:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date 首次发证日期： 2023-11-30
Effective Date 生效日期： 2023-11-30
Latest Revision Date 最新发证日期： 2024-10-16
Expiry Date 有效期至： 2026-11-29



...making excellence a habit.™

Certificate No. **MD 782925**
持有证书：

# Registered Scope:

The design, development, manufacture, distribution, installation and servicing of in-vitro diagnostic analyzers used in the diagnosis and detection of infectious diseases, cardiac markers, cancer, inflammation, coagulation, microbial infections, blood analytes, blood components, endocrine disorders, fertility testing, immune status, pregnancy testing, hormones, urine components and specific proteins.

The design, development, manufacture and distribution of in -vitro diagnostic reagents used in the diagnosis and detection of infectious diseases, cardiac markers, cancer, inflammation, coagulation, microbial infections, blood analytes, blood components, endocrine disorders, fertility testing, immune status, pregnancy testing, hormones, urine components and specific proteins.
用于诊断和检测传染病，心脏标志物，癌症，炎症，凝血，微生物感染，血液分析，血液成分，内分泌失调，生育能力测试，免疫状态，怀孕测试，激素，尿液成分及特定蛋白的体外诊断仪器的设计和开发、制造和分销、安装和服务

用于诊断和检测传染病，心脏标志物，癌症，炎症，凝血，微生物感染，血液分析，血液成分，内分泌失调，生育能力测试，免疫状态，怀孕测试，激素，尿液成分及特定蛋白的体外诊断试剂的设计和开发、制造和分销

Original Registration Date 首次发证日期： 2023-11-30
Effective Date 生效日期： 2023-11-30
Latest Revision Date 最新发证日期： 2024-10-16
Expiry Date 有效期至： 2026-11-29

Certificate No. **MD 782925**
持有证书：

| Location 地点 | Registered Activities 认证活动 |
|---|---|
| Zybio Inc.<br>Floor 1 to Floor 5,Building 30<br>No. 6 of Taikang Road<br>Block C of Jianqiao Industrial Park<br>Dadukou District<br>Chongqing<br>400082<br>China<br>中元汇吉生物技术股份有限公司<br>915001043278176610<br>中国<br>重庆市<br>大渡口区<br>建桥工业园C区<br>太康路6号<br>30栋1-5层<br>邮编：400082 | The design and development of in-vitro diagnostic analyzers used in the diagnosis and detection of infection disease, cardiac marker,cancer, inflammation, coagulation, microbial infections, blood analytes, blood components, endocrine disorders, fertility testing, immune status, pregnancy testing, hormone, urine components and specific protein.<br>用于诊断和检测传染病，心脏标志物，癌症，炎症，凝血，微生物感染，血液分析，血液成分，内分泌失调，生育能力测试，免疫状态，怀孕测试，激素，尿液成分及特定蛋白的体外诊断仪器的设计和开发。 |
| Zybio Inc.<br>Floor 1 to Floor 5, Building 38<br>No. 5 of Taikang Road<br>Block C of Jianqiao Industrial Park<br>Dadukou District<br>Chongqing<br>400082<br>China<br>中元汇吉生物技术股份有限公司<br>915001043278176610<br>中国<br>重庆市<br>大渡口区<br>建桥工业园 C 区<br>太康路 5 号<br>38 栋第1-5 层<br>邮编：400082 | The design and development, manufacture and distribution of in-vitro diagnostic reagents used in the diagnosis and detection of infection disease, cardiac marker, cancer, inflammation, coagulation, microbial infections, blood analytes, blood components, endocrine disorders, fertility testing, immune status, pregnancy testing, hormone, urine components and specific protein.<br>The installation and servicing of in-vitro diagnostic analyzers used in the diagnosis and detection of infection disease, cardiac marker, cancer, inflammation, coagulation, microbial infections, blood analytes, blood components, endocrine disorders, fertility testing, immune status, pregnancy testing, hormone, urine components and specific protein.<br>用于诊断和检测传染病，心脏标志物，癌症，炎症，凝血，微生物感染，血液分析，血液成分，内分泌失调，生育能力测试，免疫状态，怀孕测试，激素，尿液成分及特定蛋白的体外诊断试剂的设计和开发，生产和分销。<br>用于诊断和检测传染病，心脏标志物，癌症，炎症，凝血，微生物感染，血液分析，血液成分，内分泌失调，生育能力测试，免疫状态，怀孕测试，激素，尿液成分及特定蛋白的体外诊断仪器的安装和服务。 |

Original Registration Date 首次发证日期： 2023-11-30
Effective Date 生效日期： 2023-11-30
Latest Revision Date 最新发证日期： 2024-10-16
Expiry Date 有效期至： 2026-11-29

Certificate No. **MD 782925**
持有证书：

| Location 地点 | Registered Activities 认证活动 |
|---|---|
| Zybio Inc.<br>No.3-4, Jianqiao Biomedical Park<br>No.333 Haixing Road<br>Tiaodeng Town<br>Dadukou District<br>Chongqing<br>400082<br>China<br>中元汇吉生物技术股份有限公司<br>915001043278176610<br>中国<br>重庆市<br>大渡口区<br>海兴路<br>跳磴镇<br>333 号建桥生物医药园附 3-4 号<br>邮编：400082 | The manufacture and distribution of in-vitro diagnostic analyzers used in the diagnosis and detection of infection disease, cardiac marker, cancer, inflammation, coagulation, microbial infections, blood analytes, blood components, endocrine disorders, fertility testing, immune status, pregnancy testing, hormone, urine components and specific protein.<br>用于诊断和检测传染病，心脏标志物，癌症，炎症，凝血，微生物感染，血液分析，血液成分，内分泌失调，生育能力测试，免疫状态，怀孕测试，激素，尿液成分及特定蛋白的体外诊断仪器的制造和分销。 |
| Zybio Inc.<br>Floor 1 to Floor 4, Building 27/28<br>No. 10 of Taikang Road<br>Block C of Jianqiao Industrial Park<br>Dadukou District<br>Chongqing<br>400082<br>China<br>中元汇吉生物技术股份有限公司<br>915001043278176610<br>中国<br>重庆市<br>大渡口区<br>建桥工业园 C 区<br>太康路 10 号<br>27/28栋第 1-4 层<br>邮编：400082 | The design and development, manufacture and distribution of in-vitro diagnostic reagents used in the diagnosis and detection of infection disease, cardiac marker, cancer, inflammation, coagulation, microbial infections, blood analytes, blood components, endocrine disorders, fertility testing, immune status, pregnancy testing, hormone, urine components and specific protein.<br>用于诊断和检测传染病，心脏标志物，癌症，炎症，凝血，微生物感染，血液分析，血液成分，内分泌失调，生育能力测试，免疫状态，怀孕测试，激素，尿液成分及特定蛋白的体外诊断试剂的设计和开发，制造和分销。 |

Original Registration Date 首次发证日期： 2023-11-30
Effective Date 生效日期： 2023-11-30
Latest Revision Date 最新发证日期： 2024-10-16
Expiry Date 有效期至： 2026-11-29

Certificate No. **MD 782925**
持有证书：

| Location 地点 | Registered Activities 认证活动 |
| --- | --- |
| Zybio Inc.<br>No.45, Shilin Avenue<br>Tiaodeng Town<br>Dadukou District<br>Chongqing<br>400082<br>China<br>中元汇吉生物技术股份有限公司<br>915001043278176610<br>中国<br>重庆市<br>大渡口区跳磴镇<br>石林大道45号<br>邮编：400082 | Post market surveillance for in-vitro diagnostic reagent and analyzer<br>体外诊断试剂和仪器的上市后监督 |

Original Registration Date 首次发证日期： 2023-11-30
Latest Revision Date 最新发证日期： 2024-10-16

Effective Date 生效日期： 2023-11-30
Expiry Date 有效期至： 2026-11-29

# Declaration of Conformity

**No. ZYIN2022018**

**According to the In Vitro Diagnostic Medical Devices Directive 98/79/EC**

**Manufacturer**

Zybio Inc.

Floor 1 to Floor 5, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA

**EC Representative**

Lotus NL B.V.

Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

**Product Name**

See the attachment

**Specification**

See the attachment

**Product Classification**

Other device, not in annex II and not for self-testing, not for performance evaluation

**Conformity Assessment Route**

IVDD 98/79/EC Annex III (excluding Section 6)

We herewith declare under sole responsibility that the above mentioned product meets the provisions of the Council Directive 98/79/EC on in vitro diagnostic medical devices.

**General applicable directive**

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

(Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) )
(Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures)

**Standards Applied**

| | | | |
|---|---|---|---|
| EN ISO 13485:2016 | EN ISO 23640:2015 | EN 13641:2002 | ISO 20916:2019 |
| EN ISO 14971:2019 | EN 13612:2002 | EN ISO 18113-1:2011 | EN ISO 18113-2:2011 |
| EN ISO 15223-1:2021 | EN ISO17511:2021 | | |

CE

| | |
|---|---|
| Place | Chongqing, China |
| Date of Issue | 2022-05-20 |
| Version | 01 |
| Signature: | Rui Shao |
| Name of Authorized Signatory: | Rui Shao |
| Position: | RA Manager |

**Attachment**

| No. | Product Name | Specification |
|---|---|---|
| 1 | Urinalysis Strip (Dry Chemistry Method) | 11FU: 100 Tests<br>12FU: 100 Tests<br>14FU: 100 Tests |
| 2 | Urinalysis Strip (Dry Chemistry Method) | 11U: 30 Tests<br>11U: 100 Tests<br>12U: 30 Tests<br>12U: 100 Tests<br>14U: 30 Tests<br>14U: 100 Tests |
| 3 | Focusing Fluid | 60 mL/Bottle<br>125 mL/Bottle |
| 4 | Color Control | Control (red): 1×8 mL<br>Control (green): 1×8 mL<br>Control (blue): 1×8 mL<br>Control (red, green, blue): 3×8 mL |
| 5 | US-Calibrator | 30 mL/Bottle<br>60 mL/Bottle<br>125 mL/Bottle |
| 6 | Sediment Control | Negative control: 60 mL/Bottle<br>Negative control: 125 mL/Bottle<br>Positive control: 60 mL/Bottle<br>Positive control: 125 mL/Bottle |
| 7 | Conductivity Control | Level 1: 1×8 mL<br>Level 2: 1×8 mL<br>2 levels × 1× 8 mL |
| 8 | Turbidity Control | Level 1: 1×8 mL<br>Level 2: 1×8 mL<br>Level 3: 1×8 mL |

| | | |
|---|---|---|
| | | 3 levels×1×8 mL |
| 9 | SG Control | Level 1: 1×8 mL<br>Level 2: 1×8 mL<br>Level 3: 1×8 mL<br>3 levels×1×8 mL |
| 10 | SG Calibrator | 3 levels×1×8 mL |
| 11 | UDC-Control | Negative: 8 mL×1<br>Positive: 8 mL×1<br>Negative: 8 mL×1; Positive: 8 mL×1 |
| 12 | Turbidity Calibrator | 2 levels×1×8 mL |
| 13 | Conductivity Calibrator | 3 levels×1×8 mL |

# Declaration of Conformity

**No. ZYIN2022013**

**According to the In Vitro Diagnostic Medical Devices Directive 98/79/EC**

**Manufacturer**

Zybio Inc.

Floor 1 to Floor 5, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA

**EC Representative**

Lotus NL B.V.

Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

**Product Name**

Urinalysis Hybrid System

**Model and Specification**

U3600, U3601, U3602

**Product Classification**

Others device, not in annex II and not for self-testing, not for performance evaluation

**Conformity Assessment Route**

IVDD 98/79/EC Annex III (excludes section 6)

We herewith declare under sole responsibility that the above mentioned products meet the provisions of the Council Directive 98/79/EC on in vitro diagnostic medical devices. All supporting documentations are retained at the premises of the manufacturer.

**General applicable directive**

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

**Standards Applied**

| | | |
|---|---|---|
| EN 61326-2-6:2013 | EN 13612:2002 | EN ISO 14971:2019 |
| EN ISO 18113-1:2011 | EN ISO 18113-3:2011 | EN ISO 15223-1:2021 |
| EN 62304:2006/A1:2015 | EN 61326-1:2013 | EN 61010-1:2010/A1:2019 |
| EN 62366-1:2015 | EN 61010-2-101:2017 | EN ISO 13485:2016 |

CE

| | |
|---|---|
| Place | Chongqing, China |
| Date of Issue | 2022-05-20 |
| Version | 01 |
| Signature: | Rui Shao. |
| Name of Authorized Signatory: | Rui Shao |
| Position: | RA Director |

# EU Declaration of Conformity

## Manufacturer

| | |
|---|---|
| Name: | Zybio Inc. |
| Address: | Floor 1 to Floor 5, Building 30, No. 6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA |
| SRN: | CN-MF-000003349 |

## Authorized Representative

| | |
|---|---|
| Name: | Lotus NL B.V. |
| Address: | Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands. |
| SRN: | NL-AR-000000121 |

## Product Identification

| | |
|---|---|
| Product Name: | Cleanser |
| REF: | 01.09.1F.01.13.23 |
| Basic UDI-DI: | 69732628600044ZS |
| GMDN Code: | 59058 |
| GMDN Term: | Wash/cleaning solution IVD, automated/semi-automated system |
| EMDN Code: | W010109 |
| Risk Class: | Class A |
| Intended Purpose: | The product is suitable for cleaning the fluid path of the Urine Chemistry Analyzer. It should be used by healthcare professionals and properly trained personnel. |

We declare that the above mentioned *in vitro* diagnostic medical device is in conformity with the following legislation(s) and carries the CE marking accordingly:

**Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices**

Conformity Route: Self-Declaration of Conformity

**Relevant Harmonized Standards:**

| | | |
|---|---|---|
| EN ISO 13485:2016 | EN ISO 15223-1:2021 | EN ISO 18113-1:2011 |
| EN ISO 18113-2:2011 | EN 13612:2002/AC:2002 | EN ISO 23640:2015 |
| EN ISO 14971:2019 | EN 62366-1:2015 | |

All supporting documentation is retained under the control of Zybio Inc. and make available for review up on request.

This declaration of conformity is issued under the sole responsibility of Zybio Inc.

This declaration supersedes any declaration issued previously for the same product.

| | |
|---|---|
| Place | Chongqing, China |
| Signature | ShaoRui |
| Name | Rui Shao |
| Position | PRRC |
| Date of issue | 2022.12.29 |

# EU Declaration of Conformity

## Manufacturer

| | |
|---|---|
| Name: | Zybio Inc. |
| Address: | Floor 1 to Floor 5, Building 30, No. 6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA |
| SRN: | CN-MF-000003349 |

## Authorized Representative

| | |
|---|---|
| Name: | Lotus NL B.V. |
| Address: | Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands. |
| SRN: | NL-AR-000000121 |

## Product Identification

| | |
|---|---|
| Product Name: | Wash Solution |
| REF: | 01.09.1F.01.13.11<br>01.09.1F.01.13.12 |
| Basic UDI-DI: | 69732628600045ZU |
| GMDN Code: | 59058 |
| GMDN Term: | Wash/cleaning solution IVD, automated/semi-automated system |
| EMDN Code: | W010109 |
| Risk Class: | Class A |
| Intended Purpose: | The product is used for thoroughly cleaning the fluid path system of the applicable instruments, including the flow cell. It should be used by healthcare professionals and properly trained personnel. |

We declare that the above mentioned *in vitro* diagnostic medical device is in conformity with the following legislation(s) and carries the CE marking accordingly:

**Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices**

Conformity Route: Self-Declaration of Conformity

**Relevant Harmonized Standards:**

| | | |
|---|---|---|
| EN ISO 13485:2016 | EN ISO 15223-1:2021 | EN ISO 18113-1:2011 |
| EN ISO 18113-2:2011 | EN 13612:2002/AC:2002 | EN ISO 23640:2015 |
| EN ISO 14971:2019 | EN 62366-1:2015 | |

All supporting documentation is retained under the control of Zybio Inc. and make available for review up on request.

This declaration of conformity is issued under the sole responsibility of Zybio Inc.

This declaration supersedes any declaration issued previously for the same product.

| | |
|---|---|
| Place | Chongqing, China |
| Signature | ShaoRui |
| Name | Rui Shao |
| Position | PRRC |
| Date of issue | 2022.12.29 |

# EU Declaration of Conformity

## Manufacturer

| | |
|---|---|
| Name: | Zybio Inc. |
| Address: | Floor 1 to Floor 5, Building 30, No. 6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA |
| SRN: | CN-MF-000003349 |

## Authorized Representative

| | |
|---|---|
| Name: | Lotus NL B.V. |
| Address: | Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands. |
| SRN: | NL-AR-000000121 |

## Product Identification

| | |
|---|---|
| Product Name: | Sheath Fluid |
| REF: | 01.09.1F.01.11.11<br>01.09.1F.01.11.12<br>01.09.1F.01.11.13 |
| Basic UDI-DI: | 69732628600042ZN |
| GMDN Code: | 58236 |
| GMDN Term: | Buffered wash solution IVD, automated/semi-automated system |
| EMDN Code: | W010109 |
| Risk Class: | Class A |
| Intended Purpose: | The product is used for diluting urine samples to form sheath flow, which is conducive to cell counting and classification by analytical instruments. It should be used by healthcare professionals and properly trained personnel. |

We declare that the above mentioned *in vitro* diagnostic medical device is in conformity with the following legislation(s) and carries the CE marking accordingly:

**Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices**

Conformity Route: Self-Declaration of Conformity

**Relevant Harmonized Standards:**

| | | |
|---|---|---|
| EN ISO 13485:2016 | EN ISO 15223-1:2021 | EN ISO 18113-1:2011 |
| EN ISO 18113-2:2011 | EN 13612:2002/AC:2002 | EN ISO 23640:2015 |
| EN ISO 14971:2019 | EN 62366-1:2015 | |

All supporting documentation is retained under the control of Zybio Inc. and make available for review up on request.

This declaration of conformity is issued under the sole responsibility of Zybio Inc.

This declaration supersedes any declaration issued previously for the same product.

| | |
|---|---|
| Place | Chongqing, China |
| Signature | Shao Rui |
| Name | Rui Shao |
| Position | PRRC |
| Date of issue | 2022.12.29. |

# EU Declaration of Conformity

## Manufacturer

| | |
|---|---|
| Name: | Zybio Inc. |
| Address: | Floor 1 to Floor 5, Building 30, No. 6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA |
| SRN: | CN-MF-000003349 |

## Authorized Representative

| | |
|---|---|
| Name: | Lotus NL B.V. |
| Address: | Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands. |
| SRN: | NL-AR-000000121 |

## Product Identification

| | |
|---|---|
| Product Name: | Urinalysis Diluent |
| REF: | 01.09.1F.01.12.05<br>01.09.1F.01.12.06 |
| Basic UDI-DI: | 69732628600043ZQ |
| GMDN Code: | 58237 |
| GMDN Term: | Buffered sample diluent IVD, automated/semi-automated system |
| EMDN Code: | W010109 |
| Risk Class: | Class A |
| Intended Purpose: | The product is used for diluting urine samples to form sheath flow, which is conducive to cell counting and classification by analytical instruments. It should be used by healthcare professionals and properly trained personnel. |

We declare that the above mentioned *in vitro* diagnostic medical device is in conformity with the following legislation(s) and carries the CE marking accordingly:

**Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices**

Conformity Route: Self-Declaration of Conformity

**Relevant Harmonized Standards:**

| | | |
|---|---|---|
| EN ISO 13485:2016 | EN ISO 15223-1:2021 | EN ISO 18113-1:2011 |
| EN ISO 18113-2:2011 | EN 13612:2002/AC:2002 | EN ISO 23640:2015 |
| EN ISO 14971:2019 | EN 62366-1:2015 | |

All supporting documentation is retained under the control of Zybio Inc. and make available for review up on request.

This declaration of conformity is issued under the sole responsibility of Zybio Inc.

This declaration supersedes any declaration issued previously for the same product.

| | |
|---|---|
| Place | Chongqing, China |
| Signature | ShaoRui |
| Name | Rui Shao |
| Position | PRRC |
| Date of issue | 2022.12.29 |

zybio

Qualified

TRAINING CERTIFICATE

# CERTIFICATION

To

**Vitalie Goreacii**

From

Sanmedico

Accomplish the training on

Fully automatic desktop biochemical analyzer EXC200 & Fully-automatic Urinalysis U3600

During

January 19th, 2024.

Training contents:

- **Basic knowledge**
- **Basic principle**
- **Reagent kits**
- **Operation**
- **Installation**
- **Maintenance**
- **Mechanical structure**

The trainee is authorized to do installation, maintenance and repair on above machine.

Trainer: Perry Jiang

Date: 2024.01.20

Cert. Code: 20240120PJP01

Validity date (2 Years)

Zybio Inc.

zybio

# Urinalysis Hybrid System U3600

An integrated system for upgrading your lab urinalysis solution

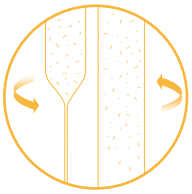

## Urinalysis

www.zybio.com

# Urinalysis Hybrid System U3600

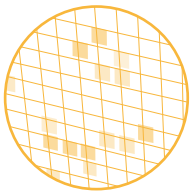
U3600 is an integrated machine that combines the functions of urine physical analysis, chemical analysis and formed particle analysis. It is designed for upgrading your urine analysis solutions, which could provide 16 items chemical analysis, 46 items formed particles analysis, and 5 items physical analysis. The U3600 utilizes laminar flow technology, high-speed photograph technology, and medical image recognition technology to provide high-resolution images and accurate urine particle classification.

# Features



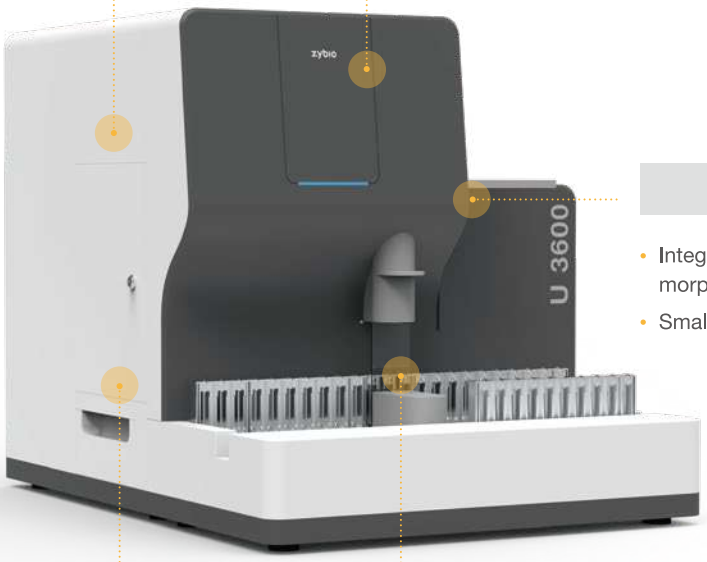
## Advanced Technology

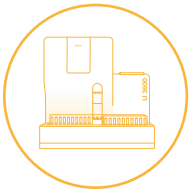
- Laminar flow technology
- High-speed photograph technology
- Medical image recognition
- Photometer technology applies full spectrum instead of multi-wave-length



## Accurate Recognition

- No overlap, gather or morphology changes of formed particles
- High-definition images provide a clear view of particles
- Powerful clinical database



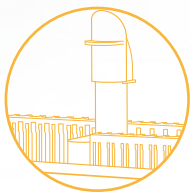



## Compact Design

- Integration of physical, chemical and morphology analysis
- Small footprint for space saving

## Convenient Operation

- Automatically handle test strips and mix sample
- Without centrifugation, staining or rotation of lens
- The images can be reviewed and decrease microscopy rate
- Priority for emergency sample

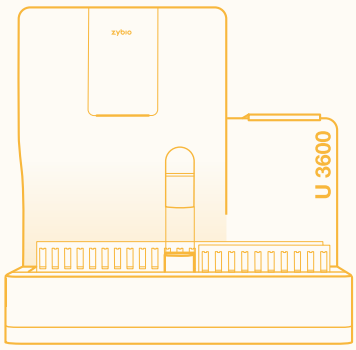


## Improved Productivity

- 240 T/H for Chemistry Mode
- 120 T/H for Formed Particles Mode/Hybrid Mode
- Automatic strip feeder with a capacity of 300 strips
- Physical analysis of urine includes Color, SG, Turbidity, Conductivity and Osmolality

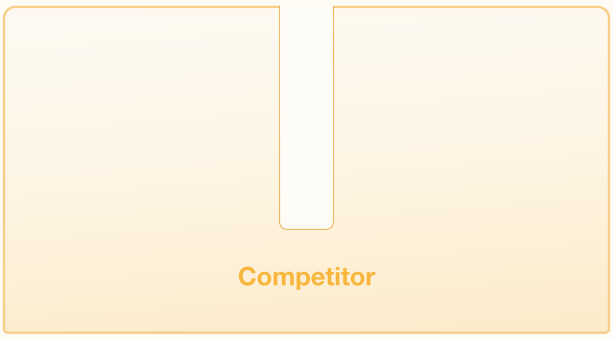
# Compact Design Combined With More Detection Modes

- **Save about 50% space**
- **Integrated urinalysis solution**




687 mm

Hybrid System




>1200 mm

Workstation

# Test Menu

## 05 items

**Physical analysis** — Color · SG · Turbidity · Conductivity · Osmolality

## 16 items

**Chemical analysis** — URO · BIL · KET · LEU · NIT · PRO · BLD · PCR · ACR · Ca · VC · pH · SG · GLU · CRE · MALB

## 46 items

**Formed particles analysis** — RBC · WBC · WBCC · PHCY · SQEP · NSE · BYST · HYST · BACI · SUCO · SPRM · MUCS · UNCL · UNCX · MAPH · CAPH · TYRO · URIC · AUCR · COM · COD · AMOR · FAT · HYAL · UNCC

Note: Only some items are listed.

# Technical Parameters

| | |
|---|---|
| Principle | Laminar flow technology |
| | High-speed photography technology |
| | Medical image recognition |
| Throughput | 240 T/H for Chemistry Mode |
| | 120 T/H for Formed Particles Mode/Hybrid Mode |
| Test Items | Chemical analysis: URO, BIL, KET, LEU, NIT, PRO, BLD, MALB, CRE, GLU, SG, |
| | pH , VC, Ca, ACR, PCR |
| | Formed particles analysis: RBC, WBC, WBCC, PHCY, SQEP, NSE, BYST, HYST, |
| | BACI, SUCO, SPERM, MUCS, HYAL, UNCC, FAT, AMOR, COM, COD, URIC, |
| | AUCR, TYRO, CAPH, MAPH, UNCX, UNCL |
| | Physical analysis: Color, Specific Gravity, Turbidity, Conductivity, Osmolality |
| Sample Capacity | 10 samples × 6 racks |
| Test Mode | Auto loader mode, STAT mode |
| Reagents | Urinalysis Strip |
| | UDC-Control |
| | Sheath Fluid |
| | Focusing Fluid |
| | US-Calibrator |
| | Sediment Control |
| | Conductivity Control |
| | Wash solution |
| Operation Environment | Temperature: 10~30°C |
| | Humidity: < 80% |
| | Atmospheric Pressure: 70~106 kPa |
| Power Supply | 90~264 V, 47~63 Hz |
| Dimension (mm) | 687 (W) × 512 (D) × 530 (H) |
| Weight (kg) | 55 |

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EN-C-NF-U3600-20220628H

# Urinalysis

# Sediment Control

## Specifications

| REF | Specifications | |
|---|---|---|
| 01.09.1F.01.08.08 | Negative Control | 60 mL/Bottle |
| 01.09.1F.01.08.06 | Negative Control | 125 mL/Bottle |
| 01.09.1F.01.08.07 | Positive Control | 60 mL/Bottle |
| 01.09.1F.01.08.05 | Positive Control | 125 mL/Bottle |

## Intended purpose

This product is applicable to testing process quality control (QC) of urine sediment analyzer or urinalysis hybrid system to ensure the accuracy of the instrument.

## Test principles

It is based on the principle of flow microscopy imaging. Particles in the sample pass through the thin-layer structure of the flow cell of the instrument, and the imaging area of the sediment is illuminated by a high-frequency light source after being shaped by the lighting component. At the same time, the camera takes pictures at the same frequency to form sediment images, which are then recognized and classified by the instrument. The instrument calculates the concentration of sediment in the sample (the number of particles per unit volume) according to the number of "particles" in the sample and the volume of the urine sample passing through the flow cell.

After focusing and calibrating the detection instrument, the control for urine sediment analysis is tested as the sample to be tested. The control of known "particle" concentration is used to conduct the QC of detection system, so as to ensure the reliability of measurement results of detection system.

## Materials provided

| Common component | Negative control | Positive control |
|---|---|---|
| Sediment control | 1 bottle | 1 bottle |
| Element | PBS | mouse blood |
| Instructions for use | 1 pc | 1 pc |

Note: the control assigned value of different batches is slightly different and has batch specificity. For details, please refer to the product target value sheet. Reagents from different batches cannot mixed.

## Materials required (but not provided)

Urine analyzer, general laboratory equipment.

## Storage and stability

1. Unopened: the validity period is 12 months when stored under 2–8°C and kept away from sunlight. The product can’t be stored under frozen conditions.
2. Opened: the validity period is 30 days when stored under 2–8°C and kept away from sunlight. The product can’t be stored under frozen conditions.
3. See packaging label for date of manufacture and expiry date.

## Applicable instruments

Zybio Urine sediment analyzer (model: U2600, U2601, U2602, U2610, U2611, U2612), and Urinalysis hybrid system (model: U3600, U3601, U3602)

## Assay procedure

Please follow the instructions of this product and the instructions of the applicable instruments.

1. The QC test shall be performed at the instrument restart or before starting test every day, and both negative and positive controls shall be used for QC as much as possible.
2. Gently invert it several times to homogenize it.
3. During test with urine sediment analyzer/urinalysis hybrid system: set the instrument at Control status. Pour the control into a dry and clean test tube. Place the test tube on the target position for QC testing of the instrument.
4. The test result shall be within the indicated value range. If it is beyond the range, please check whether the control is expired and whether the instrument works normally.

## Performance characteristics

1. Range of control: for negative control, particle content ⩽20 pcs/uL; for positive control, the relative deviation between the test result and the indicated value shall be within ±5.0%.
2. Homogeneity:

| Level | Requirements |
|---|---|
| Positive control | $CV_{within\text{-}bottle}$ ⩽15%<br>The between-bottle homogeneity of between-bottle counting results should be good. |

## Precautions

1. This product is applicable to the calibration of urine. This product is only applicable to the testing process QC of urine sediment analyzer or urinalysis hybrid system. Please do not use it for other purposes.
2. Avoid contact with the skin and eyes. If this product is splashed into the eye, rinse it with running warm water for several minutes; seek medical treatment immediately if pain or swelling occurs; in case of contact with skin, rinse the skin with soapy water, and completely rinse off the product with clean water.
3. Please use this product as required by the instructions. The accuracy of the results cannot be guaranteed for purposes other than the prescribed instructions and intended purpose.
4. Routine precautions for laboratory operations must be followed when this product is used.
5. The control disposal and the containers that have been in contact with the control shall follow the relevant waste regulations such as medical waste or industrial waste. All waste shall be treated as a potential infection source.
6. The control that was unsealed shall be sealed and stored as instructed; do not use expired products.
7. This product shall be stored as instructed, and kept away from direct sunlight during operation.

# Sediment Control

## Symbol interpretation

| Symbol | Title and Description | Symbol | Title and Description |
|---|---|---|---|
| IVD | In vitro diagnostic medical device |  | Date of manufacture |
| LOT | Batch code |  | Use-by date |
|  | Consult instructions for use |  | Temperature limit |
|  | Keep away from sunlight | REF | Catalogue number |
| CE | CE marking of conformity |  | Manufacturer |
| EC REP | Authorized Representative in the European Community | | |

## References

1. Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline—Third Edition，from NCCLS Document GP16-A, 2009.
2. Cong Yulong, Ma Junlong, et al. Modern Urinalytical Technology and Clinic Application, China Science and Technology Press, 1998.
3. Cong Yulong, Ma Junlong, et al. Practical Urinalytical Technology and Clinical Application, People's Health Publishing House, first edition, September, 2013.

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EC REP

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IFU Revision: 02 Release date: 2022-05-20

# Cleanser

## Product Name

Cleanser
Model: D12

## Specifications

| REF | Specifications |
|---|---|
| 01.09.1F.01.13.23 | 200 mL/ Bottle |

## Intended purpose

The product is suitable for cleaning the fluid path of the Urine Chemistry Analyzer. It should be used by healthcare professionals and properly trained personnel.

## Operating principle

The surfactant component of the cleanser solution can significantly reduce the surface tension of the solution, making the residual sample solution in the fluid path easily rinsed off.

## Main components

Polidocanol (main ingredient of the surfactant): 0.5%-2%.

## Storage and stability

1. Validity period: 12 months if sealed and stored at 4℃-30℃, dry, and kept away from sunlight; 60 days after opening if stored at 4℃-30℃, and kept away from sunlight.
2. See the label for the manufacture date and expiry date.

## Applicable instruments

Urine Chemistry Analyzer (model: U1600, U1601, U1602) manufactured by Zybio Inc. Other models shall be used after verification.

## Usage

1. Rotate to open the cleanser container cover (keep the cover unremoved), and then use water to wash it.
2. Pour the cleanser of 200 ml into the container and add pure water of about 9.8 L for dilution.
3. Connect the cleanser container to the Urine Chemistry Analyzer for use. See the operation manual of the Urine Chemistry Analyzer for the specific connection method.

## Performance characteristics

pH: 7.00 ± 2.00 at 25℃.

## Warnings and precautions

1. Instructions for use must be carefully followed. It is for in vitro diagnostic use only.
2. Avoid contact with skin and eyes; In case of eye contact, please rinse with flowing warm water for several minutes. If it is painful or swollen, seek medical care immediately; In case of skin contact, rinse with soapy water and then rinse thoroughly with water.

## Symbol interpretation

| Symbol | Title and Description | Symbol | Title and Description |
|---|---|---|---|
| IVD | In vitro diagnostic medical device | LOT | Batch code |
| | Consult instructions for use | | Use-by date |
| CE | CE marking of conformity | | Manufacturer |
| EC REP | Authorized Representative in the European Community | | Temperature limit |
| REF | Catalogue number | | Keep away from sunlight |
| | Date of manufacture | | Warning |

## References

1. Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline—Third Edition, from NCCLS Document GP16-A, 2009.
2. Cong Yulong, Ma Junlong, et al. Modern Urinalytical Technology and Clinic Application, China Science and Technology Press, 1998.

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Current Revision and Release Date: 03, 2022-11

# Color Control

## Specifications

| REF | Specifications |
|---|---|
| 01.09.1F.01.04.04 | Control (Red): 1×8 mL |
| 01.09.1F.01.04.05 | Control (Green): 1×8 mL |
| 01.09.1F.01.04.06 | Control (Blue): 1×8 mL |
| 01.09.1F.01.04.03 | Control (Red, Green, Blue): 3×8 mL |

## Intended purpose

This product is applicable to the QC test of urine chemistry analyzer and urinalysis hybrid system.

## Test principles

The QC of the test system is performed by measuring a control of with a known concentration, so as to ensure the reliability of the results of from the instrument.

## Materials provided

| Common component | RED | GREEN | BLUE | 3-color |
|---|---|---|---|---|
| Color control | 1bottle | 1bottle | 1bottle | 3bottles |
| Instructions for use | 1 pc | 1 pc | 1 pc | 1 pc |

Note: Products of different batches cannot be used together.

## Materials required (but not provided)

Urine analyzer, general laboratory equipment.

## Storage and stability

1. Unopened: the validity period is 12 months when stored under 2-8°C and kept away from sunlight. The product can't be stored under frozen conditions.
2. Opened: the validity period is 30 days when stored under 2-8°C and kept away from sunlight. The product can't be stored under frozen conditions.
3. See packaging label for date of manufacture and expiry date.

## Applicable instruments

Zybio Urine chemistry analyzer (model: U1600, U1601, U1602), Urinalysis hybrid system (model: U3600, U3601, U3602).

## Assay procedure

Refer to the instructions on this product and the instructions on compatible instruments.
1. The QC test shall be performed before the instrument restart or daily test, and controls 2 levels or more shall be used for QC as much as possible.
2. Before use, leave the control under room temperature for 30 minutes.
3. To use it, gently invert it several times to homogenize it.
4. During test with urine chemistry analyzer: put the instrument at QC status. Pour the control into a dry and clean test tube. Place the test tube at a test position in a compatible instrument for testing.
5. The test result shall be consistent with the indicated result. If not consistent, the user shall check the detection system, such as the validity period of the control, performance and status of instrument, etc.

## Performance characteristics

Test value: the test result is the same as the indicated value.
Uniformity: consistency of test results ⩾90%.

## Precautions

1. This product is only applicable to the QC test of color module of urine chemistry analyzer or urinalysis hybrid system, and shall not be used for other purposes.
2. Avoid contact with the skin and eyes. If this product is splashed into the eyes, rinse with running warm water for several minutes; seek medical attention immediately if pain or swelling occurs. In case of contact with skin, rinse with soapy water, and completely rinse off the product with clean water.
3. Please use this product as required by the instructions. The accuracy of the results cannot be guaranteed for purposes other than the prescribed instructions and intended purpose.
4. Routine precautions for laboratory operations must be followed when this product is used.
5. The control disposal and the containers that have been in contact with the control shall follow the relevant waste regulations such as medical waste or industrial waste. All waste shall be treated as a potential infection source.
6. The control that was opened shall be sealed and stored according to the specified method; do not use expired products.
7. Please keep this product according to the storage method, and avoid direct sunlight during operation.

## Symbol interpretation

| Symbol | Title and Description | Symbol | Title and Description |
|---|---|---|---|
| IVD | In vitro diagnostic medical device | | Date of manufacture |
| LOT | Batch code | | Use-by date |
| | Consult instructions for use | | Temperature limit |
| | Keep away from sunlight | REF | Catalogue number |
| CE | CE marking of conformity | | Manufacturer |
| EC REP | Authorized Representative in the European Community | | |

# Color Control


**References**

1. Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline—Third Edition，from NCCLS Document GP16-A, 2009.
2. Cong Yulong, Ma Junlong, et al. Modern Urinalytical Technology and Clinic Application, China Science and Technology Press, 1998.
3. Cong Yulong, Ma Junlong, et al. Practical Urinalytical Technology and Clinical Application, People's Health Publishing House, first edition, September, 2013.



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IFU Revision: 02 Release date: 2022-05-20

# Urinalysis Diluent

## Product Name
Urinalysis Diluent

## Specifications

| REF | Specifications |
|---|---|
| 01.09.1F.01.12.05 | 100 mL/Bottle |
| 01.09.1F.01.12.06 | 500 mL/Bottle |

## Intended purpose
The product is used for sample dilution and preparation of cell suspension before urinalysis. It should be used by healthcare professionals and properly trained personnel.

## Operating principle
The osmotic pressure and pH of the Urinalysis Diluent are close to the urine sample, and will not affect the form and quantity of the formed particles in the urine, and can be used to dilute the high-concentration urine sample.

## Main components
Sodium chloride: 0.3%-3%.
Phosphate buffer: 0.2%-3%.
Proclin300: 0.02%-1%.

## Storage and stability
1. Validity period: 12 months if sealed and stored at 4°C-30°C, dry, and kept away from sunlight; 30 days after opening if stored at 4°C-30°C, and kept away from sunlight.
2. See the label for the date of manufacture and expiry date.

## Applicable instruments
Urine sediment analyzer (model: U2600, U2601, U2602, U2610, U2611, U2612), and Urinalysis hybrid system (model: U3600, U3601, U3602) manufactured by Zybio Inc. Other models shall be used after verification.

## Usage
After mixing the high concentration of urine sample, put the urine sample in a clean test tube, add different volumes of urinalysis diluent according to the dilution multiple requirements, and then test it. The final result is obtained by multiplying the test result by the dilution multiple.
For more details, refer to the operation manual of the applicable instruments.

## Performance characteristics
1. pH: 7.00 ± 1.00.
2. Conductivity: 10-20 mS/cm.

## Warnings and precautions
1. Instructions for use must be carefully followed. It is for in vitro diagnostic use only.
2. Avoid contact with skin and eyes; In case of eye contact, please rinse with flowing warm water for several minutes. If it is painful or swollen, seek medical care immediately; In case of skin contact, rinse with soapy water and then rinse thoroughly with water.
3. This product does not contain biological components but contains chemical components, which may have potential risks of hazardous chemicals. Appropriate protective measures shall be taken during sample collection, treatment, storage, and testing.

## Symbol interpretation

| Symbol | Title and Description | Symbol | Title and Description |
|---|---|---|---|
| IVD | In vitro diagnostic medical device | LOT | Batch code |
|  | Consult instructions for use |  | Use-by date |
| CE | CE marking of conformity |  | Manufacturer |
| EC REP | Authorized Representative in the European Community |  | Temperature limit |
| REF | Catalogue number |  | Keep away from sunlight |
|  | Date of manufacture |  | Warning |

## References
1. Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline—Third Edition, from NCCLS Document GP16-A, 2009.
2. Cong Yulong, Ma Junlong, et al. Modern Urinalytical Technology and Clinic Application, China Science and Technology Press, 1998.


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Current Revision and Release Date: 03, 2022-11

zybio

CE IVD

# Focusing Fluid

## Specifications

| REF | Specifications |
|---|---|
| 01.09.1F.01.09.04 | 60 mL/Bottle |
| 01.09.1F.01.09.03 | 125 mL/Bottle |

## Intended purpose

This product is used to determine the position of focal plane of microscopic imaging system in the urine sediment analyzer or the urinalysis hybrid system.

## Test principles

It is based on the principle of flow microscopy imaging. The particles in the sample pass through the thin-layer structure of the flow cell of the instrument, and the shooting area of sediment is illuminated by a high-frequency light source after being shaped by the lighting component. At the same time, the camera takes pictures at the same frequency to form sediment images, which are then recognized and classified by the instrument. The instrument calculates the concentration of sediment in the sample according to the number of "particles" in the sample and the volume of the urine sample.

Before testing the sample on the instrument, it is necessary to use the focusing fluid to focus the camera of the instrument, so as to adjust the best shooting focal length: when the focusing fluid is used for focusing, the camera automatically adjusts the focal length, adopts different focal lengths to shoot the particles in the focusing fluid, and the best focal length is determined according to the clearest particle image. When the sample is being imaged, the camera will take pictures at the determined optimal focal length to ensure that the particles imaged during the test are clear and easy to identify.

## Materials provided

| Common component | 60 mL | 125mL |
|---|---|---|
| Focusing Fluid | 1 bottle | 1 bottle |
| Element | mouse blood | |
| Instructions for use | 1 pc | 1 pc |

Note: this product is batch-specific. For the detailed target value, see the product label of each batch. Calibrators from different batches cannot be used together.

## Materials required (but not provided)

Urine analyzer, general laboratory equipment.

## Storage and stability

1. Unopened: the validity period is 12 months when stored under 2–8°C and kept away from sunlight. The product can't be stored under frozen conditions.
2. Opened: the validity period is 30 days when stored under 2–8°C and kept away from sunlight. The product can't be stored under frozen conditions.
3. See packaging label for date of manufacture and expiry date.

## Applicable instruments

Zybio Urine sediment analyzer (model: U2600, U2601, U2602, U2610, U2611, U2612), and Urinalysis hybrid system (model: U3600, U3601, U3602)

## Assay procedure

Please follow the instructions of this product and the instructions of the applicable instruments.

1. Focusing should be performed at the restart of the instrument or before the test every day.
2. Gently invert it several times to homogenize it.
3. During test with urine sediment analyzer/urinalysis hybrid system: set the instrument at focus status. Pour the focusing fluid into a dry and clean test tube. Place the test tube on the target position of the instrument for focusing.
4. If the focusing fails, the user shall check the detection system, please check whether the focusing fluid is expired and whether the instrument works normally.

## Performance characteristics

1.Accuracy: the particle content of the focusing fluid is 1,500 pcs/μL–2,000 pcs/μL, and the relative deviation should be less than or equal to 7.0%;
2. Homogeneity:
2.1Within-bottle homogeneity: $CV_{within\text{-}bottle} \leqslant 15\%$;
2.2Between-bottle homogeneity: the between-bottle homogeneity of the counting results shall be good.

## Precautions

1. This product is can be only used to determine of focal plane position of microscopic imaging system of the urine sediment analyzer or urinalysis hybrid system. Do not use it for other purposes.
2. Avoid contact with the skin and eyes. If this product is splashed into eyes, rinse with running warm water for several minutes; seek medical attention immediately if pain or swelling occurs. In case of contact with skin, rinse with soapy water, and completely rinse off the product with clean water.
3. Please use this product as required by the instructions. The accuracy of the results cannot be guaranteed for purposes other than the prescribed instructions and intended purpose.
4. Routine precautions for laboratory operations must be followed when this product is used.
5. The focusing fluid disposal and the containers that have been in contact with the control shall follow the relevant waste regulations such as medical waste or industrial waste. All waste shall be treated as a potential infection source.
6. The focusing fluid that was opened shall be sealed and stored as instructed, and do not use expired product.
7. This product shall be stored as instructed, and kept away from direct sunlight during operation.

## Symbol interpretation

| Symbol | Title and Description | Symbol | Title and Description |
|---|---|---|---|

# Focusing Fluid

| | | | |
|---|---|---|---|
| IVD | In vitro diagnostic medical device | | Date of manufacture |
| LOT | Batch code | | Use-by date |
| | Consult instructions for use | | Temperature limit |
| | Keep away from sunlight | REF | Catalogue number |
| CE | CE mark of conformity | | Manufacturer |
| EC REP | Authorized Representative in the European Community | | |

## References

1. Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline—Third Edition，from NCCLS Document GP16-A, 2009.
2. Cong Yulong, Ma Junlong, et al. Modern Urinalytical Technology and Clinic Application, China Science and Technology Press, 1998.
3. Cong Yulong, Ma Junlong, et al. Practical Urinalytical Technology and Clinical Application, People's Health Publishing House, first edition, September, 2013.

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IFU Revision: 02 Release date: 2022-05-20

# SG Calibrator

## Specifications

| REF | Specifications |
|---|---|
| 01.09.1F.01.15.02 | 3 levels×1×8 mL |

## Intended purpose

This product is used for calibration of the SG module of urine chemistry analyzer and urinalysis hybrid system.

## Test principles

The calibrator of a known concentration is measured for the purpose of calibration on the detection system, so as to establish the metrological traceability of the measurement result obtained from that system.

## Materials provided

| Common component | 3 levels |
|---|---|
| SG Calibrator | 3 bottles |
| Instructions for use | 1 pc |

Note:

| Indicated value | Uncertainty |
|---|---|
| See bottle label | See bottle label |

Traceability: traceable to enterprise reference.

## Materials required (but not provided)

Urine analyzer, general laboratory equipment.

## Storage and stability

1. Unopened: the validity period is 12 months when stored under 2–8℃ and kept away from light.
2. Opened: the validity period is 7 days when stored under 2–8℃ and kept away from light.
3. See packaging label for date of manufacture and expiry date.

## Applicable instruments

Zybio Urine chemistry analyzer (model: U1600, U1601, U1602), Urinalysis hybrid system (model: U3600, U3601, U3602).

## Assay procedure

Please follow the instructions of this product and the instructions of the applicable instruments.
1.Calibration shall be performed in case of invalid control for instrument or based on a monthly interval. Calibrators of 3 levels must be used.
2. Before use, leave the control under room temperature for 30 minutes.
3.Gently invert it several times to homogenize it.
4.During test with urine chemistry analyzer: set the instrument at calibration status. Pour the calibrator all into a dry and clean test tube. Place the test tube on the target position for calibration of the instrument.
5.After the calibration is completed, the instrument will display successful calibration. If the calibration has failed, please check whether the calibrator is expired and whether the instrument works normally.

## Performance characteristics

Accuracy: correctness of measuring value transfer $|En| \leqslant 1$.
Homogeneity:
1)$CV_{within\text{-}bottle} \leqslant 5\%$;
2)$CV_{between\text{-}bottle} \leqslant 5\%$.

## Precautions

1. This product is only applicable to the calibration of SG module of urine chemistry analyzer or urinalysis hybrid system. Please do not use it for other purposes.
2. The value assignment of calibrators varies with different batches. See bottle label for specific indicated value.
3. Avoid contact with the skin and eyes. If this product is splashed into the eye, rinse with running warm water for several minutes; seek medical attention immediately if pain or swelling occurs. In case of contact with skin, rinse the skin with soapy water, and completely rinse off the product with clean water.
4. Please use this product as required by the instructions. The accuracy of the results cannot be guaranteed for purposes other than the prescribed instructions and intended purpose.
5. Routine precautions for laboratory operations must be followed when using it.
6. The calibrator disposal and the containers that have been in contact with the control shall follow the relevant waste regulations such as medical waste or industrial waste. All waste shall be treated as a potential infection source.
7. The calibrator that was opened shall be sealed and stored as instructed, and do not use expired product.
8. This product shall be stored as instructed, and kept away from direct sunlight during operation.

## Symbol interpretation

| Symbol | Title and Description | Symbol | Title and Description |
|---|---|---|---|
| IVD | In vitro diagnostic medical device | | Date of manufacture |
| LOT | Batch code | | Use-by date |
| | Consult instructions for use | | Temperature limit |
| | Keep away from sunlight | REF | Catalogue number |
| CE | CE marking of conformity | | Manufacturer |
| EC REP | Authorized Representative in the European Community | | |

## References

1. Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline—Third Edition，from NCCLS Document GP16-A, 2009.

2. Cong Yulong, Ma Junlong, et al. Modern Urinalytical Technology and Clinic Application, China Science and Technology Press, 1998.
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IFU Revision: 02 Release date: 2022-05-20

# SG Control

## Specifications

| REF | Specifications |
|---|---|
| 01.09.1F.01.05.04 | Level 1: 1×8 mL |
| 01.09.1F.01.05.05 | Level 2: 1×8 mL |
| 01.09.1F.01.05.06 | Level 3: 1×8 mL |
| 01.09.1F.01.05.03 | 3 levels×1×8 mL |

## Intended purpose

This product is used for the QC test of SG module of urine chemistry analyzer and urinalysis hybrid system.

## Test principles

The QC of the test system is performed by measuring a control of with a known concentration, so as to ensure the reliability of the results of the instrument.

## Materials provided

| Common component | Level 1 | Level 2 | Level 3 | 3 levels |
|---|---|---|---|---|
| SG control | 1bottle | 1bottle | 1bottle | 3bottles |
| Instructions for use | 1 pc | 1 pc | 1 pc | 1 pc |

Note: The control value assigned for different batches is slightly different and has batch specificity. For details, please refer to the attached table of the product. Controls from different batches cannot be mixed.

## Materials required (but not provided)

Urine analyzer, general laboratory equipment.

## Storage and stability

1. Unopened: the validity period is 12 months when stored under 2-8°C and kept away from sunlight. The product can't be stored under frozen conditions.
2. Opened: the validity period is 30 days when stored under 2-8°C and kept away from sunlight. The product can't be stored under frozen conditions.
3. See packaging label for date of manufacture and expiry date.

## Applicable instruments

Zybio Urine chemistry analyzer (model: U1600, U1601, U1602), Urinalysis hybrid system (model: U3600, U3601, U3602).

## Assay procedure

Please follow the instructions of this product and the instructions of the applicable instruments.
1.The QC test shall be performed at the instrument restart or before starting test every day, and controls of more than 2 levels shall be used for QC as much as possible.
2.Before use, leave the control under room temperature for 30 minutes.
3.Gently invert it several times to homogenize it.
4.During test with urine chemistry analyzer: set the instrument at QC status. Pour the control into a dry and clean test tube. Place the test tube on the target position for QC testing of the instrument.
5.The test result shall be within the indicated value range. If it is beyond the range, please check whether the control is expired and whether the instrument works normally.

## Performance characteristics

Test value: test results shall be within the indicated range.
Homogeneity: the $CV_{between\text{-}bottle} \leqslant 5\%$.

## Precautions

1. This product is only applicable to the QC of SG module of urine chemistry analyzer or urinalysis hybrid system. Please do not use it for other purposes.
2. Avoid contact with the skin and eyes. If this product is splashed into the eyes, rinse with running warm water for several minutes; seek medical attention immediately if pain or swelling occurs. In case of contact with skin, rinse with soapy water, and completely rinse off the product with clean water.
3. Please use this product as required by the instructions. The accuracy of the results cannot be guaranteed for purposes other than the prescribed instructions and intended purpose.
4. Routine precautions for laboratory operations must be followed when this product is used.
5. The control disposal and the containers that have been in contact with the control shall follow the relevant waste regulations such as medical waste or industrial waste. All waste shall be treated as a potential infection source.
6. The control that was unsealed shall be sealed and stored as instructed; do not use expired products.
7. This product shall be stored as instructed, and kept away from direct sunlight during operation.

## Symbol interpretation

| Symbol | Title and Description | Symbol | Title and Description |
|---|---|---|---|
| IVD | In vitro diagnostic medical device | | Date of manufacture |
| LOT | Batch code | | Use-by date |
| | Consult instructions for use | | Temperature limit |
| | Keep away from sunlight | REF | Catalogue number |
| CE | CE marking of conformity | | Manufacturer |
| EC REP | Authorized Representative in the European Community | | |

# SG Control

## References

1. Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline—Third Edition，from NCCLS Document GP16-A, 2009.
2. Cong Yulong, Ma Junlong, et al. Modern Urinalytical Technology and Clinic Application, China Science and Technology Press, 1998.
3. Cong Yulong, Ma Junlong, et al. Practical Urinalytical Technology and Clinical Application, People's Health Publishing House, first edition, September, 2013.

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IFU Revision: 02 Release date: 2022-05-20

# Sheath Fluid

## Product name
Sheath Fluid

## Package specifications

| REF | Specifications |
|---|---|
| 01.09.1F.01.11.11 | 10 L/Bucket |
| 01.09.1F.01.11.12 | 15 L/Bucket |
| 01.09.1F.01.11.13 | 20 L/Bucket |

## Intended purpose
The product is used for diluting urine samples to form sheath flow, which is conducive to cell counting and classification by analytical instruments. It should be used by healthcare professionals and properly trained personnel.

## Main components
Sodium azide: 0.05%-0.1%.
Polyoxyethylene lauryl ether: 0.1%-1%.
Ethylenediaminetetraacetic acid: 0.01%-0.2%.
Sodium chloride: 0.3%-3%.
Trometamol: 0.01%-0.2%.
Tri (hydroxymethyl) aminomethane hydrochloride: 0.1%-0.5%.

## Materials provided

| Common component | 10L | 15 L | 20 L |
|---|---|---|---|
| Sheath Fluid | 1 Bucket | 1 Bucket | 1 Bucket |
| Instructions for use | 1 pc | 1 pc | 1 pc |
| CPU Card | 1 pc | 1 pc | 1 pc |

## Operating principle
The sheath fluid used by the analytical system in the testing process is an isotonic, particle-free, buffered solution, which can ensure that the formed particles of the urine sample always flow in a monolayer and independent manner. Flow cytometry is used to ensure that each formed particle flows from the microscope lens and the CCD camera within the focus range of the microscope lens, and then is captured and imaged at high speed.

## Storage and stability
1. Validity period: 12 months if sealed and stored at 4°C-30°C, dry, and kept away from sunlight, sealed; 60 days after opening if stored at 4°C-30°C, and kept away from sunlight.
2. See the label for the manufacture date and expiry date.

## Applicable instruments
Urine sediment analyzer (model: U2600, U2601, U2602, U2610, U2611, U2612), and Urinalysis hybrid system (model: U3600, U3601, U3602) manufactured by Zybio Inc.
Other models shall be used after verification.

## Usage
The CPU card is used for replenishing the sheath fluid volume in the instrument.
1. Press the dot-lined round part on the packaging box of sheath fluid to open a round hole on the packaging box.
2. Pull up the container lid with the container neck stuck by the round hole.
3. Rotate to open the lid, keep the lid retained to prohibit foreign matter from entering the container.
4. Insert the sheath fluid sensor upright into the sheath fluid container. Tight the container lid of the sensor onto the container mouth.
5. Open the charging interface of the CPU of the lower computer software, Insert the CPU card into the card reading port of the host.
6. Pop out the charging confirmation interface of the sheath liquid card, and click OK, that is, the charging is complete.
For more details, refer to the operation manual for applicable instruments.

## Performance characteristics
1. pH: 7.50 ± 0.50.
2. Conductivity: 9-15 mS/cm.
3. Osmolarity: 200-300 mOsmol/kg.
4. Particle counting: less than 8 on the average, and no more than 15 on the maximum.

## Warnings and precautions
1. Instructions for use must be carefully followed. It is for in vitro diagnostic use only.
2. If the sheath fluid contacts the mouth or eyes or skin, rinse immediately with water and seek medical advice if necessary.
3. The disposal of liquid waste should be by local laws and regulations.
4. Check before use， and do not use in case of flocculent precipitation, turbidity, and other pollution phenomena.
5. Do not use it after being exposed to the air with the cap opened or in direct sunlight for a long time.
6. This product does not contain human components but contains chemical components, which may have potential risks of hazardous chemicals. Appropriate protective measures shall be taken during sample collection, treatment, storage, and testing.

## Symbol Interpretation

| Symbol | Title and Description | Symbol | Title and Description |
|---|---|---|---|
| IVD | In vitro diagnostic medical device | LOT | Batch code |
| | Consult instructions for use | | Use-by date |
| CE | CE marking of conformity | | Manufacturer |

# Sheath Fluid

| | | | |
|---|---|---|---|
| EC REP | Authorized Representative in the European Community |  | Temperature limit |
| REF | Catalogue number |  | Keep away from sunlight |
|  | Date of manufacture |  | Warning |

**References**

1. Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline—Third Edition, from NCCLS Document GP16-A, 2009.
2. Cong Yulong, Ma Junlong, et al. Modern Urinalytical Technology and Clinic Application, China Science and Technology Press, 1998.

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Current Revision and Release Date: 03, 2022-11

# Turbidity Calibrator

## Specifications

| REF | Specifications |
|---|---|
| 01.09.1F.01.16.02 | 2 levels×1×8 mL |

## Intended purpose

This product is used for calibration of the turbidity module of urine chemistry analyzer and urinalysis hybrid system.

## Test principles

The calibrator of a known concentration is measured for the purpose of calibration on the detection system, so as to establish the metrological traceability of the measurement result of this system.

## Materials provided

| Common component | 2 Levels |
|---|---|
| Turbidity Calibrator | 2 bottles |
| Instructions for use | 1 pc |

Note:

| Indicated value | Uncertainty |
|---|---|
| See bottle label | See bottle label |

Traceability: traceable to GBW12001 standard.

## Materials required (but not provided)

Urine analyzer, general laboratory equipment.

## Storage and stability

1. Unopened: the validity period is 12 months when stored under 2–8℃ and kept away from sunlight.
2. Opened: the validity period is 7 days when stored under 2–8℃ and kept away from sunlight.
3. See packaging label for date of manufacture and expiry date.

## Applicable instruments

Zybio Urine chemistry analyzer (model: U1600, U1601, U1602), Urinalysis hybrid system (model: U3600, U3601, U3602).

## Assay procedure

Please follow the instructions of this product and the instructions of the applicable instruments.
1. Calibration shall be performed in case of invalid control for instrument or based on a monthly interval. Calibrators with 2 levels must be used for calibration.
2. Before use, leave the control under room temperature for 30 minutes.
3. Gently invert it several times to homogenize it.
4.During test with urine chemistry analyzer: set the instrument at calibration status. Pour the calibrator into a dry and clean test tube. Place the test tube on the target position for calibration of the instrument.
5.After the calibration is completed, the instrument will display successful calibration. If the calibration has failed, please check whether the calibrator is expired and whether the instrument works normally.

## Performance characteristics

Accuracy: correctness of measuring value transfer $|En| \leqslant 1$.
Homogeneity:
1) $CV_{within\text{-}bottle} \leqslant 5\%$;
2) $CV_{between\text{-}bottle} \leqslant 5\%$.

## Precautions

1. This product is only applicable to the calibration of turbidity module of urine chemistry analyzer or urinalysis hybrid system. Please do not use it for other purposes.
2. The value assignment of calibrators varies with different batches. See bottle label for specific indicated value.
3. Avoid contact with the skin and eyes. If this product is splashed into eyes, rinse with running warm water for several minutes; seek medical treatment immediately if pain or swelling occurs. In case of contact with skin, rinse the skin with soapy water, and completely rinse off the product with clean water.
4. Please use this product as required in the instructions. The accuracy of the results cannot be guaranteed for purposes other than the prescribed instructions and intended purpose.
5. Routine precautions for laboratory operations must be followed when this product is used.
6. The calibrator disposal and the containers that have been in contact with the control shall follow the relevant waste regulations such as medical waste or industrial waste. All waste shall be treated as a potential infection source.
7. The calibrator that was opened shall be sealed and stored as instructed, and do not use expired product.
8. This product shall be stored as instructed, and kept away from direct sunlight during operation.

## Symbol interpretation

| Symbol | Title and Description | Symbol | Title and Description |
|---|---|---|---|
| IVD | In vitro diagnostic medical device | | Date of manufacture |
| LOT | Batch code | | Use-by date |
| | Consult instructions for use | | Temperature limit |
| | Keep away from sunlight | REF | Catalogue number |
| CE | CE marking of conformity | | Manufacturer |
| EC REP | Authorized Representative in the European Community | | |

## References

1. Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved

Guideline—Third Edition，from NCCLS Document GP16-A, 2009.
2. Cong Yulong, Ma Junlong, et al. Modern Urinalytical Technology and Clinic Application, China Science and Technology Press, 1998.
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IFU Revision: 02 Release date: 2022-05-20

# Turbidity Control

## Specifications

| REF | Specifications |
|---|---|
| 01.09.1F.01.06.04 | Level 1: 1×8 mL |
| 01.09.1F.01.06.05 | Level 2: 1×8 mL |
| 01.09.1F.01.06.06 | Level 3: 1×8 mL |
| 01.09.1F.01.06.03 | 3 levels×1×8 mL |

## Intended purpose

This product is applicable to the QC test of Urine Chemistry Analyzer and Urinalysis Hybrid System.

## Test principles

The QC of the test system is performed by measuring a control with a known concentration, to ensure the reliability of results from the instrument.

## Materials provided

| Common component | Level 1 | Level 2 | Level 3 | 3 levels |
|---|---|---|---|---|
| Turbidity control | 1bottle | 1bottle | 1bottle | 3bottles |
| Instructions for use | 1 pc | 1 pc | 1 pc | 1 pc |

Note: the control assigned value of different batches is slightly different and has batch specificity. For details, please refer to the product target value sheet. Reagents from different batches cannot be mixed.

## Materials required (but not provided)

Urine analyzer, general laboratory equipment.

## Storage and stability

1. Unopened: the validity period is 12 months when stored under 2-8°C and kept away from sunlight. The product can't be stored under frozen conditions.
2. Opened: the validity period is 30 days when stored under 2-8°C and kept away from sunlight. The product can't be stored under frozen conditions.
3. See packaging label for date of manufacture and expiry date.

## Applicable instruments

Zybio Urine chemistry analyzer (model: U1600, U1601, U1602), Urinalysis hybrid system (model: U3600, U3601, U3602).

## Assay procedure

Refer to the instructions on this product and the instructions on compatible instruments.
1. The QC test shall be performed before the instrument restart or daily test, and controls 2 levels or more shall be used for QC as much as possible.
2. Before use, leave the control under room temperature for 30 minutes.
3. To use it, gently invert it several times to homogenize it.
4. During test with urine chemistry analyzer: put the instrument at QC status, pour the control into a dry and clean test tube, place the test tube at a test position in a compatible instrument for testing.
5. The test result shall be consistent with the indicated result. If not consistent, the user shall check the detection system, such as the validity period of the control, performance and status of instrument, etc.

## Performance characteristics

Test value: the test result is the same as the indicated value.
Uniformity: consistency of test results ⩾90%.

## Precautions

1. This product is only applicable to the QC of turbidity module of urine chemistry analyzer or urinalysis hybrid system. Please do not use it for other purposes.
2. Avoid contact with the skin and eyes. If this product is splashed into eyes, flush with running warm water for several minutes; seek medical treatment immediately if pain or swelling occurs. In case of contact with skin, rinse with soapy water, and completely rinse off the product with clean water.
3. Please use this product as required by the instructions. The accuracy of the results cannot be guaranteed for purposes other than the prescribed instructions and intended purpose.
4. Routine precautions for laboratory operations must be followed when this product is used.
5. The control disposal and the containers that have been in contact with the control shall follow the relevant waste regulations such as medical waste or industrial waste. All waste shall be treated as a potential infection source.
6. The control that was unsealed shall be sealed and stored as instructed, and do not use expired products.
7. This product shall be stored as instructed, and kept away from direct sunlight during operation.

## Symbol interpretation

| Symbol | Title and Description | Symbol | Title and Description |
|---|---|---|---|
| IVD | In vitro diagnostic medical device | | Date of manufacture |
| LOT | Batch code | | Use-by date |
| | Consult instructions for use | | Temperature limit |
| | Keep away from sunlight | REF | Catalogue number |
| CE | CE marking of conformity | | Manufacturer |
| EC REP | Authorized Representative in the European Community | | |

# Turbidity Control

## References

1. Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline—Third Edition，from NCCLS Document GP16-A, 2009..
2.Cong Yulong, Ma Junlong, et al. Modern Urinalytical Technology and Clinic Application, China Science and Technology Press, 1998.
3.Cong Yulong, Ma Junlong, et al. Practical Urinalytical Technology and Clinical Application, People's Health Publishing House, first edition, September, 2013.

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IFU Revision: 02 Release date: 2022-05-20

zybio

CE IVD

# UDC-Control

## Specifications

| REF | Specifications |
|---|---|
| 01.09.1F.01.03.05 | Negative: 8 mL×1; |
| 01.09.1F.01.03.06 | Positive: 8 mL×1; |
| 01.09.1F.01.03.04 | Negative: 8 mL×1;<br>Positive: 8 mL×1 |

## Intended purpose

The product is applicable to the QC of the urine chemistry analyzer and urinalysis hybrid system. QC can be performed on analysis strips and instruments for 13 test items, i.e., urobilinogen (URO), bilirubin (BIL), ketone (KET), leukocyte (LEU), nitrite (NIT), protein(PRO),blood(BLD),microalbumin(mALB),creatinine (CRE), glucose(GLU), specific gravity (SG), pH, and calcium (Ca).

## Test principles

The urobilinogen substitute, bilirubin substitute, ketone substitute, leukocyte substitute, nitrite, protein, ionic, erythrocyte substitute, glucose, creatinine, calcium, etc. contained in the urine can react chemically with the urinalysis strip, which makes the strip color change.

## Materials provided

| Common component | Negative control | Positive control | Combination |
|---|---|---|---|
| UDC-Control | 1 bottle | 1 bottle | 2 bottles |
| Instructions for use | 1 pc | 1 pc | 1 pc |

Note: Control target values are batch-specific.

## Materials required (but not provided)

Urine analyzer, general laboratory equipment.

## Precautions

- Before use, please restore the control to 18-30°C, and invert the bottle several times to homogenize it.
- When using, avoid contact with the eye and skin; if accidentally in contact, please rinse with water immediately; tighten the cap immediately after use and store it at 2–8°C.
- The control is only used by personnel with professional skills in medical and health departments and laboratories. It is only applicable to daily indoor QC and external quality assessment, but not so to calibration as calibrators.
- The test tube containing the control shall be clean and dry to prevent residual detergent or other substances from interfering with the measurement result.
- The urine chemistry analyzer shall use matching urinalysis strips to ensure the accuracy of QC.
- The user shall not touch the reagent part of the urinalysis strip used for QC. The urinalysis strip slot shall be kept clean to prevent the reagent block from being contaminated and affecting the QC result. During the test, the urinalysis strip shall be placed at the correct position in strip slot to avoid deviation of test results.

## Storage and stability

1. Unopened: the validity period is 12 months when stored under 2-8°C and kept away from sunlight. The product can't be stored under frozen conditions.
2. Opened: the validity period is 30 days when stored under 2-8°C and kept away from sunlight.
3. See packaging label for date of manufacture and expiry date.

## Applicable instruments

Zybio Urine analyzer (model: EXU300, EXU500)，Urine chemistry analyzer (model: U1600, U1601, U1602), Urinalysis hybrid system (model: U3600, U3601, U3602).

## Assay procedure

1. The controls shall be restored to room temperature and mixed by gently inverting the bottle a few times before use.
2. During a test with a semi-automated urine chemistry analyzer: take out the control. Homogenize the control until it is restored to the environmental temperature. Pour an appropriate amount of the control into a dry and clean test tube. Completely immerse the prepared urinalysis strip into the urine control inside. Soak the strip and take it out (if the method of giving the sample in a dropping bottle is used, drop the homogenized control on the urinalysis strip, and ensure that the urine test strip is soaked). Use filter paper (or other strongly absorbent paper) to absorb excess urine control on the test strip, and then put the strip on the urinalysis strip slot correctly for testing.
3. When testing with a urine chemistry analyzer: put the instrument at QC status. Pour the control into a dry and clean test tube. Place the test tube at a test position in a compatible instrument for testing.

## Interpretation of test result

1. Testing under too high or too low temperature outside of the 10°C–30°C range, or in an environment with excessive humidity (⩾80% RH), the QC results may deviate from the QC range.
2. When operating strictly according to the operation manual, if the result exceeds the QC range in the attached table, it suggests that the control over urine chemistry analyzer and the supporting urinalysis strip test system may be invalid. If the factor of the QC material is then excluded, the control over the test system can be considered as invalid.

## Performance characteristics

Control test value: the test result of each item shall be within the target value range.

## Limitations

The bilirubin and urobilinogen in the control are substituted by chemicals; the strip reacts with them to render color, and this color is slightly different from that rendered with the direct bilirubin and urobilinogen in urine.

# UDC-Control

## Symbol interpretation

| Symbol | Title and Description | Symbol | Title and Description |
|---|---|---|---|
| IVD | In vitro diagnostic medical device | | Date of manufacture |
| LOT | Batch code | | Use-by date |
| | Consult instructions for use | | Temperature limit |
| | Keep away from sunlight | REF | Catalogue number |
| CE | CE marking of conformity | | Manufacturer |
| EC REP | Authorized Representative in the European Community | | |

## References

1. Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline—Third Edition，from NCCLS Document GP16-A, 2009.
2. Cong Yulong, Ma Junlong, et al. Modern Urinalytical Technology and Clinic Application, China Science and Technology Press, 1998.

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IFU Revision: 02 Release date: 2022-05-20

# Urinalysis Strip (Dry Chemistry Method)

## Specifications

| Model | Test item | REF | Spec. |
|---|---|---|---|
| 11FU | Urobilinogen, Bilirubin, Ketone, Leukocyte, Nitrite, Protein, Blood, Glucose, Specific gravity, pH, Vitamin C | 01.09.1F.01.01.04 | 100 Tests |
| 12FU | Urobilinogen, Bilirubin, Ketone, Leukocyte, Nitrite, Protein, Blood, Microalbumin, Glucose, Specific gravity, pH, Vitamin C | 01.09.1F.01.01.05 | 100 Tests |
| 14FU | Urobilinogen, Bilirubin, Ketone, Leukocyte, Nitrite, Protein, Blood, Microalbumin, Creatinine, Glucose, Specific gravity, pH, Vitamin C, Calcium | 01.09.1F.01.01.06 | 100 Tests |

## Intended purpose

The urinalysis strips are used for in vitro qualitative and semi-quantitative detection of urobilinogen (URO), bilirubin(BIL), ketone (KET), leukocyte (LEU), nitrite(NIT) , protein(PRO), blood (BLD), microalbumin (mALB) , creatinine(CRE), glucose (GLU), specific gravity (SG) , pH,Vitamin C(Vc) and calcium (Ca) in human urine.

## Summary and explanation

It is mainly used for the auxiliary diagnosis of glucose, renal, liver, acid-base balance, and urinary tract infections. The strips are only used for clinical examination screening tests in hospitals.

## Test principle

1.Urobilinogen(URO):the urobilinogen couples with diazonium salt under strongly acidic condition to produce fuchsia dye.
2.Bilirubin(BIL):the direct bilirubin couples with dichloroaniline diazonium salt under acidic condition to produce an azo dye.
3.Ketone (KET): the acetoacetic acid reacts with sodium nitroferricyanide under alkaline condition to form fuchsia compound.
4. Leukocyte (LEU): the phenolic ester is hydrolyzed by esterase in neutrophil to form free phenol, which couples with diazonium salt to produce purple azo dye.
5.Nitrite (NIT): the diazotization reaction of nitrite and sulfonamide produces diazo compound, and the diazo compound couples with tetrahydrobenzoquinolin-3-ol to produce red azo dye.
6.Protein (PRO): the anion produced by pH indicator combines with the protein with cation to produce compound, which promotes the further ionization of the pH indicator and makes its color change. This phenomenon is called the error method of indicator protein.
7.Blood (BLD): the hemoglobin has peroxidase-like activity, with which peroxide can be decomposed to release nascent oxygen (O), and the nascent oxygen (O) oxidizes the indicator and makes its color change.
8.Microalbumin (mALB): it is tested by sulfophthalein dye with high sensitivity to albumin according to the principle of protein error.
9.Creatinine (CRE): the creatinine reacts with the 3,5-dinitrobenzoic acid to produce colored compound under strongly alkaline condition.
10.Glucose (GLU): the glucose monohydrate produces gluconic acid and hydrogen peroxide under the action of glucose oxidase. Under the action of peroxidase, the hydrogen peroxide releases nascent oxygen (O); the nascent oxygen (O) oxidizes potassium iodide, and the color changes.
11.Specific gravity (SG): the methyl vinyl ether-maleic acid copolymer is a weakly acidic (-COOH group) ion exchanger. The M+ cation (mainly Na+) in the electrolyte (M+X-) that exists in the form of salt in urine reacts with the ion exchanger to replace the hydrogen ion. The hydrogen ion reacts with the acid-base indicator to change its color.
12.pH: the acid-base indicator method is used.
13.Vitamin C (Vc):The ascorbic acid has a reducing group of 1,2-enediol, which, in alkaline condition, reduces the oxidized blue 2,6-dichlorophenol indophenol dye to colorless 2,6-dichlorobis-p-phenolamine.
14.Calcium (Ca): the calcium ion reacts with o-cresolphthalein complexone to produce fuchsia color, and the color depth is proportional to the concentration of the calcium ion.

## Materials provided

| Common component | Quantity |
|---|---|
| Urinalysis strip (Including: PET substrate, test paper, double-sided tape, blank block) | 100 strips |
| Instructions for use | 1 pc |
| Strip bottle | 1 bottle |

## Materials required (but not provided)

Detection instrument, quality controls, general laboratory equipment.

## Precautions

1.This reagent is for in vitro diagnostic use only.
2. It is for professional use only.
3.The strip must be stored in the original container; unless it is to be used immediately, the strip must not be taken out of the vial; re-cap immediately after removing the strip. Do not remove the desiccant.
4.Do not use expired products. The deterioration of the strip will make the color of the reaction zone lighter or darker. If the test result is inconsistent with the expected result, please check the strip for whether it is still valid and use the control for the test.
5.Water cannot be used as a negative control.
6.If the strip is not completely immersed in urine, uneven coloring may be caused and judgment may be affected.
7.When the strip is taken out of the urine, immediately remove the excess urine so as not to affect the result.
8.This product is for single use only. Please read the operation manual carefully before use, and operate in strict accordance with the requirements of the manual. Any operation or sample type that is not according to the requirements of the manual may cause an erroneous result. If the test result is abnormal or





# Urinalysis Strip (Dry Chemistry Method)

there is any doubt about the test result, the test shall be conducted again, and further verification shall be done in combination with other clinical results.
9.Do not store this product in the refrigerator. Do not touch the test areas on the strip.
10.This product does not contain human-derived components, but contains chemical components, even some hazardous chemicals with potential risks. All samples and reaction wastes shall be treated as potential sources of infection. Appropriate protective measures shall be taken during sample collection, handling, storage, and the entire testing process. After being used, the product shall be treated as a biological pollutant and disposed in accordance with local regulations

## Storage and stability

1.Unopened: the validity period is 12 months when stored under 4–30°C and kept away from sunlight.
2.Opened: the validity period is 3 months when stored at a cool and dry place under 4–30°C. Keep bottles tightly closed when not in use.
3.See packaging label for date of manufacture and expiry date.

## Sample requirements

1.Collect fresh urine in a clean, dry container, and conduct the test as soon as possible.
2.The storage time of the urine sample at ambient temperature shall not exceed 1 hour. Otherwise, the urine sample shall be stored in a refrigerator of 2–8°C, and the measurement shall be done within 2 hours. When taken out, the refrigerated urine sample shall be restored to the ambient temperature, and stirred and shaken for homogenization before the test.
3.Do not add preservatives to the urine sample.
4.The urine sample shall not be centrifuged. Thoroughly mix the urine sample before the test.

## Applicable instruments

Zybio Urine chemistry analyzer (model: U1600, U1601, U1602), and Urinalysis hybrid system (model: U3600, U3601, U3602).

## Assay procedure

This product can be used for both instruments and visual reading. To make test result more reliable, please read the operation manual carefully before the test.
Working temperature: 10–30°C, humidity: ⩽80%.
1. Visual reading:
① Immerse all of the test areas on the strip into the sample and take it out immediately;
② Remove the excess urine;
③ Compare the test area on the strip with the color scale, and the result shall be read and recorded within 1–2 minutes. A result read after 2 minutes is invalid.
2. Instrument measurement:
Please follow operation instructions on testing of the selected instrument.

## Reference interval

Reference value of normal human urine for urinalysis strip:

| Item | Reference | Item | Reference |
|---|---|---|---|
| URO | 3.4–17 μmol/L | mALB | ＜30mg/L |
| BIL | 0 μmol/L | CRE | 4.4-17.7mmol/L |
| KET | 0mmol/L | GLU | ＜2.8mmol/L |
| LEU | 0 Leu/μL | SG | 1.010-1.025 |
| NIT | 0mg/dL | pH | 5.5-7.0 |
| PRO | ＜15mg/dL | Vc | 0mmol/L |
| BLD | ＜10 Ery/μL | Ca | 2.5-7.5mmol/L |

Reference value is determined based on the clinical urine test results of 200 healthy people. It is recommended that each laboratory establish its own reference range.

## Interpretation of test result

1.Magnitude setting of test result

| Strip zone | Magnitude setting | | | | | | |
|---|---|---|---|---|---|---|---|
| URO | μmol/L | 3.4 | 17 | 34 | 68 | 135 | / |
| | Semi-quantitative symbol | Norm | Norm | 1+ | 2+ | 3+ | / |
| BIL | μmol/L | 0 | 17 | 51 | 103 | / | / |
| | Semi-quantitative symbol | - | 1+ | 2+ | 3+ | / | / |
| KET | mmol/L | 0 | 0.5 | 1.5 | 3.9 | 7.8 | 16 |
| | Semi-quantitative symbol | - | ± | 1+ | 2+ | 3+ | 4+ |
| LEU | Leu/μL | 0 | 15 | 70 | 125 | 500 | / |
| | Semi-quantitative symbol | - | ± | 1+ | 2+ | 3+ | / |
| NIT | mg/dL | 0 | 0.125 | 0.25 | / | / | / |
| | Semi-quantitative symbol | - | 1+ | 2+ | / | / | / |
| PRO | g/L | 0 | 0.15 | 0.3 | 1 | 3 | ⩾20 |
| | Semi-quantitative symbol | - | ± | 1+ | 2+ | 3+ | 4+ |
| BLD | Ery/μL | 0 | 10 | 25 | 80 | 200 | / |
| | Semi-quantitative symbol | - | ± | 1+ | 2+ | 3+ | / |
| mALB | mg/L | 10 | 30 | 80 | 150 | / | / |
| CRE | mmol/L | 0.9 | 4.4 | 8.8 | 17.7 | 26.5 | / |
| GLU | mmol/L | 0 | 2.8 | 5.6 | 14 | 28 | 56 |
| | Semi-quantitative symbol | - | ± | 1+ | 2+ | 3+ | 4+ |
| SG | value | 1.000, | 1.005, | 1.010, | 1.015, | 1.020, | 1.025, 1.030 |
| pH | value | 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0 | | | | | |
| Vc | mmol/L | 0 | 0.6 | 1.4 | 2.8 | 5.7 | / |
| Ca | mmol/L | 1 | 2.5 | 5 | 7.5 | ⩾10 | / |

**1.URO:** in this test area, urobilinogen with a concentration as low as 3 μmol/L (about 0.2 Ehrlich) in urine can be detected. The normal content is 3.4–17 μmol/L. A result of 33 μmol/L may be the critical value between normal and abnormal state, which needs further examination. A negative result of this test does not mean that urobilinogen is not present in the sample.

**2.BIL:** under normal circumstances, the presence of bilirubin in urine cannot be detected even using the most sensitive method. The presence of a trace amount of bilirubin in urine will produce positive results, which requires further examination. Certain drug metabolites that show color at lower pH values, such as phenazopyridine, will interfere with the detection of bilirubin. A high concentration of Vitamin C may lead to false negative results in samples with bilirubin

# Urinalysis Strip (Dry Chemistry Method)

concentration around 17 μmol/L.

**3.KET:** the reagent of this part reacts with acetoacetic acid in urine, not with acetone or β-hydroxybutyric acid. Normal urine will generally only give negative results. False positive results may be produced from urine samples containing pigments or large amounts of levodopa metabolites.

**4.LEU:** this strip reacts with esterases in leukocytes (neutrophils), and the normal urine samples produce negative test results. A single critical result is clinically dubious; however, if such result appears repeatedly, it is indicative of highly clinical significance. Due to the contamination of vaginal excretions, a positive result is occasionally obtained in randomly selected female urine samples. The high specific gravity urine will produce lower test results.

**5.NIT:** nitrite reductase in Gram-negative bacterium in urine will reduce nitrate (extracted from food) to nitrite. This test is specific to nitrite, which doesn't react with other substances excreted in normal urine. Pink spots or lines shall not be determined as positive, while any pink coloration shall be determined as a positive result, indicating the presence of 100,000 or more Gram-negative bacteria per milliliter in the sample. However, the degree of coloration is not proportional to the number of cells present, and the negative result doesn't confirm the absence of a large number of cells. Negative results may appear in the following situations: the facts that the urine does not contain reductase microorganisms that can cause the nitrate-to-nitrite conversion, the diet lacks nitrate, and the urine does not remain in the bladder for more than 4 hours, result in the impossibility to complete the nitrate-to-nitrite conversion. The reactivity of this test will be reduced for high-specific-gravity urine samples. When Vitamin C concentration is ⩾1.4mmol/L, samples with nitrite concentration around 0.125mg/dL may show false negative results.

**6.PRO:** although the protein test area is more sensitive to albumin than globulin, hemoglobin, Bence-Jones protein and mucoprotein, a "negative" result cannot rule out the existence of these proteins. Normal people will excrete a small amount of protein, which cannot be detected by general normal methods. If the color is deeper than "±", it means that the urine contains protein. False-positive results may be caused highly buffered alkaline urine, or if the urine sample is contaminated with a quaternary ammonium compound, or a certain preservative or detergent.

**7.BLD:** the critical reaction has different meanings for different patients. For a rare case, its determination requires clinical examination before a definite diagnosis can be made. If green spots (intact erythrocytes) and green color (hemoglobin/myoglobin) appear in the reaction zone within 60 seconds of adding the sample, this then means that the patient needs to be further examined. This test is very sensitive to blood erythrocytes, so it can be used to supplement microscopy. The sensitivity of this strip is slightly lower for high-specific-gravity urine, and this strip has the same sensitivity for hemoglobin and myoglobin. Certain oxidizing contaminants, for example hypochlorite can cause false positive results. Discharge that accompanies a urinary tract infection can also cause false-positive results. The result of blood test with urine from menstrual females is usually positive. When Vitamin C concentration is ⩾1.4mmol/L, samples with blood concentration around 10Ery/μL may show false negative results.

**8.CRE:** the creatinine concentration in normal adult urine is 0.6–2.0 g/24 hours (the test result of the strip is about 4.4–17.7 mmol/L), and the creatinine test result of random urine samples varies greatly, within the range of 0.9–26.5mmol/L. The content in concentrated urine and morning urine is higher (the test result of the strip may be higher than 17.7mmol/L); urine dilution due to polyuria, excessive drinking of water or other conditions will result in typical low-concentration urine.

**9.mALB:** this test area is used for the detection of urinary albumin. A 150 mg/L test result indicates clinical proteinuria. The microalbumin strip can sensitively detect albumin in urine, and its sensitivity to other proteins is nine times lower than that to albumin.

**10.GLU:** this test area is specific to glucose. Only glucose in urine will produce positive result. When Vitamin C concentration ⩾2.8 mmol/L and acetoacetic acid ⩾1.0 mmol/L, samples with glucose concentrations around 2.8 mmol/L may have false-negative results. Under normal circumstances a small amount of glucose may be discharged through the kidney, and usually such a small amount is below the sensitivity of this strip test.

**11.SG:** this reaction zone can be used to detect the specific gravity between 1.000 and 1.030 in urine. Generally, the error between the result of this test and the result obtained using the refraction coefficient method is within 0.005. In order to improve its accuracy, when the pH value of urine is equal to or greater than 6.5, 0.005 shall be added to the visual reading of urine specific gravity. The urine chemistry analyzer automatically makes adjustment for this when reading the strip. The test is not affected by some of the non-ionic components in the urine, such as glucose, and is also not affected by opaque dyes. Highly buffered alkaline urine will give lower readings under this method than other methods. When the urine contains protein (1 g/L–7.5 g/L), the specific gravity reading can be on the high side.

**12.pH:** the measurement range of the pH is 5.0–9.0.

**13.Vc:** this test area is used to detect ascorbic acid in urine. Through the test of this item, the level of ascorbic acid in the human body can be known, and the impact of ascorbic acid on bilirubin, nitrite, blood, and glucose test results can be evaluated.

**14.Ca:** when a large amount of magnesium ion (>10 mmol/L) exists, the test result will be on the high side or even false positive.

## Performance characteristics

1. Accuracy: the difference between the test result and the label value of the corresponding reference shall not exceed one order of magnitude in the same direction, and there shall be no reverse difference. Negative results must not appear with the positive reference, and positive results shall not appear with the negative reference.
2. Repeatability: the consistency of test result shall not be less than 90%.
3. Limit of detection: the first non-negative magnitude shall be detectable for each test item except for specific gravity and pH.

## Limitations

1. This product can only be used for the measurement of urine, not for that of samples of other body fluids.





# Urinalysis Strip (Dry Chemistry Method)

2. pH: for samples that exceed the linear range, it may not be possible to find a corresponding block of similar color.
3. This product is for semi-quantitative or qualitative detection only. The limit of detection is set and verified according to the actual situation when using the product. The limit of detection for URO, CRE, mALB, and Ca is the concentration corresponding to the first order of magnitude. The limit of detection for other items is the concentration corresponding to the first non-negative magnitude. The specific limit of detection of each test item is shown in the following table:

| Test item | Limit of detection | Test item | Limit of detection | Test item | Limit of detection |
|---|---|---|---|---|---|
| URO | 3.4 μmol/L | PRO | 15 mg/dL | SG | / |
| BIL | 17 μmol/L | BLD | 10 Ery/μL | pH | / |
| KET | 0.5 mmol/L | CRE | 0.9mmol/L | Vc | 0.6 mmol/L |
| LEU | 15 Leu/μL | mALB | 10 mg/L | Ca | 1.0 mmol/L |
| NIT | 0.125mg/dL | GLU | 2.8 mmol/L | / | / |

## Technical assistance

For customer support, contact your local technical support provider or distributor.

## Symbol interpretation

| Symbol | Title and Description | Symbol | Title and Description |
|---|---|---|---|
| IVD | In vitro diagnostic medical device | | Use-by date |
| LOT | Batch code | | Temperature limit |
| | Consult instructions for use | | Do not re-use |
| | Date of manufacture | | Keep away from sunlight |
| REF | Catalogue number | Σ | Contains sufficient for <n> tests |
| CE | CE marking of conformity | | Manufacturer |
| EC REP | Authorized Representative in the European Community | | |

## References

1. Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline—Third Edition，from NCCLS Document GP16-A, 2009.
2.Cong Yulong, Ma Junlong, etc. Modern Urinalytical Technology and Clinic Application, China Science and Technology Press, 1998.
3.Cong Yulong, Ma Junlong, etc. Practical Urinalysis Technology and Clinical Application, People's Health Publishing House, first edition, September, 2013.

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IFU Revision: 02 Release date: 2022-05-20

# US-Calibrator

## Specifications

| REF | Specifications |
|---|---|
| 01.09.1F.01.10.05 | 30 mL/Bottle |
| 01.09.1F.01.10.04 | 60 mL/Bottle |
| 01.09.1F.01.10.03 | 125 mL/Bottle |

## Intended purpose

This product is applicable to the calibration of urine sediment analyzer or urinalysis hybrid system to ensure the accuracy of the instrument.

## Test principles

It is based on the principle of flow microscopy imaging. The particles in the sample pass through the thin-layer structure of the flow cell of the instrument with the thickness of monolayer cell, and the imaging area of the sediment is illuminated by a high-frequency light source after being shaped by the lighting component. At the same time, the camera takes pictures at the same frequency to form sediment images, which are then recognized and classified by the instrument. The instrument calculates the concentration of sediment in the sample (the number of particles per unit volume) according to the number of "particles" in the sample and the volume of the urine sample passing through the flow cell. The calibrator of a known concentration is measured for the purpose of calibration on the detection system, so as to establish the metrological traceability of the measurement result obtained from that system.

## Materials provided

| Common component | 30 mL | 60 mL | 125 mL |
|---|---|---|---|
| US-Calibrator | 1 bottle | 1 bottle | 1 bottle |
| Element | mouse blood | | |
| Instructions for use | 1 pc | 1 pc | 1 pc |

Note: this product is batch-specific. For the detailed target value, see the product label of each batch. Calibrators from different batches cannot be used together.

## Materials required (but not provided)

Urine analyzer, general laboratory equipment.

## Storage and stability

1. Unopened: the validity period is 12 months when stored under 2–8℃ and kept away from sunlight. The product can't be stored under frozen conditions.
2. Opened: the validity period is 30 days when stored under 2–8℃ and kept away from sunlight. The product can't be stored under frozen conditions.
3. See packaging label for date of manufacture and expiry date.

## Applicable instruments

Zybio Urine sediment analyzer (model: U2600, U2601, U2602, U2610, U2611, U2612), and Urinalysis hybrid system (model: U3600, U3601, U3602)

## Assay procedure

Please follow the instructions of this product and the instructions of the applicable instruments.
1. The instrument shall be calibrated based on a monthly interval.
2. Gently invert it several times to homogenize it.
3. During test with urine sediment analyzer/urinalysis hybrid system: set the instrument at calibration status. Pour the calibrator into a dry and clean test tube. Place the test tube on the target position for calibration of the instrument.
4. After the calibration is completed, the instrument will display successful calibration. If the calibration has failed, please check whether the calibrator is expired and whether the instrument works normally.

## Performance characteristics

1.Accuracy: after calibration is performed with the US-calibrator, the relative deviation of the measurement result shall not exceed ±15% when the enterprise reference material is measured;
2. Homogeneity:
2.1Within-bottle homogeneity: $CV_{within\text{-}bottle} \leqslant 15\%$;
2.2Between-bottle homogeneity: the between-bottle homogeneity of the counting results shall be good.

## Precautions

1.This product is applicable to the calibration of urine sediment analyzer or urinalysis hybrid system. Do not use it for other purposes.
2.Avoid contact with the skin and eyes. If this product is splashed into eyes, rinse it with running warm water for several minutes; seek medical treatment immediately if pain or swelling occurs; in case of contact with skin, rinse with soapy water, and completely rinse off the product with clean water.
3.Please use this product as required by the instructions. The accuracy of the results cannot be guaranteed for purposes other than the prescribed instructions and intended purpose.
4.Routine precautions for laboratory operations must be followed when this product is used.
5.The calibrator disposal and the containers that have been in contact with the calibrator shall follow the relevant waste regulations such as medical waste or industrial waste. All waste shall be treated as a potential infection source.
6.The calibrator that was opened shall be sealed and stored as instructed, and do not use expired product.
7.This product shall be stored as instructed, and kept away from direct sunlight during operation.

## Symbol interpretation

| Symbol | Title and Description | Symbol | Title and Description |
|---|---|---|---|
| IVD | In vitro diagnostic medical device | | Date of manufacture |

# US-Calibrator

| | | | |
|---|---|---|---|
| LOT | Batch code | | Use-by date |
| | Consult instructions for use | | Temperature limit |
| | Keep away from sunlight | REF | Catalogue number |
| CE | CE marking of conformity | | Manufacturer |
| EC REP | Authorized Representative in the European Community | | |

**References**


1. Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline—Third Edition，from NCCLS Document GP16-A, 2009.
2. Cong Yulong, Ma Junlong, et al. Modern Urinalytical Technology and Clinic Application, China Science and Technology Press, 1998.
3. Cong Yulong, Ma Junlong, et al. Practical Urinalytical Technology and Clinical Application, People's Health Publishing House, first edition, September, 2013.



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IFU Revision: 02 Release date: 2022-05-20

# Wash Solution

## Product Name

Wash Solution
Model: D21

## Specifications

| REF | Specifications |
|---|---|
| 01.09.1F.01.13.11 | 100 mL/Bottle |
| 01.09.1F.01.13.12 | 500 mL/Bottle |

## Intended purpose

The product is used for thoroughly cleaning the fluid path system of the applicable instruments, including the flow cell. It should be used by healthcare professionals and properly trained personnel.

## Operating Principle

Through hydrolysis, the sodium hypochlorite forms hypochlorous acid so as to achieve the disinfection and sterilization effect. The hypochlorous acid is further decomposed to form new ecological oxygen [O], so as to kill pathogenic microorganisms.

## Main Components

Sodium hypochlorite: 0.01%-0.5%.

## Storage and stability

1. Validity period: 12 months if sealed and stored at 4°C-30°C, dry, and kept away from sunlight; 60 days after opening if stored at 4°C-30°C and kept away from sunlight .
2. See the label for the manufacture date and expiry date.

## Applicable instruments

Urine chemistry analyzer (model: U1600, U1601, U1602), Urine sediment analyzer (model: U2600, U2601, U2602, U2610, U2611, U2612), and Urinalysis hybrid system (model: U3600, U3601, U3602) manufactured by Zybio Inc. Other models shall be used after verification.

## Usage

Wash Solution can be used for cleaning the fluid path of all the applicable instruments before shut down. Moreover, it can be used for cleaning the flow cell of Urine Sediment Analyzer and Urinalysis Hybrid System.

1. Fill the test tube with about 3 mL of wash solution, put it at the first position of the tube rack, and then put the tube rack on the right side of the rack-in module.
2. After confirming the cleaning operation, the test tube rack will be automatically pushed to the sample aspiration position, where the sample probe will aspirate about 2 mL of wash solution.
3. After soaking with the wash solution for about 3 minutes, shut down the instrument when you perform thorough cleaning, or repeat the operation of cleaning when you clean the flow cell.

For more instructions, refer to the operation manual for applicable instruments.

## Performance characteristics

pH ⩾9.00 at 25°C.

## Warnings and Precautions

1. Instructions for use must be carefully followed. It is for in vitro diagnostic use only.
2. Avoid contact with skin and eyes; In case of eye contact, please rinse with flowing warm water for several minutes. If it is painful or swollen, seek medical care immediately; In case of skin contact, rinse with soapy water and then rinse thoroughly with water.
3. This product does not contain biological components, but contains chemical components, which may have potential risks of hazardous chemicals. Appropriate protective measures shall be taken during sample collection, treatment, storage, and testing.

## Symbol interpretation

| Symbol | Title and Description | Symbol | Title and Description |
|---|---|---|---|
| IVD | In vitro diagnostic medical device | LOT | Batch code |
| | Consult instructions for use | | Use-by date |
| CE | CE marking of conformity | | Manufacturer |
| EC REP | Authorized Representative in the European Community | | Temperature limit |
| REF | Catalogue number | | Keep away from sunlight |
| | Date of manufacture | | Warning |

## References

1. Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline—Third Edition, from NCCLS Document GP16-A, 2009.
2. Cong Yulong, Ma Junlong, et al. Modern Urinalytical Technology and Clinic Application, China Science and Technology Press, 1998.

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