

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.

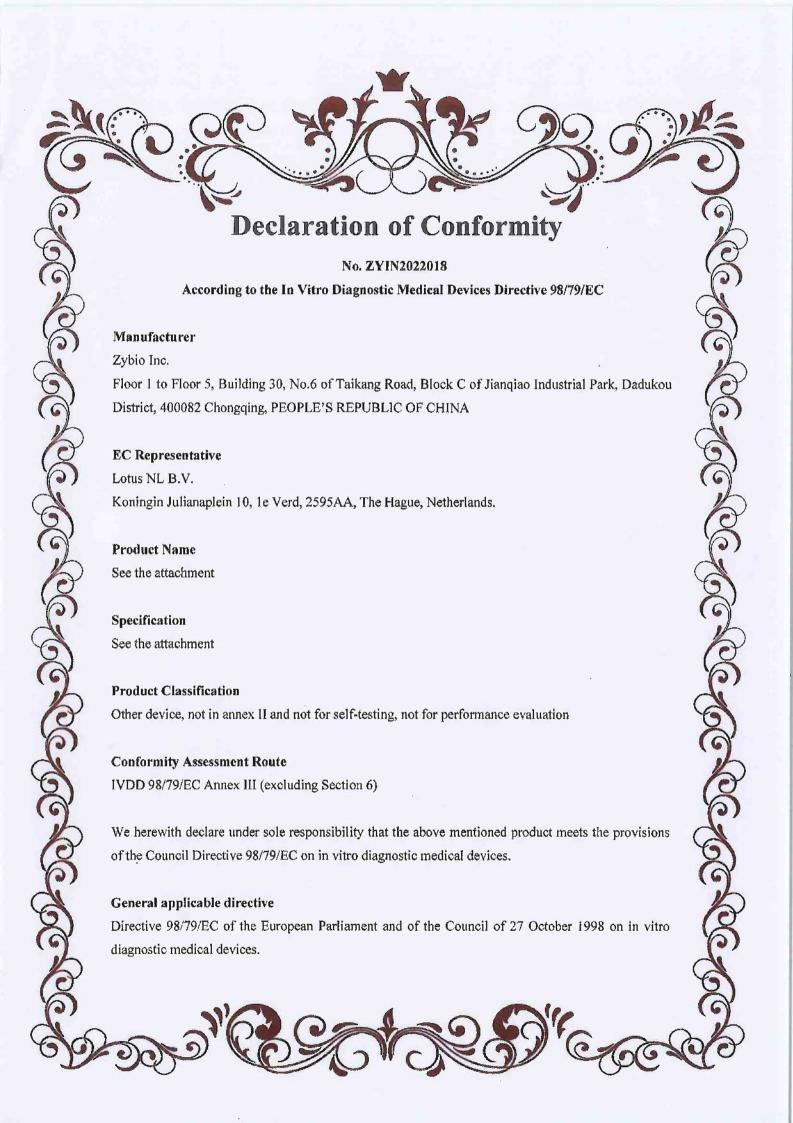
We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Place: Chongqing, China

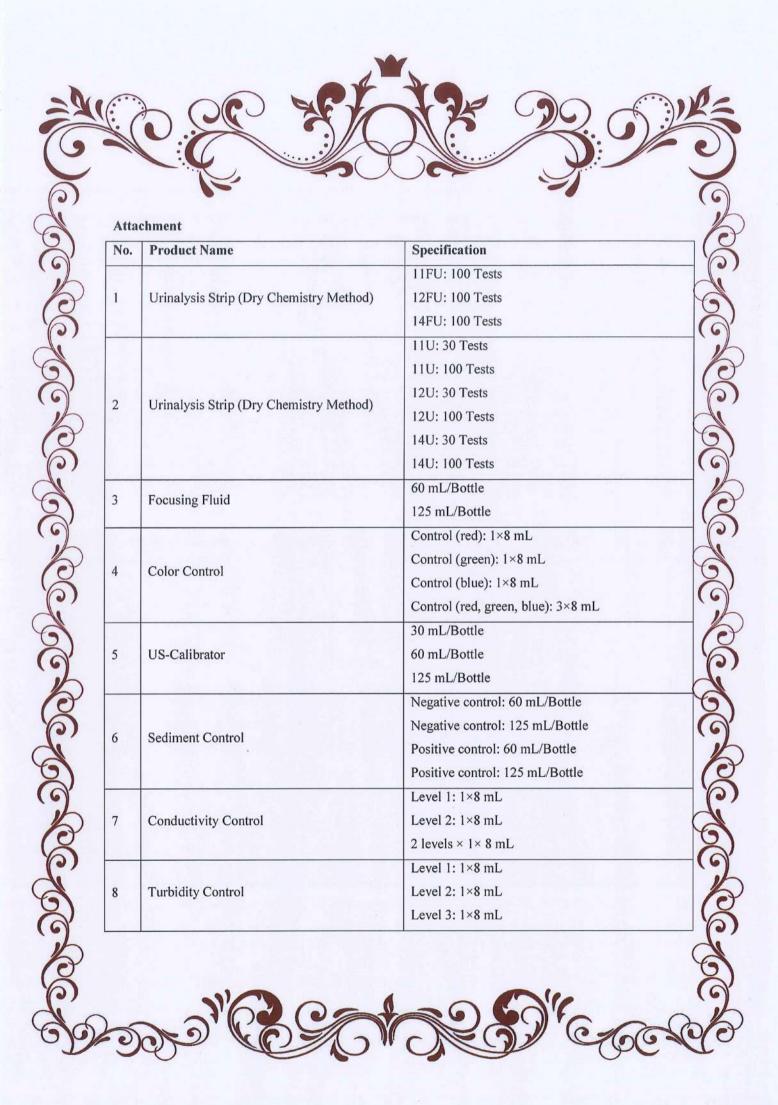


Floor 1 to Floor 5, Building 30, No.6 of Taikang Road,

Block C of Jianqiao Industrial Park, Dadukou District, Chongqing, China 400082







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



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

Chongging, China

Signature

Rui Shao

Name Position

DDDC

Date of issue

2022.12.29



Manufacturer

Name:

Zybio Inc.

Address:

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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 01.09.1F.01.11.12 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



Document ID: 212-011-XBZ-001

Version: 01



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

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Place

Chongqing, China

Signature

Rui Shao

Name Position

PRRC

Date of issue

2022-12-29.

Document ID: 212-011-XBZ-001



Manufacturer

Name:

Zybio Inc.

Address:

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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 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



Document ID: 212-012-XBZ-001

Version: 01



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

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EN 62366-1:2015

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Page 2 of 2



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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 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:

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Conformity Route: Self-Declaration of Conformity



Document ID: 212-014-XBZ-001

Version: 01



Relevant Harmonized Standards:

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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

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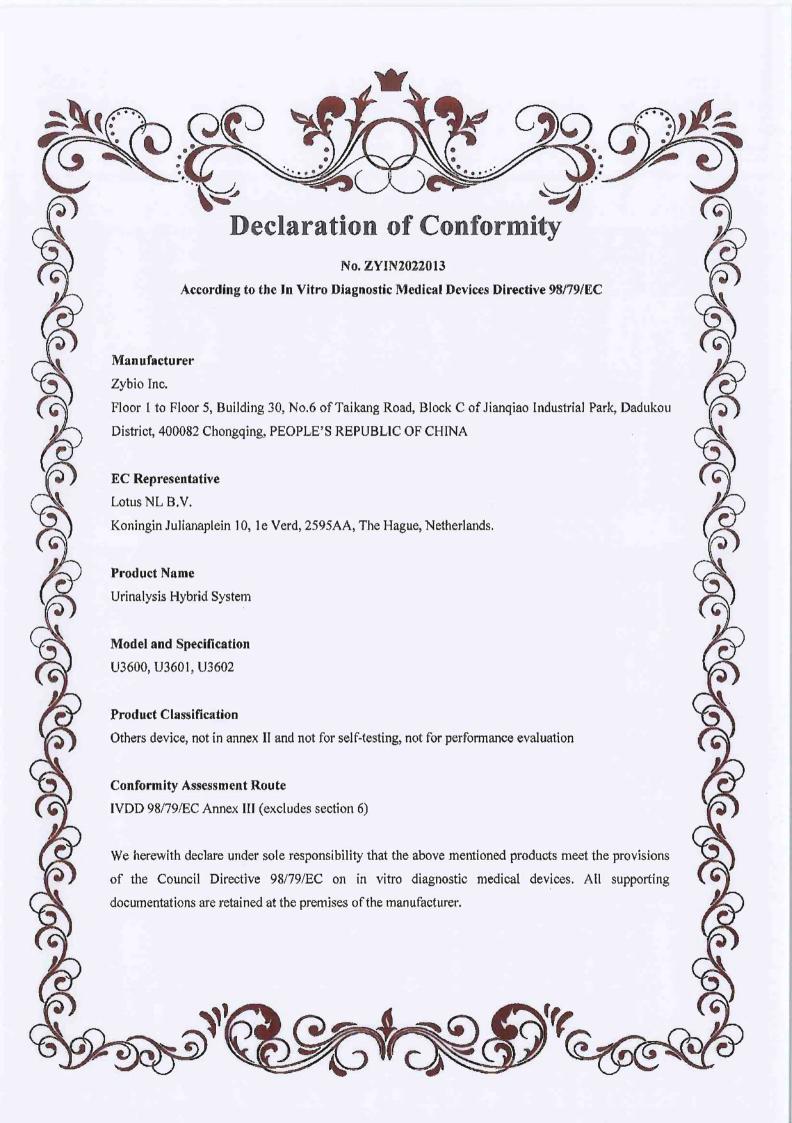
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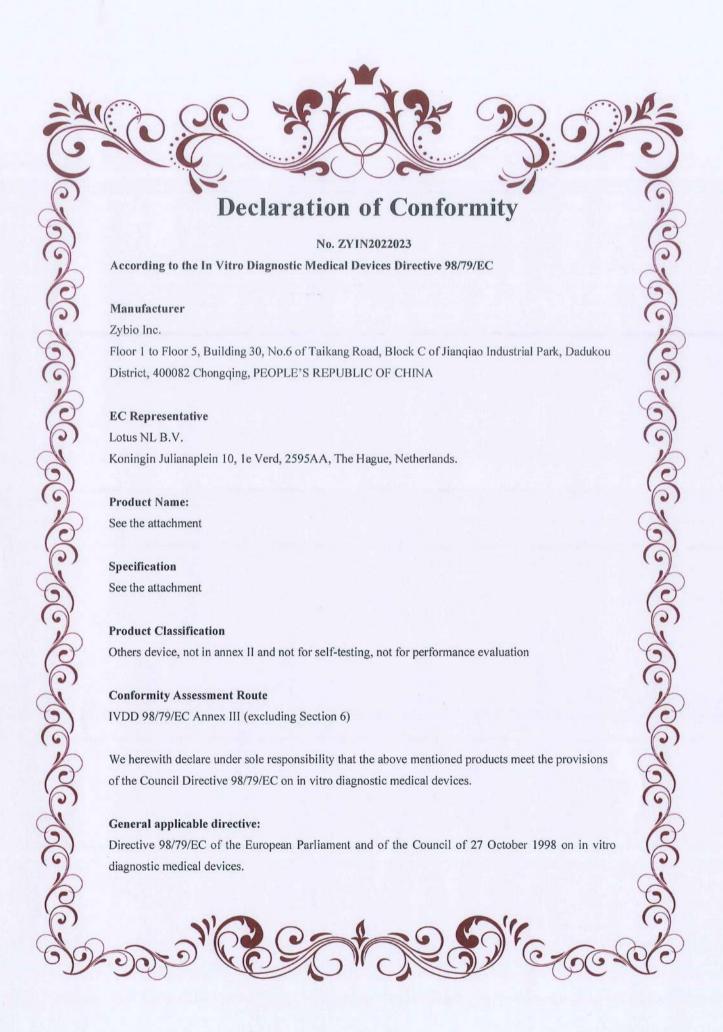
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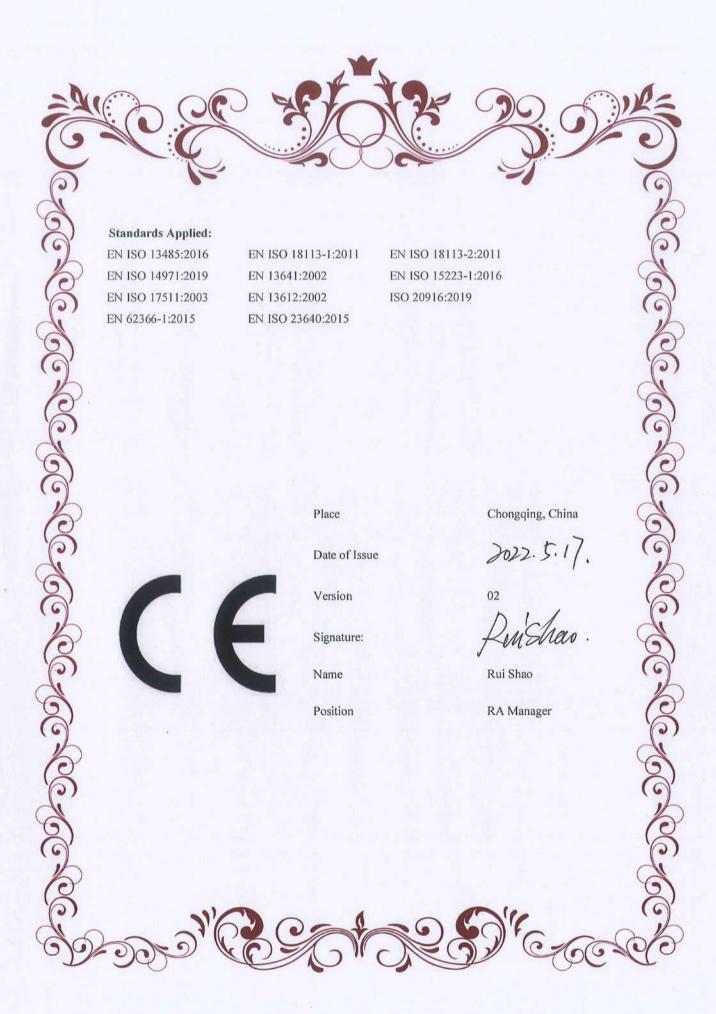
Version: 01

Page 2 of 2











12	Low Density Lipoprotein Cholesterol (LDL-C) Kit	R1 30 mL × 3, R2 10 mL × 3, Calibrator 1 Level × 1.0 mL × 1, Control 2 Levels × 1.0 mL × 1
	(Enzymatic Method)	R1 45 mL \times 2, R2 15 mL \times 2, Calibrator 1 Level \times
E		$1.0 \text{ mL} \times 1$, Control $2 \text{ Levels} \times 1.0 \text{ mL} \times 1$
13	Albumin (ALB) Kit (Bromocresol	R 30 mL × 6
- Herek	Green Method)	R 60 mL × 2
14	Alkaline Phosphatase (ALP) Kit	R1 30 mL \times 3, R2 7.5 mL \times 3
	(Enzymatic Method)	R1 48 mL × 2, R2 12 mL × 2
15	Total Protein (TP) Kit (Biuret	R 30 mL × 6
	Method)	R 60 mL × 2
16	Gamma-Glutamyl Transferase	R1 30 mL \times 3, R2 7.5 mL \times 3
	(GGT) Kit (Enzymatic Method)	R1 48 mL × 2, R2 12 mL × 2
		R1 15 mL \times 2, R2 10 mL \times 1, Lyse 50 mL \times 2,
		Calibrator 5 Levels × 1.0 mL × 1, Control 2 Levels ×
17	Glycated Hemoglobin A1c	$1.0 \text{ mL} \times 1$
17	(HbA1c) Kit (Immunoturbidimetric Method)	R1 15 mL \times 2, R2 10 mL \times 1, Lyse 50 mL \times 2,
		Calibrator 5 Levels \times 1.0 mL \times 1, Control 2 Levels \times
		1.0 mL × 1
		R 30 mL × 6
	Magnesium (Mg) Kit (Xylidyl Blue	R 60 mL × 2
18	Method)	R 30 mL \times 6, Calibrator 1 Level \times 1.0 mL \times 1
		R 60 mL × 2, Calibrator 1 Level × 1.0 mL × 1
	Lipase (LPS) Kit (Colorimetric Method)	R1 30 mL × 3, R2 10 mL × 3, Calibrator 1 Level ×
19		1.0 mL \times 1, Control 2 Levels \times 1.0 mL \times 1
		R1 45 mL × 2, R2 15 mL × 2, Calibrator 1 Level ×
		$1.0 \text{ mL} \times 1$, Control 2 Levels $\times 1.0 \text{ mL} \times 1$
	Calcium (Ca) Kit (Arsenazo III	R 30 mL × 6
20	Method)	R 60 mL × 2

21	D-Dimer (D-D) Kit (Latex Enhanced Immunoturbidimetric Method)	R1 30 mL × 3, R2 10 mL × 3, Calibrator 1 Level × 1.0 mL × 1, Control 2 Levels × 1.0 mL × 1
		R1 45 mL \times 2, R2 15 mL \times 2, Calibrator 1 Level \times
		$1.0 \text{ mL} \times 1$, Control 2 Levels $\times 1.0 \text{ mL} \times 1$
		R1 30 mL \times 3, R2 10 mL \times 3, Calibrator 5 Levels \times
22	Myoglobin (MYO) Kit (Latex Enhanced Immunoturbidimetric	$0.6 \mathrm{mL} \times 1$, Control 2 Levels $\times 0.6 \mathrm{mL} \times 1$
	Method)	R1 45 mL \times 2, R2 15 mL \times 2, Calibrator 5 Levels \times
		$0.6~\mathrm{mL} \times 1$, Control 2 Levels \times $0.6~\mathrm{mL} \times 1$
		R1 30 mL $ imes$ 3, R2 7.5 mL $ imes$ 3, Calibrator 2 Levels $ imes$
23	N-acetyl-β-D-glucosaminidase (NAG) Kit (Rate Method)	1.0 mL \times 1, Control 2 Levels \times 1.0 mL \times 1
		R1 48 mL \times 2, R2 12 mL \times 2, Calibrator 2 Levels \times
		$1.0 \text{ mL} \times 1$, Control 2 Levels $\times 1.0 \text{ mL} \times 1$
		R1 30 mL \times 3, R2 7.5 mL \times 3, Calibrator 4 Levels \times
24	Prealbumin (PA) Kit	0.6 mL × 1
	(Immunoturbidimetric Method)	R1 48 mL \times 2, R2 12 mL \times 2, Calibrator 4 Levels \times
		0.6 mL × 1
		R1 30 mL \times 3, R2 7.5 mL \times 3, Calibrator 5 Levels \times
25	Anti-Streptolysin O (ASO) Kit (Latex Enhanced Immunoturbidimetric Method)	$1.0 \text{ mL} \times 1$, Control 2 Levels $\times 1.0 \text{ mL} \times 1$
		R1 48 mL \times 2, R2 12 mL \times 2, Calibrator 5 Levels \times
		1.0 mL \times 1, Control 2 Levels \times 1.0 mL \times 1
	Apolipoprotein A1 (Apo A1) Kit (Immunoturbidimetric Method)	R1 30 mL \times 3, R2 7.5 mL \times 3, Calibrator 4 Levels \times
		$0.5 \mathrm{mL} imes 1$
26		
		R1 48 mL × 2, R2 12 mL × 2, Calibrator 4 Levels ×
		$0.5 \text{ mL} \times 1$

		R1 30 mL × 3, R2 7.5 mL × 3, Calibrator 4 Levels ×
27	Apolipoprotein B (Apo B) Kit (Immunoturbidimetric Method)	0.5 mL × 1
21		R1 48 mL × 2, R2 12 mL × 2, Calibrator 4 Levels ×
		0.5 mL × 1
		R1 30 mL × 3, R2 7.5 mL × 3, Calibrator 5 Levels ×
28	Cholyglycine (CG) Kit (Latex Enhanced Immunoturbidimetric	$0.6 \text{ mL} \times 1$, Control 2 Levels \times $0.6 \text{ mL} \times 1$
	Method)	R1 48 mL × 2, R2 12 mL × 2, Calibrator 5 Levels ×
		$0.6 \text{ mL} \times 1$, Control 2 Levels $\times 0.6 \text{ mL} \times 1$
		R1 30 mL × 1, R2 10 mL × 1, Calibrator 1 Level ×
29	Complement 3 (C3) Kit (Immuno- transmission Turbidimetric Method)	1.0 mL × 1
		R1 45 mL \times 2, R2 15 mL \times 2, Calibrator 1 Level \times
		1.0 mL × 1
		R1 30 mL $ imes$ 1, R2 10 mL $ imes$ 1, Calibrator 1 Level $ imes$
30	Complement 4 (C4) Kit (Immuno- transmission Turbidimetric	1.0 mL × 1
	Method)	R1 45 mL \times 2, R2 15 mL \times 2, Calibrator 1 Level \times
		1.0 mL × 1
31	Creatine Kinase (CK) Kit (Rate	R1 30 mL \times 3, R2 7.5 mL \times 3
- ACC.	Method)	R1 48 mL \times 2, R2 12 mL \times 2
	Cystatin C (Cys C) Kit (Latex Enhanced Immunoturbidimetric Method)	R1 30 mL \times 3, R2 6 mL \times 3, Calibrator 6 Levels \times 0.6 mL \times 1, Control 2 Levels \times 0.6 mL \times 1
32		
		R1 50 mL × 2, R2 10 mL × 2, Calibrator 6 Levels ×
		$0.6 \text{ mL} \times 1$, Control 2 Levels $\times 0.6 \text{ mL} \times 1$
		R1 30 mL × 3, R2 15 mL × 3, Calibrator 6 Levels ×
33	Ferritin (Fer) Kit (Latex Enhanced Immunoturbidimetric Transmission Method)	$0.6 \text{ mL} \times 1$, Control 2 Levels $\times 0.6 \text{ mL} \times 1$
		R1 40 mL \times 2, R2 20 mL \times 2, Calibrator 6 Levels \times
		$0.6 \text{ mL} \times 1$, Control 2 Levels $\times 0.6 \text{ mL} \times 1$

		D1 20 ml V 2 D2 6 ml V 2 Calibrator 1 Lavel V 0.4
		R1 30 mL \times 3, R2 6 mL \times 3, Calibrator 1 Level \times 0.5 mL \times 1, Control 2 Levels \times 0.5 mL \times 1
34	Glutathione Reductase (GR) Kit (Rate Method)	
	(Kate Method)	R1 50 mL \times 2, R2 10 mL \times 2, Calibrator 1 Level \times
		$0.5 \text{ mL} \times 1$, Control 2 Levels $\times 0.5 \text{ mL} \times 1$
		R1 30 mL × 3, R2 10 mL × 3, Calibrator 6 Levels ×
35	High Sensitive C-Reactive Protein (hs-CRP) Kit (Immunoturbidimetric	0.6 mL × 1
33	Method)	R1 45 mL × 2, R2 15 mL × 2, Calibrator 6 Levels ×
		0.6 mL × 1
		R1 30 mL × 3, R2 8 mL × 3, Calibrator 5 Levels ×
		$0.6 \text{ mL} \times 1$, Control 2 Levels \times $0.6 \text{ mL} \times 1$
36	Homocysteine (HCY) Kit	R1 15 mL × 3, R2 4 mL × 3, Calibrator 5 Levels ×
	(Enzymatic Method)	0.6 mL \times 1, Control 2 Levels \times 0.6 mL \times 1
		R1 47 mL × 2, R2 13 mL × 2, Calibrator 5 Levels ×
		$0.6 \text{ mL} \times 1$, Control 2 Levels $\times 0.6 \text{ mL} \times 1$
	e, relevieur en la religi	R1 30 mL \times 3, R2 6 mL \times 3, Calibrator 1 Level \times 1.0
	Immunoglobulin A (IgA) Kit	$mL \times 1$
37	(Immunoturbidimetric Method)	
		R1 50 mL \times 2, R2 10 mL \times 2, Calibrator 1 Level \times 1.0 mL \times 1
-		R1 30 mL \times 3, R2 6 mL \times 3, Calibrator 1 Level \times 1.0
		mL × 1
38	Immunoglobulin G (IgG) Kit (Immunoturbidimetric Method)	
	(Immunoturbidinietric Method)	R1 50 mL \times 2, R2 10 mL \times 2, Calibrator 1 Level \times
		1.0 mL × 1
	Immunoglobulin M (IgM) Kit	R1 30 mL \times 3, R2 6 mL \times 3, Calibrator 1 Level \times 1.0
39		$mL \times 1$
39	(Immunoturbidimetric Method)	R1 50 mL × 2, R2 10 mL × 2, Calibrator 1 Level ×
		1.0 mL × 1

40	Inorganic Phosphorus (P) Kit	R 30 mL \times 6
	(Direct UV Method)	R 60 mL × 2
41	Lactate Dehydrogenase Isoenzyme 1 (LDH1) Kit (Rate Method)	R1 30 mL × 3, R2 7.5 mL × 3, Calibrator 1 Level × 1.0 mL × 1, Control 2 Levels × 1.0 mL × 1
		R1 48 mL \times 2, R2 12 mL \times 2, Calibrator 1 Level \times
		1.0 mL × 1, Control 2 Levels × 1.0 mL × 1
		R1 30 mL \times 3, R2 10 mL \times 3, Calibrator 5 Levels \times
40	Lipoprotein (a) (Lp(a)) Kit	$0.6 \text{ mL} \times 1$, Control 2 Levels $\times 0.6 \text{ mL} \times 1$
42	(Immunoturbidimetric Method)	R1 45 mL × 2, R2 15 mL × 2, Calibrator 5 Levels ×
		$0.6 \text{ mL} \times 1$, Control 2 Levels \times $0.6 \text{ mL} \times 1$
		R1 30 mL × 3, R2 7.5 mL × 3, Calibrator 6 Levels ×
	Microalbuminuria (mALB) Kit (Immunoturbidimetric Method)	$0.6 \text{ mL} \times 1$, Control 2 Levels \times $0.6 \text{ mL} \times 1$
43		D1 40 1 V 2 D2 12 1 V 2 G17 1 V C G17 1 V
		R1 48 mL × 2, R2 12 mL × 2, Calibrator 6 Levels ×
		0.6 mL × 1, Control 2 Levels × 0.6 mL × 1
	Serum Amyloid A (SAA) Kit	R1 30 mL \times 3, R2 7.5 mL \times 3, Calibrator 5 Levels \times 0.6 mL \times 1, Control 2 Levels \times 0.6 mL \times 1
44	(Latex Enhanced Immunoturbidimetric Method)	
		R1 48 mL × 2, R2 12 mL × 2, Calibrator 5 Levels ×
_		0.6 mL × 1, Control 2 Levels × 0.6 mL × 1 R1 30 mL × 3, R2 10 mL × 3, Calibrator 1 Level ×
	Sialic Acid (SA) Kit (Enzymatic Method)	1.0 mL \times 1, Control 2 Levels \times 1.0 mL \times 1
45		
		R1 45 mL \times 2, R2 15 mL \times 2, Calibrator 1 Level \times
		$1.0 \text{ mL} \times 1$, Control 2 Levels \times 1.0 mL \times 1
46	Total Bile Acids (TBA) Kit	R1 30 mL \times 3, R2 7.5 mL \times 3
40	(Enzymatic Cycling Method)	R1 48 mL \times 2, R2 12 mL \times 2
47	α-Amylase (α-AMY) Kit (E-pNP-	R1 30 mL \times 3, R2 7.5 mL \times 3
7/	G7 Method)	R1 48 mL \times 2, R2 12 mL \times 2

48	α-Hydroxybutyric Acid Dehydrogenase (α-HBDH) Kit (Rate Method)	R1 30 mL × 3, R2 7.5 mL × 3 R1 48 mL × 2, R2 12 mL × 2
49	C-Reactive Protein (CRP) Kit (Latex Enhanced	R1 30 mL \times 3, R2 10 mL \times 3, Calibrator 6 Levels \times 0.6 mL \times 1
	Immunoturbidimetric Method)	R1 45 mL \times 2, R2 15 mL \times 2, Calibrator 6 Levels \times 0.6 mL \times 1
50	Immunoglobulin E (IgE) Kit (Latex Enhanced Immunoturbidimetric Method)	R1 16 mL \times 3, R2 8 mL \times 3, Calibrator 6 Levels \times 0.6 mL \times 1, Control 2 Levels \times 0.6 mL \times 1
		R1 40 mL \times 2, R2 20 mL \times 2, Calibrator 6 Levels \times 0.6 mL \times 1, Control 2 Levels \times 0.6 mL \times 1
51	Rheumatoid Factor (RF) Kit (Latex Enhanced Immunoturbidimetric Method)	R1 30 mL \times 3, R2 7.5 mL \times 3, Calibrator 1 Level \times 1.0 mL \times 1
31		R1 48 mL \times 2, R2 12 mL \times 2, Calibrator 1 Level \times 1.0 mL \times 1
52	Glycated Albumin (GA) Kit (Enzymatic Method)	R1 16 mL \times 1, R2 4 mL \times 1, R3 20 mL \times 1, Calibrator 2 Levels \times 1.0 mL \times 1,Control 2 Levels \times 1.0 mL \times 1
02		R1 48 mL \times 1, R2 12 mL \times 1, R3 60 mL \times 1, Calibrator 2 Levels \times 1.0 mL \times 1, Control 2 Levels \times 1.0 mL \times 1
53	Creatinine (CREA) Kit (Enzymatic Method)	R1 30 mL × 2, R2 10 mL × 2 R1 30 mL × 1, R2 10 mL × 1 R1 45 mL × 2, R2 15 mL × 2
54	Clinical Chemistry Multi-analyte Calibrator	1 Level × 5 mL × 10 1 Level × 5 mL × 6 1 Level × 5 mL × 1



Manufacturer

Name:

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

Zybio Inc.

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: Chemistry Analyzer

Model EXC200, EXC220

REF: 02-10-02-0002-00, 02-10-02-0003-00

Basic UDI-DI: 69732628600024ZL

GMDN Code: 56676

GMDN Term: Multiple clinical chemistry analyser IVD, laboratory, automated

EMDN Code: W0201010101

Risk Class: Class A (according to rule <5b> Annex VIII of In vitro Diagnostic Medical

Device Regulation)

The Chemistry Analyzer is an automated device for in vitro diagnostic use in

Intended Purpose: clinical laboratories. It is used for the quantitative detection of chemical

components in serum, plasma, urine and other samples.

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 Applied Standards:



Document ID: 117-001-DOC-001

Version: 01



EN ISO 13485:2016 EN ISO 15223-1:2021 EN ISO 18113-1:2011 EN ISO 18113-3:2011 EN 13612:2002 EN 62304:2006/A1:2015

EN ISO 18113-3:2011 EN 13012:2002 EN 02504.2000/A1.2015

IEC 61326-2-6:2012 EN ISO 14971:2019 EN 62366-1:2015

IEC 61010-1:2010+A1:2016 IEC 61010-2-010:2019 IEC 61010-2-101:2018

IEC 61326-1:2012 ISO 20916:2019 EN IEC 63000:2018

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Place Chongqing, China

Signature Lou Sharo -

Name Rui Shao
Position PRRC

Date of Issue Aug 19, 2022



Urinalysis Hybrid System U3600

An integrated system for upgrading your lab urinalysis solution



Urinalysis



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-wavelength



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

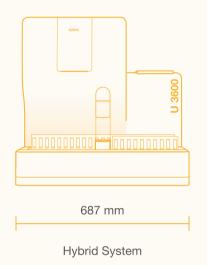


Improved Productivity

- 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





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

SQEP

BYST

BACI

SPRM

MUCS

WBCC

NSE

HYST

SUCO

PHCY

UNCL

UNCX

MAPH

CAPH

TYRO

URIC

COM

AMOR

FAT

HYAL

AUCR

COD

UNCC

Note: Only some items are listed.

Technical Parameters

	Laminar flow technology		
Principle	High-speed photography technology		
	Medical image recognition		
Throughput	240 T/H for Chemistry Mode		
mougnput	120 T/H for Formed Particles Mode/Hybrid Mode		
	Chemical analysis: URO, BIL, KET, LEU, NIT, PRO, BLD, MALB, CRE, GLU, SG,		
	pH , VC, Ca, ACR, PCR		
Test Items	Formed particles analysis: RBC, WBC, WBCC, PHCY, SQEP, NSE, BYST, HYST,		
rest items	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		
	Urinalysis Strip		
	UDC-Control		
	Sheath Fluid		
Pagganta	Focusing Fluid		
Reagents	US-Calibrator		
	Sediment Control		
	Conductivity Control		
	Wash solution		
	Temperature: 10~30°C		
Operation Environment	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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Urinalysis



Chemistry Analyzer EXC 200

A cost-effective choice dedicated for small healthcare sites



Chemistry



Function



User Friendly

- · Integrated design combines operation system with the analyzer
- · Colorful touch screen and intuitive user-friendly navigation menu
- Waste with high concentration and low concentration are discharged separately, more environmentally friendly
- Support various sample tube types
- · Various sample types are available
- Matched with around 100 testing items



Economic Usage

- Lower reaction volume: 90 μL
- Less water consumption: 5 L/H
- Precise reagent absorption with step by 0.5 μL
- Semi-permanent plastic cuvette and permanent quartz cuvette optional



Excellent Performance

- 24-hour non-stop cooling to keep reagent in good condition
- High pressure wash probe both inside and outside to keep low carry-over : ≤0.005%
- Probe designed with liquid detection, auto-depth adjustment and collision protection
- Key parts imported from top companies
- Advanced absorbance reading with the linearity is 0-4.0 Abs
- Post spectrophotometry optical system to make a more reliable result

Assay Menu

Zybio is well known as a professional clinical chemistry reagent manufacturer, whose chemistry menu range ranks the top 5 in China. With around 100 chemistry reagents, our assay menu covers hepatic, renal, lipids, diabetes, electrolyte, specific proteins and etc. and matches with calibrators of metrological traceability as well as controls for EXC 200.

- · Ready to use
- Stable liquid
- · Comprehensive menu
- · Bulk package available upon request

Hepatic Panel

ALB, TP, DBIL, TBIL, AST, ALT, ALP, GGT, TBA, PA, CG, ChE, 5'-NT, m-AST, GLDH, LAP, MAO, FN, ADA, GR, AAT, HAP

Renal Panel

UREA, UA, CREA, Cys C, RBP, α1-MG, UTRF, β2-MG, NGAL, NAG, mALB

Lipids Panel

CHOL, Apo A1, Apo B, Apo E, NEFA, TG, LDL-C, HDL-C, Lp(a)

Cardiac & Cardiovascular Panel

ACE, LDH, LDH1, CK, CK-MB, α-HBDH, MYO, cTnl, H-FABP, hs-CRP, HCY, Lp-PLA₂, MPO

Diabetes

GLU, HbA1c, GA, GSP, LAC

Tumor

PGI, PGII, SA, Fer

Coagulation

D-D, FIB, FDP

Specific Proteins

IgA, IgG, IgM, IgE, C3, C4, C1q, CSF/UTP, TRF, SOD

Rheumatic & Rheumatoid Panel

anti-CCP, RF, ASO

Electrolytes

Fe, Zn, CO₂, Ca, P, Mg

Inflammation

PCT, SAA, CRP

Pancreatitis

α-AMY, LPS

Specification

General Feature	
Throughput	240 T/H for single reagent; 160 T/H for dual reagents
Methodology	End point, Fixed-time (two point), Kinetic
Principle	Absorbance photometry, Turbidimetry
Programming	Open/close system(optional)
Optical System	
Light source	Halogen-tungsten lamp
Wavelength	(340-800) nm, in total 12 wavelengths
Absorption range	0-4.0 Abs
Resolution	0.0001 Abs
Sample System	
Sample capacity	40 positions
Sample volume	2 uL -50 uL, step by 0.25 uL
Sample probe	Liquid level detection, auto-depth adjustment, and collision protection
Sample type	Serum, plasma, urine, and CSF
Reagent System	
Reagent capacity	40 positions
Reagent volume	10 uL-400 uL, step by 0.5 uL
Reaction System	
Cuvette	63 cuvettes with 5mm optical path diameter
Reaction volume	90 uL-450 uL
Reaction temperature	37± 0.1 °C
Cuvette Washing	
6-step washing station	
Control	
Control type	Real-time, within-day, between-day control and etc
Control rule	Westgard
Calibration	
Calibration mode	One-point, two-point, multi-point, Logistic-Log4/5P, Exponential-5P, Polynomial-5P and Spline
Operation System	
Operation system	Windows 10, support LIS
Host interface	RS232, TCP/IP
Others	
Power supply	100-240 V ~, 50/60 Hz
Cooling way	Constant air cooling
Water consumption	≤5 L/H
Dimension(mm)	710(W)×705(D) ×635(H)
Weight	90 kg



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Chemistry



Clinical Chemistry Reagent

Your diagnostic solution partner

Chemistry

Company Profile

Zybio Inc. (referred to as "Zybio") is a national high tech enterprise founded in 2008, one of the leading. Chinese medical companies dedicated in a comprehensive line of IVD reagents and equipment, including Hematology, Chemistry, CLIA, POCT, Molecule, Microbiology.

Since the beginning, Zybio has implemented high standard in all aspects in terms of research &development, production, marketing, sales and technical services, to satisfy the needs of our users.

Now, there are over 3000 employees totally and one-third of them are engaged in R&D, of which more than 50% have a master's degree or above.

We have built 8 R&D centers in China, including Chongqing R&D center, Shanghai R&D center, Guangzhou R&D center, Shenzhen R&D center, Beijing R&D center, Xiamen R&D center, Nanjing R&D center and Changchun R&D center. Strong R&D team guarantees more diverse and high-quality product, which drives us forward. In addition, we have an independent service center allocating more than 100 service or application engineers to serve our clients throughout the world.

Based on the ideology of "plan together, create together, share together", we have set up a network of operations throughout China and keep expanding globally.



Our Mission:

To make diagnosis more accurate, to make life healthier

Our Vision:

To build a world-class brand leading in the global diagnostics field



Content

Reagents	01
Hepatic Panel	02
Renal Panel	03
Lipids Panel	04
Cardiac & Cardiovascular Panel	05
Diabetes	06
Coagulation	07
Specific Proteins	07
Rheumatism & Rheumatoid Panel	08
Electrolytes	08
Inflammation	09
Pancreatitis	09
Zybio Calibrator	10-11
Zybio Control	12-13
Recommended Chemistry	14

A Chemistry Specialist

As a national high-tech medical enterprise, we are also recognized as a professional clinical chemistry reagent manufacturer who offers a wide range of reagents. About 100 chemistry reagents include but not limit to hepatic, renal, cardiac, lipids, diabetes, electrolytes, specific proteins assays as well as a line of exclusive products such as sdLDL-C, mAST are now available.

In addition to reagents which specialized for our own chemistry analyzer, we also offer you with a variety of dedicated bottle of reagents for other brands.

Flexible package size is available upon request.

Zybio reagents feature

Large range assay menu: about 100 chemistry markers Cost effective, optimized reaction ratio
High quality, ISO13485 manufacturing
Liquid, ready to use, easy to use
3rd party calibrator and control for general chemistry
Original calibrator and control for special chemistry

Stable to expiry date at 2-8°C



Abbr.	Measurement Method	Volume	Package	Calibration Routine	Sample Type/ Min. Sample Vol (µL)	Linearity Range	Calibration Cycle / On-board Stability	Optimum Absorbance Wavelength			Calibrator	Control
Hepatio	c Panel											
ALB	Bromocresol green	120mL	R:60mL*2	- End-point	Sari im/3	10.0~	Batch-wise/	630 nm	Ready	12 months	· ,	/
ALD	Bromodiesor green	180mL	R:30mL*6	сна роше	Geruiti/G	60.0g/L	30 days	000 1111	-to-use	(2-8 °C)	,	,
TD	6	120mL	R:60mL*2		0 /5	10.0~	Batch-wise/	F.40	Ready	12 months	,	,
TP	Biuret	180mL	R:30mL*6	- End-point	Serum/5	120.0g/L	30 days	546 nm	-to-use	(2-8 °C)	' /	/
		112.5mL	R1:30mL*3 R2:7.5mL*3		Serum,	2.0-	Batch-wise/		Ready	12 months		
DBIL	Vanadate oxidizing	120mL	R1:48 mL*2 R2:12 mL*2	End-point	Plasma/10	300.0 µmol/L	30 days	450 nm	-to-use	(2-8 °C)	' /	/
		112.5mL	R1:30mL*3 R2:7.5mL*3		Serum,	3.0-	Batch-wise/	450	Ready	12 months		,
TBIL	Vanadate oxidizing	120mL	R1:48mL*2 R2:12mL*2	- End-point	Plasma/10	500.0 μmol/L	30 days	450 nm	-to-use	(2-8 °C)	/	/
ACT		112.5mL	R1:30mL*3 R2:7.5mL*3	D-:	Serum,	10-	Batch-wise/	0.40	Ready	12 months		,
AST	Enzymatic	120mL	R1:48mL*2 R2:12mL*2	Rate	Plasma/12	1000.0 U/L	28 days	340 nm	-to-use	(2-8 °C)	' /	/
ALT	Enzymatic	112.5mL	R1:30mL*3 R2:7.5mL*3	- Rate	Serum,	5.0~	Batch-wise/	340 nm	Ready	12 months	,	/
ALI	Lizymauc	120mL	R1:48mL*2 R2:12mL*2	nate	Plasma/12	1000.0 U/L	28 days	J40 IIII	-to-use	(2-8 °C)		
ALP	Enzymatic	112.5mL	R1:30mL*3 R2:7.5mL*3	- Rate	Serum,	25.0-	Batch-wise/	405 nm	Ready	12 months	,	/
/ \L	⊶ 1∠y++iQUO	120mL	R1:48mL*2 R2:12mL*2	riato	Plasma/5	1000.0 U/L	30 days	700 IIII	-to-use	(2-8 °C)	,	
GGT	Enzymatic	112.5mL	R1:30mL*3 R2:7.5mL*3	- Rate	Serum,	10.0-	Batch-wise/	405 nm	Ready	12 months	,	/
aaı	LIZYIIIQUO	120mL	R1:48mL*2 R2:12mL*2	i iaie	Plasma/25	600 U/L	28 days	+00 IIII	-to-use	(2-8 °C)	,	/
TBA	Enzymatic avaling	112.5mL	R1:30mL*3 R2:7.5mL*3	Rate	Serum,	2.0~	Batch-wise/	405 nm	Ready	12 months	,	/
IDA	Enzymatic cycling	120mL	R1:48mL*2 R2:12mL*2	⊓al⊎	Plasma/4	150.0 µmol/L	30 days	400 11111	-to-use	(2-8 °C)	/	/
۸۵۸	Enzymatic	112.5mL	R1:30mL*3 R2:7.5mL*3	Pata	Serum,	3.0~	Batch-wise/	516 pm	Ready	18 months	7,60	Zubio
ADA	Enzymatic	120mL	R1:48mL*2 R2:12mL*2	Rate	Plasma/4	200.0 U/L	14 days	546 nm	-to-use	(2-8 °C)	' Zybio	Zybio
D.4		112.5mL	R1:30mL*3 R2:7.5mL*3		0 /0	20.0~	Batch-wise/	0.40	Ready	12 months		,
PA	Immunoturbidimetric	120mL	R1:48mL*2 R2:12mL*2	End-point	Serum/6	650.0 mg/L	30 days	340 nm	-to-use	(2-8 °C)	Zybio	/

Abbr.	Measurement Method	Volume	Package	Calibration Routine	Sample Type/ Min. Sample Vol (µL)	Linearity Range	Calibration Cycle / On-board Stability	Optimum Absorbance Wavelength			Calibrator	Control
CG	Latex enhanced	112.5mL	R1:30mL*3 R2:7.5mL*3	- End-point	Serum/5	0.5~	Batch-wise/	600 nm	Ready	12 months	Zybio	Zybio
	immunoturbidimetric	120mL	R1:48mL*2 R2:12mL*2			50.0 mg/L	30 days		-to-use	(2-8 °C)	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
CG	Homogeneous enzyme	112.5mL	R1:30mL*3 R2:7.5mL*3	- End-point	Serum/12	1.5~	Batch-wise/	340 nm	Ready	12 months	Zybio	Zybio
	immune	120mL	R1:48mL*2 R2:12mL*2			50.0 mg/L	14 days		-to-use	(2-8 °C)		
ChE	Butyryl thiocholine	112.5mL	R1:30mL*3 R2:7.5mL*3	Rate	Serum,	1000.0-	Batch-wise/	405 nm	Ready	12 months	,	/
		120mL	R1:48mL*2 R2:12mL*2		Plasma/3	25,000.0 U/L	15 days		-to-use	(2-8 °C)		
5'-NT	Enzymatic	40mL	R1:30mL*1 R2:10mL*1	Rate	Serum/6	5.0~	Batch-wise /	546 nm	Ready	18 months	Zybio	Zybio
3 -111	Litzymatic	120mL	R1:45mL*2 R2:15mL*2	riale	Serumo	200.0 U/L	30 days	340 1111	-to-use	(2-8 °C)	Zybio	Zybio
mAST	Enzymatic inhibition	112.5mL	R1:30mL*3 R2:7.5mL*3	Rate	Serum/25	5.0~	Batch-wise/	340 nm	Ready	18 months	Zybio	Zybio
111/101	Enzymatio il il ilbition	120mL	R1:48mL*2 R2:12mL*2	riato	OGIGITI/20	300.0 U/L	28 days	04011111	-to-use	(2-8 °C)	Zybio	2,010
OLDU.	Data	20mL	R1:16mL*1 R2:4mL*1	Data	C/00	5.0-	Batch-wise/	0.40	Ready	12 months	,	,
GLDH	Rate	120mL	R1:48mL*2 R2:12mL*2	Rate	Serum/20	200.0 U/L	30 days	340 nm	-to-use	(2-8 °C)	/	/
		20mL	R1:16mL*1 R2:4mL*1									
LAP	Rate	37.5mL	R1:30mL*1 R2:7.5mL*1	Rate	Serum/15	2.0~ 300.0 U/L	Batch-wise/ 30 days	405 nm	Ready -to-use	18 months (2-8 °C)	/	/
		120mL	R1:48mL*2 R2:12mL*2									
		112.5mL	R1:30mL*3 R2:7.5mL*3		0 400	2.0 ~	Batch-wise/	0.40	Ready	12 months		
MAO	Rate	120mL	R1:48mL*2 R2:12mL*2	Rate	Serum/20	200.0 U/L	10 days	340 nm	-to-use	(2-8 °C)	Factor	Zybio
FN	Immunoturbidimetric	80mL	R1:30mL*2 R2:10mL*2	End-point	Serum/7	20.0~	Batch-wise/	340 nm	Ready	12 months	Zybio	Zybio
111	mmunotarbamouro	120mL	R1:45mL*2 R2:15mL*2	Life point	Octain, i	600.0 mg/L	28 days	04011111	-to-use	(2-8 °C)	Zybio	Zybio
GR	Rate	108mL	R1:30mL*3 R2:6mL*3	Rate	Serum,	10.0~	Batch-wise/	340 nm	Ready	12 months	Zybio	Zubio
Gh	nale	120mL	R1:50mL*2 R2:10mL*2	nate	Plasma/ 10	300.0 U/L	30 days	340 1111	-to-use	(2-8 °C)	Zybio	Zybio
ЦΛР	Immunoturbidim stri -	108mL	R1:30mL*3 R2:6mL*3	End-point	Corum/0	10.0-	Batch-wise/	240 pm	Ready-to-	12 months	Zubia	Zubia
HAP	Immunoturbidimetric	120mL	R1:50mL*2 R2:10mL*2	cna-point	Serum/2	400.0 mg/dL	10 days	340 nm	use	(2-8 °C)	Zybio	Zybio
ΛΛΤ	Immunoturbidimetrie	108mL	R1:30mL*3 R2:6mL*3	- End point	Sorum/4	20.0-	Batch-wise/	340 pm	Ready-to-	12 months	Zubio	Zubic
AAT	Immunoturbidimetric	120mL	R1:50mL*2 R2:10mL*2	End-point	Seruill/4	400.0 mg/dL	10 days	340 nm	use	(2-8 °C)	Zybio	Zybio
Renal F	Panel											
LIDE^	Liveage OLDIL	112.5mL	R1:30mL*3 R2:7.5mL*3	Dota	Serum,	0.5-	Batch-wise/	240	Ready	12 months		
UREA	Urease-GLDH	120mL	R1:48mL*2 R2:12mL*2	Rate	Plasma/3	40.0 mmol/L	30 days	340 nm	-to-use	(2-8 °C)	/	/
		40mL	R1:30mL*1 R2:10mL*1									
CREA	Enzymatic	80mL	R1:30mL*2 R2:10mL*2	End-point	Serum, Plasma/5	20.0~ 2,000.0 µmol/L	Batch-wise/ 30 days	540 nm	Ready -to-use	12 months (2-8 °C)	/	/
	,	120mL	R1:45mL*2			2,000.0 µmol/L 3		54U nm				

Abbr.	Measurement Method	Volume	Package	Calibration Routine	Sample Type/ Min. Sample Vol (µL)	Linearity Range	Calibration Cycle / On-board Stability	Optimum Absorbance Wavelength	Preparation before Usage	Shelf-Life	Calibrator	Control
		40mL	R1:30mL*1 R2:10mL*1			10.0-120.0 mg/	,					
RBP	Latex enhanced immunoturbidimetric	80mL	R1:30mL*2 R2:10mL*2	End-point	Serum, Plasma, Urine/3	L (blood) 0.2-15.0 mg/L	Batch-wise/	600 nm	Ready -to-use	12 months (2-8 °C)	Zybio	Zybio
		120mL	R1:45mL*2 R2:15mL*2			(urine)						
1.14	Liviagos	112.5mL	R1:30mL*3 R2:7.5mL*3	- End-point	Serum,	100.0-1190.0	Batch-wise/	F46 pm	Ready	12 months	/	
UA	Uricase	120mL	R1:48mL*2 R2:12mL*2	Ena-point	Plasma/5	µmol/L	30 days	546 nm	-to-use	(2-8 °C)	/	/
0)/0 0	Colloidal gold	112.5mL	R1:30mL*3 R2:7.5mL*3	F1	Serum,	0.4~	Batch-wise/	F.40	Ready	14 months	7	7:-
CYS C	immunoturbidmetric	120mL	R1:48mL*2 R2:12mL*2	End-point	Plasma/3	8.0 mg/L	10 days	546 nm	-to-use	(2-8 °C)	Zybio	Zybio
0.40	Latex enhanced	108mL	R1:30mL*3 R2:6mL*3		Serum,	0.4~	Batch-wise/		Ready	12 months		
CYS C	immunoturbidimetric	120mL	R1:50mL*2 R2:20mL*1	End-point	Plasma/3	8.0 mg/L	28 days	600 nm	-to-use	(2-8 °C)	Zybio	Zybio
	Latex enhanced	120mL	R1:30mL*3 R2:10mL*3		Serum,	2.0-160.0 mg/L (blood)	Batch-wise/		Ready	12 months		
α1-MG	immunoturbidimetric	120mL	R1:45mL*2 R2:15mL*2	End-point	Plasma, Urine/2	0.5-200.0 mg/L (urine)		570 nm	-to-use	(2-8 °C)	Zybio	Zybio
	Latex enhanced	120mL	R1:30mL*3 R2:10mL*3			0.2~	Batch-wise/		Ready	12 months	-	-
TRF	immunoturbidimetric	120mL	R1:45mL*2 R2:15mL*2	End-point	Urine/5	15.0 mg/L	30 days	570 nm	-to-use	(2-8 °C)	Zybio	Zybio
00 MC	Latex enhanced	112.5mL	R1:30mL*3 R2:7.5mL*3	End point	Serum,	0.4-20mg/L (blood)	Batch-wise/	600 nm	Ready	12 months	Zybio	Zubio
β2-MG	immunoturbidimetric	120mL	R1:48mL*2 R2:12mL*2	- End-point	Plasma, Urine/3	0.15-24mg/L (urine)	30 days	600 nm	-to-use	(2-8 °C)	Zybio	Zybio
NGAL	Latex enhanced	112.5mL	R1:30mL*3 R2:7.5mL*3	End point	Serum,	30~	Batch-wise/	546 nm	Ready	12 months	Zubio	Zubio
NGAL	immunoturbidimetric	120mL	R1:48mL*2 R2:12mL*2	- End-point	Plasma, Urine/3	3000 ng/mL	30 days	340 IIII	-to-use	(2-8 °C)	Zybio	Zybio
NIAC	Doto	112.5mL	R1:30mL*3 R2:7.5mL*3	Doto	Llvino/16	4.0~	Batch-wise/	340 nm	Ready	12 months	Zvbio	Zubio
NAG	Rate	120mL	R1:48mL*2 R2:12mL*2	Rate	Urine/16	200.0 U/L	30 days	340 NM	-to-use	(2-8 °C)	Zybio	Zybio
m ALD	loopo un otrushidio otsio	112.5mL	R1:30mL*3 R2:7.5mL*3	End point	Llvino/7	5.0~	Batch-wise/	340 nm	Ready	12 months	Zubio	Zulaia
mALB	Immunoturbidimetric	120mL	R1:48mL*2 R2:12mL*2	- End-point	Office/1	600.0 mg /L	30 days	340 11111	-to-use	(2-8 °C)	Zybio	Zybio
Lipids F	Panel											
CHOI		112.5mL	R1:30mL*3 R2:7.5mL*3			1.0-	Batch-wise/		Roady	18		
CHOL (Dual)	Enzymatic	120mL	R1:48mL*2 R2:12mL*2	End-point	Serum/3	1.0- 20.0 mmol/L	30 days	546 nm	Ready -to-use	months (2-8 °C)	/	/
CHOL		120mL	R:60mL*2			1.0-	Batch-wise/		Ready	12 months		
(Single)	Enzymatic	180mL	R:30mL*6	End-point	Serum/3	20.0 mmol/L	30 days	505 nm	-to-use	(2-8 °C)	/	/
Ano A1	Immunot ubidimetri e	112.5mL	R1:30mL*3 R2:7.5mL*3	End-point	Serum,	0.4~	Batch-wise/	340 nm	Ready	12 months	Zybio	
Apo A1	Immunoturbidimetric	120mL	R1:48mL*3 R2:12mL*2	Liiu-point	Plasma/3	2.5g /L	28 days	040 IIIII	-to-use	(2-8 °C)	∠yui0	/

Abbr.	Measurement Method	Volume	Package	Calibration Routine	Sample Type/ Min. Sample Vol (µL)	Linearity Range	Calibration Cycle / On-board Stability	Optimum Absorbance Wavelength		Shelf-Life	Calibrator	Control
Аро В	Immunoturbidimetric	112.5mL	R1:30mL*3 R2:7.5mL*3	- End-point	Serum,	0.4-2.5 g/L	Batch-wise/	340 nm	Ready	12 months	Zybio	/
, , , , , , , , , , , , , , , , , , , ,		120mL	R1:48mL*2 R2:12mL*2		Plasma/3		28 days		-to-use	(2-8 °C)		,
Аро Е	Immunoturbidimetric	112.5mL	R1:30mL*3 R2:7.5mL*3	End-point	Serum/3	10.0-	Batch-wise/	340 nm	Ready	12 months	Zybio	Zybio
, po L	THING TO COLOR TO COL	120mL	R1:48mL*2 R2:12mL*2	End point	Cordinac	150.0 mg/L	30 days	0101111	-to-use	(2-8 °C)		2,010
NEFA	Enzymatic	112.5mL	R1:30mL*3 R2:7.5mL*3	End-point	Serum/4	0.15~	Batch-wise/	546 nm	Ready	12 months	Zybio	Zybio
INCI /	Litzymano	120mL	R1:48mL*2 R2:12mL*2	Liid point	OGIGITI/-4	3.0 mmol/L	15 days	3401111	-to-use	(2-8 °C)	Zyblo	Zybio
TG (Dual)	Enzymatic	112.5mL	R1:30mL*3 R2:7.5mL*3	End-point	Sarum/3	0.5-	Batch-wise/	546 nm	Ready	12 months	/	/
TG (Duai)	Liizyiiiauc	120mL	R1:48mL*2 R2:12mL*2	ши-ропт	Geruii//G	10.0 mmol/L	30 days	340 IIII	-to-use	(2-8 °C)	,	
TG	Enzymatic	120 mL	R:60 mL*2	End-point	Serum/3	0.5-	Batch-wise/	505 nm	Ready	12 months	/	/
(Single)	Z. i.z.yiii.dio	180 mL	R:30 mL*6	End point	Cordinati	10.0 mmol/L	30 days	000 1111	-to-use	(2-8 °C)		
LDL-C	Enzymatic	120mL	R1:30mL*3 R2:10mL*3	End-point	Serum/3	0.2~11.60	Batch-wise/	546 nm	Ready	18 months	Zybio	Zybio
LDL O	Enzymano	120mL	R1:45mL*2 R2:15mL*2	End point	Cordinato	mmol/ L	30 days	04011111	-to-use	(2-8 °C)		Zybio
HDL-C	Enzymatic	120mL	R1:30mL*3 R2:10mL*3	End-point	Serum/3	0.2~	Batch-wise/	546 nm	Ready	18 months	Zybio	Zybio
1,52 0		120mL	R1:45mL*2 R2:15mL*2	Liid point		4.0 mmol/ L	30 days	0.10.1111	-to-use	(2-8 °C)		
l n/n)	laces up at udaidise atria	120mL	R1:30mL*3 R2:10mL*3	Final major	Serum,	5.0~	Batch-wise/	000 10100	Ready	12 months	Zulaia	7. dai a
Lp(a)	Immunoturbidimetric	120mL	R1:45mL*2 R2:15mL*2	End-point	Plasma/3	900.0 mg/L	30 days	600 nm	-to-use	(2-8 °C)	Zybio	Zybio
Cardiac	& Cardiovascular Pa	nel										
		96 mL	R:16 mL*6									
ACE	Enzymatic	120 mL	R:60 mL*2	End-point	Serum, Plasma/25	10.0- 150.0 U/L	Batch-wise/ 30 days	340 nm	Ready -to-use	12 months (2-8 °C)	Zybio	Zybio
		180 mL	R:30 mL*6									
hs-CRP	Immunoturbidimetric	120mL	R1:30 mL*3 R2:10 mL*3	End-point	Serum/3	0.5~	Batch-wise/	600 nm	Ready	12 months	Zybio	/
TIO OT II	minarotarbamono	120mL	R1:45 mL*2 R2:15 mL*2	End point	OCIUIT//O	300.0 mg/L	30 days	00011111	-to-use	(2-8 °C)	Zyolo	,
		57mL	R1:15 mL*3 R2:4 mL*3									
HCY	Enzymatic	114mL	R1:30 mL*3 R2:8 mL*3	End-point	Serum/7	3.0~ 50.0 µmol/L	Batch-wise/ 30 days	340 nm	Ready -to-use	12 months (2-8 °C)	Zybio	Zybio
		120mL	R1:47 mL*2 R2:13 mL*2									
1406	Latex enhanced	108 mL	R1:30 mL*3 R2:6 mL*3			15.0~	Batch-wise /		Ready	12 months		
MPO	immunoturbidimetric	120 mL	R1:50 mL*2 R2:10 mL*2	End-point	Serum/6	1,200.0 ng/mL		600 nm	-to-use	(2-8 °C)	Zybio	Zybio

Abbr.	Measurement Method	Volume	Package	Calibration Routine	Sample Type/ Min. Sample Vol (µL)	Linearity Range	Calibration Cycle / On-board Stability	Optimum Absorbance Wavelength		Shelf-Life	Calibrator	Control
Lp-PLA ₂	Rate	120 mL	R1:30 mL*3 R2A:9.5 mL*3 R2B:0.5 mL*3		Serum, Plasma/2	40~ 1,500.0 IU/L	Batch-wise / 24 days(R2A mix with R2B)	405 nm	Ready -to-use	12 months (2-8 °C)	Zybio	Zybio
LDH	Rate	112.5mL 120mL	R1:30 mL*3 R2:7.5 mL*3 R1:48 mL*2 R2:12 mL*2	Rate	Serum/5	25.0- 800.0 U/L	Batch-wise/ 30 days	340 nm	Ready -to-use	12 months (2-8 °C)	/	/
LDH1	Rate	112.5mL 120mL	R1:30 mL*3 R2:7.5 mL*3 R1:48 mL*2 R2:12 mL*2	Rate	Serum/5	5.0- 700.0 U/L	Batch-wise / 30 days	340 nm	Ready -to-use	12 months (2-8 °C)	Factor	Zybio
CK	Rate	112.5mL 120mL	R1:30 ml *3	Rate	Serum, Plasma/10	25- 1000 U/L	Batch-wise / 30 days	340 nm	Ready -to-use	18 months (2-8 °C)	/	/
CK-MB	Immunoinhibition	112.5mL 120mL	D1:20 ml *2	Rate	Serum, Plasma/10	2.0~ 500.0 U/L	Batch-wise / 30 days	340 nm	Ready -to-use	12 months (2-8 °C)	Factor	/
α-HBDH	Rate	112.5mL 120mL	R1:30 ml *3	Rate	Serum/6	25- 1200 U/L	Batch-wise/ 30 days	340 nm	Ready -to-use	12 months (2-8 °C)	/	/
MYO	Latex enhanced immunoturbidimetric	120mL 120mL	R1:30 mL*3 R2:10 mL*3 R1:45 mL*2	End-point	Serum, Plasma/6	10.0~ 800.0 ng/mL	Batch-wise/ 30 days	570 nm	Ready -to-use	12 months (2-8 °C)	Zybio	Zybio
cTnl	Latex enhanced immunoturbidimetric	120mL 120mL	R2:15 mL*2 R1:30 mL*3 R2:10 mL*3 R1:45 mL*2 R2:15 mL*2	End-point	Serum, Plasma/25	0.5~ 25.0 ng/mL	Batch-wise / 30 days	700 nm	Ready -to-use	12 months (2-8 °C)	Zybio	Zybio
SOD	Pyrogallol substrate	120mL 120mL	R1:30 mL*3 R2:10 mL*3 R1:45 mL*2	End-point	Serum/10	15.0~ 250.0 U/mL	Batch-wise/ 20 days	405 nm	Ready -to-use	15 months (2-8 °C)	Zybio	Zybio
H-FABP	Latex enhanced immunoturbidimetric	120mL 240mL	R2:15 mL*2 R1:30 mL*2 R2:15 mL*4 R1:60 mL*2 R2:60 mL*2	End-point	Serum, Plasma/6	2.5~ 120.0 ng/mL	Batch-wise/ 30 days	700 nm	Ready -to-use	12 months (2-8 °C)	Zybio	Zybio
Diabetes	s		112.00 THE 2									
		37.5mL	R1:30 mL*1 R2:7.5 mL*1									
GLU	Hexokinase	112.5mL	R1:30 mL*3 R2:7.5 mL*3	End-point	Serum, Plasma/3	2- 40 mmol/L	Batch-wise/ 35 days	340 nm	Ready -to-use	18 months (2-8 °C)	/	/
		120mL	R1:48 mL*2 R2:12 mL*2									
HbA1c	Immunoturbidimetric	140mL	R1: 15mL*2 R2: 10mL*2 Lyse: 50mL*2	End-point	Whole blood/8	3.6%~ 14%	Batch-wise / 30 days	660 nm	Ready -to-use	12 months (2-8 °C)	Zybio	Zybio

Abbr.	Measurement Method	Volume	Package	Calibration Routine	Sample Type/ Min. Sample Vol (µL)	Linearity Range	Calibration Cycle / On-board Stability	Optimum Absorbance Wavelength		Shelf-Life	Calibrator	Control
000	NIDT	112.5mL	R1:30 mL*3 R2:7.5 mL*3	-	Serum,	0.4~	Batch-wise /	540	Ready	12 months	7.1.	7.1.
GSP	NBT	120mL	R1:48 mL*2 R2:12 mL*2	End-point	Plasma/15	6.0 mmol/L	30 days	546 nm	-to-use	(2-8 °C)	Zybio	Zybio
GA	Enzymatic	40mL	R1:16 mL*1 R2:4 mL*1 ALB R3:20 mL*1	End-point	Serum,	1-35 g/L	Batch-wise/	Glycatedal- bumin: 546 mm	Ready	12 months	Zybio	Zybio
GA.	LIIZYIIIdiiC	120mL	R1:48 mL*1 R2:12 mL*1 ALB R3:60 mL*1	ши-ропп	Plasma/3	1-33 g/L	30 days	Albumin: 630 mm	-to-use	(2-8 °C)	Ζуρίο	Zybio
LAC	Lactate oxidase	112.5mL	R1:30 mL*3 R2:7.5 mL*3	- End-point	Placma/2	0.5-	Batch-wise /	500 nm	Ready	18 months	Zybio	
LAC	Lactate Oxidase	120mL	R1:48 mL*2 R2:12 mL*2	Ena-point	Plasifia/3	16.6 mmol/L	30 days	300 HH	-to-use	(2-8 °C)	Zybio	/
Coagu	lation											
D D	Latex enhanced	120mL	R1:30 mL*3 R2:10 mL*3	Final majest	DI=====/C	0.2~	Batch-wise/	000	Ready	12 months	7.4-:-	7: da:a
D-D	immunoturbidimetric	120mL	R1:45 mL*2 R2:15 mL*2	End-point	Plasma/6	20.0 μg/mL	30 days	600 nm	-to-use	(2-8 °C)	Zybio	Zybio
5.5		120mL	R1:30 mL*3 R2:10 mL*3		DI 49	0.5~	Batch-wise/	0.40	Ready	12 months	-	-
FIB	Immunoturbidimetric	120mL	R1:45 mL*2 R2:15 mL*2	- End-point	Plasma/2	8.0 g/L	30 days	340 nm	-to-use	(2-8 °C)	Zybio	Zybio
FDP	Latex enhanced immunoturbidimetric	120mL	R1:20 mL*3 R2:20 mL*3	End-point	Plasma/3	1.0~ 80.0 mg/L	Batch-wise/ 30 days	570 nm	Ready -to-use	12 months (2-8 °C)	Zybio	Zybio
Specifi	ic Proteins											
		108mL	R1:30 mL*3 R2:6 mL*3			1.0-	Batch-wise /		Ready	12 months		
IgG	Immunoturbidimetric	120mL	R1:50 mL*2 R2:10 mL*2	End-point	Serum/2	35.0 g/L	30 days	600 nm	-to-use	(2-8 °C)	Zybio	/
lαΛ	loope up at up die atria	108mL	R1:30 mL*3 R2:6 mL*3	End point	Cox 100 /0	0.40-	Batch-wise/	340 nm	Ready	12 months	Zubio	,
IgA	Immunoturbidimetric	120mL	R1:50 mL*2 R2:10 mL*2	- End-point	Serum/3	5.40 g/L	30 days	340 HH	-to-use	(2-8 °C)	Zybio	/
lgM	Immunoturbidimetric	108mL	R1:30 mL*3 R2:6 mL*3	End-point	Corum/0	0.20-	Batch-wise/	340 nm	Ready	12 months	Zybio	/
igivi	immunotarbiaimetric	120mL	R1:50 mL*2 R2:10 mL*2	спа-ропп	Serum/S	4.20 g/L	30 days	340 1111	-to-use	(2-8 °C)	Zybio	,
		120mL	R1:30 mL*3 R2:10 mL*3			10.0~	Batch-wise/		Ready	12 months		
SA	Enzymatic	120mL	R1:45 mL*2 R2:15 mL*2	Rate	Serum/6	200.0 mg/dL	14 days	340 nm	-to-use	(2-8 °C)	Zybio	Zybio
00	Immuno-transmission	40mL	R1:30 mL*1 R2:10 mL*1	Foot - 11	Compress / A	0.3~	Batch-wise/	040	Ready	12 months	7.1-1	
C3	turbidimetric	120mL	R1:45 mL*2 R2:15 mL*2	End-point	oerum/4	4.5 g/L	30 days	340 nm	-to-use	(2-8 °C)	Zybio	/
	Immuno-transmission	40mL	R1:30 mL*1 R2:10 mL*1			0.02~	Batch-wise/		Ready	12 months		
C4	turbidimetric	120mL	R1:45 mL*2 R2:15 mL*2	End-point	Serum/4	1.2 g/L	30 days	340 nm	-to-use	(2-8 °C)	Zybio	/

Abbr.	Measurement Method	Volume	Package	Calibration Routine	Sample Type/ Min. Sample Vol (µL)	Linearity Range	Calibration Cycle / On-board Stability	Optimum Absorbance Wavelength			Calibrator	Control
lgE	Latex enhanced	72mL	R1:16 mL*3 R2:8 mL*3	End-point	Serum/3	25.0~ 1,000.0	Batch-wise/	600 nm	Ready	12 months	Zybio	Zybio
191	immunoturbidimetric	120mL	R1:40 mL*2 R2:20 mL*2	Life point	Corarrivo	IU/mL	30 days	00011111	-to-use	(2-8 °C)	2,010	Zyolo
Fer	Latex enhanced	135mL	R1:30 mL*3 R2:15 mL*3	End point	Serum/10	10.0~ 1,000.0	Batch-wise/	570 nm	Ready	12 months	Zybio	Zybio
rei	immunoturbidimetric	120mL	R1:40 mL*2 R2:20 mL*2	End-point	Serum 10	ng/mL	30 days	37011111	-to-use	(2-8 °C)	Zybio	Zybio
PGI	Latex enhanced	112.5mL	R1:30 mL*3 R2:7.5 mL*3	End point	Serum,	10.0~	Batch-wise/	700 nm	Ready	12 months	Zubio	Zubio
PGI	immunoturbidimetric	128mL	R1:54 mL*2 R2:10 mL*2	End-point	Plasma/6	250.0 ng/mL	30 days	700 HH	-to-use	(2-8 °C)	Zybio	Zybio
	Latex enhanced	112.5mL	R1:30 mL*3 R2:7.5 mL*3		Serum.	3.0~	Batch-wise/	=	Ready	12 months		
PGII	immunoturbidimetric	128mL	R1:54 mL*2 R2:10 mL*2	End-point	Plasma/6	100.0 ng/mL	30 days	700 nm	-to-use	(2-8 °C)	Zybio	Zybio
		20mL	R1:16 mL*1 R2:4 mL*1		0 //	50.0~	Batch-wise/	0.40	Ready	12 months		-
C1q	Immunoturbidimetric	120mL	R1:48 mL*2 R2:12 mL*2	End-point	Serum/4	500.0 mg/L	10 days	340 nm	-to-use	(2-8 °C)	Zybio	Zybio
CSF/	Pyro-gallol red-	120mL	R:60 mL*2	End point	Urine,	1.0~	Batch-wise/	600 pm	Ready	12 months	Zubio	Zubio
UTP	molybdate	180mL	R:30 mL*6	End-point	CSF/4	200.0 mg/dL	10 days	600 nm	-to-use	(2-8 °C)	Zybio	Zybio
Rheum	natic & Rheumatoid Pa	ınel										
	Latex enhanced	112.5mL	R1:30 mL*3 R2:7.5 mL*3		0 (0	30.0~	Batch-wise/		Ready	12 months		,
ASO	immunoturbidimetric	120mL	R1:48 mL*2 R2:12 mL*2	End-point	Serum/6	800.0 IU/mL	30 days	600 nm	-to-use	(2-8 °C)	Zybio	/
DE	Latex enhanced	112.5mL	R1:30 mL*3 R2:7.5 mL*3	Es de cha	0	2.0~	Batch-wise/	000	Ready	12 months	7.1.	
RF	immunoturbidimetric	120mL	R1:48 mL*2 R2:12 mL*2	End-point	Serum/5	200.0 IU/mL	30 days	600 nm	-to-use	(2-8 °C)	Zybio	/
anti-	Latex enhanced	120mL	R1:30 mL*3 R2:10 mL*3			5.0~	Batch-wise/		Ready	12 months		
CCP	immunoturbidimetric	120mL	R1:45 mL*2 R2:15 mL*2	End-point	Serum/8	150.0 U/mL	10 days	546 nm	-to-use	(2-8 °C)	Zybio	Zybio
Electro	olytes											
	5-Br-	112.5mL	R1:30 mL*3 R2:7.5 mL*3			0.0	Databiaa/		Dand	10		
Fe	PADAPchromogenic end-point	120mL	R1:48 mL*2 R2:12 mL*2	End-point	Serum/25	2.0- 180.0 µmol/L	Batch-wise/ 30 days	546 nm	Ready -to-use	12 months (2-8 °C)	Zybio	/
	5-Br-	112.5mL	R1:30 mL*3 R2:7.5 mL*3									
Zn	PADAPchromogenic end-point	120mL	R1:48 mL*2 R2:12 mL*2	End-point	Serum/25	2.0- 60.0 µmol/L	Batch-wise/ 20 days	546 nm	Ready -to-use	12 months (2-8 °C)	Zybio	/
CO ₂	Enzymatic	90mL	R:30 mL*3	End-point	Seri im/3	10.0-	Batch-wise/	405 nm	Ready	12 months	Zybio	Zybio
002	Enzymano	180mL	R:30 mL*6	Ena point	Coramio	50.0 mmol/L	15 days	400 1111	-to-use	(2-8 °C)	2,010	2,010
_	_	120mL	R:60mL*2		Serum,	1.0-	Batch-wise /		Ready	12 months		
Ca	Arsenazo III	180mL	R:30 mL*6	End-point	Plasma/3	4.0 mmol/L	28 days	660 nm	-to-use	(2-8 °C)	Zybio	/
_		120mL	R:60 mL*2	_	_	0.2-	Batch-wise/		Ready	12 months		
Р	Direct UV	180mL	R:30 mL*6	End-point	Serum/5	3.0 mmol/L	30 days	340 nm	-to-use	(2-8 °C)	/	/
		120mL	R:60 mL*2						_			
				End-point	Serum,	0.2-	Batch-wise /	505 nm	Ready	12 months	Zybio	/

Measurement Method											
ivietrioù	Volume	Package	Calibration Routine	Sample Type/ Min. Sample Vol (µL)	Linearity Range	Calibration Cycle / On-board Stability	Optimum Absorbance Wavelength		Shelf-Life	Calibrator	Control
ition											
Latex enhanced	120mL	R1:30 mL*3 R2:10 mL*3	Food or sint	0/45	0.1~	Batch-wise/	000	Ready	12 months	7.4-1-	7
immunoturbidimetric	120mL	R1:45 mL*2 R2:15 mL*2	Eria point	Serum/15	60.0 ng/mL	28 days	000 1111	-to-use	(2-8 °C)	Zybio	Zybio
	112.5mL	R1:30 mL*3 R2:7.5 mL*3	End point	Serum,	2.0~	Batch-wise/	600 pm	Ready	12 months	Zubio	Zybio
0 1	120mL	R1:48 mL*2 R2:12 mL*2	End-point	Plasma/4	240.0 mg/L	28 days	600 HH	-to-use	(2-8 °C)	Zybio	Zybio
	120mL	R1:30 mL*3 R2:10 mL*3	End point	Corum/10	5.0-	Batch-wise/	240 nm	Ready	12 months	Zubio	
	120mL	R1:45 mL*2 R2:15 mL*2	Епа-ропп	Serum 12	300.0 mg/L	30 days	340 NM	-to-use	(2-8 °C)	Zybio	/
itis											
	112.5mL	R1:30 mL*3 R2:7.5 mL*3	Data	Serum,	5.0-	Batch-wise/	405	Ready	18 months	,	
'	120mL	R1:48 mL*2 R2:12 mL*2	nate	Urine/5	1000.0 U/L	30 days	HUO IIII	-to-use	(2-8 °C)	/	/
	120mL	R1:30 mL*3 R2:10 mL*3		Serum.	8.0~	Batch-wise/		Ready	18 months	7.1.	
substrate	120mL	R1:45 mL*2 R2:15 mL*2			8.0~ 300.0 U/L	Batch-wise/ 30 days	570 nm	Ready -to-use	(2-8 °C)	∠ybio	Zybio
Lii	Latex enhanced mmunoturbidimetric mmunochromatographic mmunoturbidimetric tis	Latex enhanced mmunoturbidimetric 120mL 120mL 112.5mL 120mL 120mL	Alter an Ammunoturbidimetric and the following substrate in munoturbidimetric and the following substrate in munoturbidimetric and the following substrate in 120mL in R1:30 mL*3 R2:7.5 mL*2 R2:15 mL*2 R2:15 mL*2 R2:15 mL*3 R2:7.5 mL*3 R2:7.5 mL*3 R2:10 mL*3 R2:10 mL*3 R2:10 mL*3 R2:10 mL*3 R2:15 mL*2 R2:15 mL*2 R2:15 mL*2 R2:15 mL*2 R2:15 mL*3 R2:10	Altex enhanced mmunoturbidimetric 120mL	Altex enhanced mmunoturbidimetric 120mL	Altex enhanced mmunoturbidimetric 120mL	120mL R1:30 mL*3 R2:10 mL*3 R2:10 mL*3 R2:10 mL*3 R2:15 mL*2 R2:15 mL*2 R2:15 mL*2 R2:15 mL*3 R2:7.5 mL*3 R2:7.5 mL*3 R2:10 mL*3 R2:10 mL*3 R2:10 mL*3 R2:10 mL*3 R2:10 mL*3 R2:10 mL*3 R2:15 mL*2 R2:15 mL*2 R2:15 mL*3 R2:10	120mL R1:30 mL*3 R2:10 mL*3 R2:15 mL*2 R2:15 mL*2 R2:15 mL*2 R2:15 mL*2 R2:15 mL*2 R2:15 mL*3 R2:10 mL*3 R2:10 mL*3 R2:10 mL*3 R2:10 mL*3 R2:10 mL*3 R2:15 mL*2 R2:15 mL*2 R2:15 mL*2 R2:15 mL*3 R2:10 mL*3 R2:15 mL*2 R2:15 mL*2 R2:15 mL*3 R2:10 mL*3 R2:10 mL*3 R2:15 mL*2 R2:15 mL*2 R2:15 mL*3 R2:10 mL	Action measurements and the point of the poi	Acta Part Part	Active enhanced mmunoturbidimetric R1:30 mL*3 R2:10 mL*3 R2:15 mL*2 End-point R1:45 mL*2 R2:12 mL*2 End-point R1:45 mL*2 R2:15 mL*2 End-point R1:45 mL*2 R2:12 mL*2 R2

Clinical Chemistry Reagent

Your diagnostic solution partner

Abbr.	Size	Status	Brand
Calibrator			
ADA	1 level * 0.6 mL/1 level * 1.0 mL	Liquid	Zybio
PA	4 levels * 0.6 mL/4 levels * 1.0 mL	Lyophilized	Zybio
CG (homogeneous enzyme immune method)	6 levels * 0.6 mL	Liquid	Zybio
CG (latex enhanced immunoturbidimetric method)	5 levels * 0.6 mL	Liquid	Zybio
5'-NT	1 level * 1.0 mL	Lyophilized	Zybio
mAST	1 level * 1.0 mL	Lyophilized	Zybio
FN	5 levels * 0.6 mL	Liquid	Zybio
GR	1 level * 0.5 mL	Lyophilized	Zybio
HAP	1 level * 1.0 mL	Liquid	Zybio
AAT	1 level * 0.5 mL	Liquid	Zybio
CYS C (latex enhanced immunoturbidimetric method)	6 levels * 0.6 mL	Liquid	Zybio
CYS C (colloidal gold immunoturbidimetric method)	6 levels * 0.6 mL/6 levels * 1.0 mL	Liquid	Zybio
RBP	5 levels * 0.6 mL/5 levels * 1.0 mL	Liquid	Zybio
α1-MG	6 levels * 0.6 mL/6 levels * 1.0 mL	Liquid	Zybio
TRF (urine)	5 levels * 0.6 mL/5 levels * 1.0 mL	Liquid	Zybio
β2-MG	5 levels * 0.6 mL/5 levels * 1.0 mL	Liquid	Zybio
NGAL	5 levels * 0.6 mL/5 levels * 1.0 mL	Liquid	Zybio
NAG	2 levels * 1.0 mL	Lyophilized	Zybio
mALB	6 levels * 0.6 mL	Lyophilized	Zybio
Apo A1	4 levels * 0.5 mL	Lyophilized	Zybio
Аро В	4 levels * 0.5 mL	Lyophilized	Zybio
Apo E	1 level * 1.0 mL	Lyophilized	Zybio
NEFA	1 level * 1.0 mL	Lyophilized	Zybio
LDL-C	1 level * 1.0 mL	Lyophilized	Zybio
HDL-C	1 level * 1.0 mL	Lyophilized	Zybio
Lp(a)	5 levels * 0.6 mL	Liquid	Zybio
ACE	1 level * 1.0 mL	Lyophilized	Zybio
hs-CRP	6 levels * 0.6 mL	Liquid	Zybio
HCY	5 levels * 0.6 mL	Liquid	Zybio
MPO	5 levels * 0.5 mL/5 levels * 1.0 mL	Liquid	Zybio
Lp-PLA2	1 level * 1.0 mL	Lyophilized	Zybio
LDH1	1 level * 1.0 mL	Lyophilized	Zybio
MYO	5 levels * 0.6 mL	Liquid	Zybio
cTnl	5 levels * 0.5 mL/5 levels * 1.0 mL	Liquid	Zybio
H-FABP	6 levels * 0.6 mL/6 levels * 1.0 mL	Liquid	Zybio
HbA1c	5 levels * 1.0 mL	Lyophilized	Zybio
GA	2 levels * 1.0 mL	Lyophilized	Zybio
GSP	1 level * 0.6 mL/1 level * 1.0 mL	Liquid	Zybio
LAC	1 level * 0.6 mL/1 level * 1.0 mL	Liquid	Zybio

PCIII 6 levels * 0.6 mL/6 levels * 1.0 mL Liquid Zybio Fer 6 levels * 0.6 mL Liquid Zybio SA 1 level * 1.0 mL Liquid Zybio D-D 1 level * 1.0 mL Lyophilized Zybio FIB 1 level * 1.0 mL Lyophilized Zybio FDP 1 level * 1.0 mL Lyophilized Zybio IgG 1 level * 1.0 mL Lyophilized Zybio IgA 1 level * 1.0 mL Lyophilized Zybio IgA 1 level * 1.0 mL Lyophilized Zybio C3 1 level * 1.0 mL Lyophilized Zybio C4 1 level * 1.0 mL Lyophilized Zybio C5 6 levels * 0.6 mL Liquid Zybio C1q 5 levels * 0.6 mL Liquid Zybio STRF 1 level * 1.0 mL Liquid Zybio ASO 5 levels * 1 mL Liquid Zybio RF 1 level * 1.0 mL Liquid Zybio RF 1 level	Abbr.	Size	Status	Brand
For 6 levels * 0.6 mL Liquid Zybio SA 1 level * 1.0 mL Liquid Zybio D-D 1 level * 1.0 mL Lyophilized Zybio FIB 1 level * 1.0 mL Lyophilized Zybio FDP 1 level * 1.0 mL Lyophilized Zybio IgG 1 level * 1.0 mL Lyophilized Zybio IgA 1 level * 1.0 mL Lyophilized Zybio IgM 1 level * 1.0 mL Lyophilized Zybio C3 1 level * 1.0 mL Lyophilized Zybio C4 1 level * 1.0 mL Lyophilized Zybio SDO 1 level * 1.0 mL Lyophilized Zybio C1q 5 levels * 0.6 mL Liquid Zybio STRF 1 level * 1.0 mL Liquid Zybio ASO 5 levels * 1 mL Lyophilized Zybio ASO 5 levels * 0.6 mL Liquid Zybio ASO 5 levels * 0.6 mL Liquid Zybio FE 1 level * 1.0 mL	PGI	6 levels * 0.6 mL/6 levels * 1.0 mL	Liquid	Zybio
SA 1 level*1.0 mL Liquid Zybio D-D 1 level*1.0 mL Lyophilized Zybio FIB 1 level*1.0 mL Lyophilized Zybio FDP 1 level*1.0 mL Lyophilized Zybio lgG 1 level*1.0 mL Lyophilized Zybio lgA 1 level*1.0 mL Lyophilized Zybio lgM 1 level*1.0 mL Lyophilized Zybio C3 1 level*1.0 mL Lyophilized Zybio C4 1 level*1.0 mL Lyophilized Zybio SOD 1 level*1.0 mL Lyophilized Zybio C1q 5 levels*0.6 mL Liquid Zybio C1q 5 levels*0.6 mL Liquid Zybio STRF 1 level*1.0 mL Lyophilized Zybio STRF 1 level*0.6 mL Lyophilized Zybio ASO 5 levels*0.6 mL Liquid Zybio RF 1 level*0.6 mL Liquid Zybio Tere 1 level*1.0 mL Liquid <td>PGII</td> <td>6 levels * 0.6 mL/6 levels * 1.0 mL</td> <td>Liquid</td> <td>Zybio</td>	PGII	6 levels * 0.6 mL/6 levels * 1.0 mL	Liquid	Zybio
D-D 1 level * 1.0 mL Lyophilized Zybio FIB 1 level * 1.0 mL Lyophilized Zybio FDP 1 level * 1.0 mL Lyophilized Zybio IgG 1 level * 1.0 mL Lyophilized Zybio IgA 1 level * 1.0 mL Lyophilized Zybio IgM 1 level * 1.0 mL Lyophilized Zybio C3 1 level * 1.0 mL Lyophilized Zybio C4 1 level * 1.0 mL Lyophilized Zybio SOD 1 level * 1.0 mL Lyophilized Zybio C1q 5 levels * 0.6 mL Liquid Zybio CSF/UTP 1 level * 1.0 mL Liquid Zybio STRF 1 level * 1.0 mL Liquid Zybio ASO 5 levels * 0.6 mL Liquid Zybio RF 1 level * 0.6 mL Liquid Zybio anti-CP 5 levels * 0.6 mL Liquid Zybio CO2 1 level * 0.6 mL Liquid Zybio CO2 1 level * 0.	Fer	6 levels * 0.6 mL	Liquid	Zybio
FIB	SA	1 level * 1.0 mL	Liquid	Zybio
FDP	D-D	1 level * 1.0 mL	Lyophilized	Zybio
IgG 1 level * 1.0 mL Lyophilized Zybio IgA 1 level * 1.0 mL Lyophilized Zybio IgM 1 level * 1.0 mL Lyophilized Zybio C3 1 level * 1.0 mL Lyophilized Zybio C4 1 level * 1.0 mL Lyophilized Zybio IgE 6 levels * 0.6 mL Liquid Zybio SOD 1 level * 1.0 mL Lyophilized Zybio C1q 5 levels * 0.6 mL Liquid Zybio CSF/UTP 1 level * 0.6 mL Liquid Zybio ASO 5 levels * 1 mL Lyophilized Zybio ASO 5 levels * 0.6 mL Lyophilized Zybio RF 1 level * 0.6 mL Lyophilized Zybio Fe 1 level * 0.6 mL Liquid Zybio CO2 1 level * 0.6 mL/1 level * 1.0 mL Liquid Zybio CO2 1 level * 0.6 mL/1 level * 1.0 mL Lyophilized Zybio Mg 1 level * 0.6 mL/1 level * 1.0 mL Lyophilized Zybio	FIB	1 level * 1.0 mL	Lyophilized	Zybio
IgA	FDP	1 level * 1.0 mL	Lyophilized	Zybio
IgM 1 level * 1.0 mL Lyophilized Zybio C3 1 level * 1.0 mL Lyophilized Zybio C4 1 level * 1.0 mL Lyophilized Zybio IgE 6 levels * 0.6 mL Liquid Zybio SOD 1 level * 1.0 mL Lyophilized Zybio C1q 5 levels * 0.6 mL Liquid Zybio CSF/UTP 1 level * 0.6 mL Liquid Zybio STRF 1 level * 1.0 mL Lyophilized Zybio ASO 5 levels * 1 mL Lyophilized Zybio RF 1 level * 0.6 mL Liquid Zybio anti-CCP 5 levels * 0.6 mL Liquid Zybio Fe 1 level * 1.0 mL Liquid Zybio CO2 1 level * 0.6 mL/1 level * 1.0 mL Liquid Zybio Ca 1 level * 5.0 mL Lyophilized Zybio Ca 1 level * 5.0 mL Lyophilized Zybio CA 5 levels * 0.5 mL/5 levels * 1.0 mL Lyophilized Zybio S	lgG	1 level * 1.0 mL	Lyophilized	Zybio
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CRP 6 levels * 0.6 mL/6 levels * 1.0 mL Liquid Zybio	PCT	5 levels * 0.5 mL/5 levels * 1.0 mL	Lyophilized	Zybio
	SAA	5 levels * 0.6 mL	Liquid	Zybio
LPS 1 level * 1.0 mL Lyophilized Zybio	CRP	6 levels * 0.6 mL/6 levels * 1.0 mL	Liquid	Zybio
	LPS	1 level * 1.0 mL	Lyophilized	Zybio

Clinical Chemistry Reagent

Your diagnostic solution partner

Abbr.	Size	Status	Brand
Control			
ADA	2 levels * 0.6 mL/2 levels * 1.0 mL	Liquid	Zybio
CG (homogeneous enzyme immune method)	2 levels * 0.6 mL	Liquid	Zybio
CG (latex enhanced immunoturbidimetric method)	2 levels * 0.6 mL	Liquid	Zybio
5'-NT	2 levels * 1.0 mL	Lyophilized	Zybio
mAST	2 levels * 1.0 mL	Lyophilized	Zybio
MAO	1 levels * 1.0 mL	Lyophilized	Zybio
FN	2 levels * 0.6 mL	Liquid	Zybio
GR	2 levels * 0.5 mL	Lyophilized	Zybio
HAP	2 levels * 0.5 mL	Liquid	Zybio
AAT	2 levels * 0.5 mL	Liquid	Zybio
CYS C (latex enhanced immunoturbidimetric method)	2 levels * 0.6 mL	Liquid	Zybio
CYS C (colloidal gold immunoturbidimetric method)	2 levels * 0.6 mL/2 levels * 1.0 mL	Liquid	Zybio
RBP	2 levels * 0.6 mL/2 levels * 1.0 mL	Liquid	Zybio
α1-MG	2 levels * 0.6 mL/2 levels * 1.0 mL	Liquid	Zybio
uTRF	2 levels * 0.6 mL/2 levels * 1.0 mL	Liquid	Zybio
β2-MG	2 levels * 0.6 mL/2 levels * 1.0 mL	Liquid	Zybio
NGAL	1 level * 0.6 mL/1 level * 1.0 mL	Liquid	Zybio
NAG	2 levels * 1.0 mL	Lyophilized	Zybio
mALB	2 levels * 0.6 mL	Lyophilized	Zybio
Аро Е	2 levels * 1.0 mL	Lyophilized	Zybio
NEFA	2 levels * 0.6 mL/2 levels * 1.0 mL	Liquid	Zybio
LDL-C	2 levels * 1.0 mL	Lyophilized	Zybio
HDL-C	2 levels * 1.0 mL	Lyophilized	Zybio
Lp(a)	2 levels * 0.6 mL	Liquid	Zybio
ACE	1 level * 1.0 mL	Lyophilized	Zybio
HCY	2 levels * 0.6 mL/1 level * 1mL	Liquid	Zybio
MPO	2 levels * 0.5 mL/2 levels * 1.0 mL	Liquid	Zybio
Lp-PLA2	2 levels * 1.0 mL	Lyophilized	Zybio
LDH1	2 levels * 1.0 mL	Lyophilized	Zybio
MYO	2 levels * 0.6 mL	Liquid	Zybio
cTnl	2 levels * 1.0mL	Lyophilized	Zybio
H-FABP	2 levels * 0.6 mL/2 levels * 1.0 mL	Liquid	Zybio
HbA1c	2 levels * 1.0 mL	Lyophilized	Zybio
GA	2 levels * 1.0 mL	Lyophilized	Zybio
GSP	2 levels * 0.6 mL/2 levels * 1.0 mL	Liquid	Zybio

Abbr.	Size	Status	Brand
PGI	2 levels * 0.6 mL/2 levels * 1.0 mL	Liquid	Zybio
PGII	2 levels * 0.6 mL/2 levels * 1.0 mL	Liquid	Zybio
Fer	2 levels * 0.6 mL	Liquid	Zybio
SA	2 levels * 1.0 mL	Liquid	Zybio
D-D	2 levels * 1.0 mL	Lyophilized	Zybio
FIB	2 levels * 1.0 mL	Lyophilized	Zybio
FDP	2 levels * 0.6 mL/2 levels * 1.0 mL	Lyophilized	Zybio
lgE	2 levels * 0.6 mL	Liquid	Zybio
SOD	2 levels * 1.0 mL	Lyophilized	Zybio
C1q	2 levels * 0.6 mL	Liquid	Zybio
CSF/UTP	1 level * 0.6 mL	Liquid	Zybio
sTRF	2 levels * 0.5 mL	Liquid	Zybio
anti-CCP	2 levels * 0.6 mL	Liquid	Zybio
CO2	1 level * 0.6 mL/1 level * 1.0 mL	Liquid	Zybio
PCT	1 level * 1.0 mL/2 level * 1.0 mL	Lyophilized	Zybio
SAA	2 levels * 0.6 mL	Liquid	Zybio
LPS	2 levels * 1.0 mL	Lyophilized	Zybio

Recommended Chemistry

Panel	Method
Hepatic Panel	
CG	Latex enhanced immunoturbidimetric
mAST	Enzymatic inhibition
PA	Immunoturbidimetric
Renal Panel	
CYS C	Colloidal gold immunoturbidimetric
mALB	Immunoturbidimetric
Lipids Panel	
sdLDL-C	Enzymatic
Cardiac & Cardiovascular Panel	
H-FABP	Latex enhanced immunoturbidimetric
cTnI	Latex enhanced immunoturbidimetric
SOD	Pyrogallol substrate
Lp-PLA ₂	Rate
hs-CRP	Immunoturbidimetric
HbA1c	Immunoturbidimetric
GA	Enzymatic
Coagulation	
D-D	Latex enhanced immunoturbidimetric
FDP	Latex enhanced immunoturbidimetric
Specific Proteins	
PGI	Latex enhanced immunoturbidimetric
PGII	Latex enhanced immunoturbidimetric
Rheumatic & Rheumatoid Panel	
RF	Latex enhanced immunoturbidimetric
anti-CCP	Latex enhanced immunoturbidimetric
Inflammation	
PCT	Latex enhanced immunoturbidimetric





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EN-SH-Clinical Chemistry Reagent-20230116H

Chemistry



EXC200 Operation Guide



Content

1. Login	1
2. Item Setup	2
3. Reagent Loading	
4. Calibration	
5. QC	
6. Sample test	
7. Review and Print of the Test Result	



1. Login

1.1 Input user name: Admin, password: zybio, click **Login** to enter the software; Note: communication setup should be: S-PT#: COM2; BR: 19200



1.2 Initializing: about 3min.

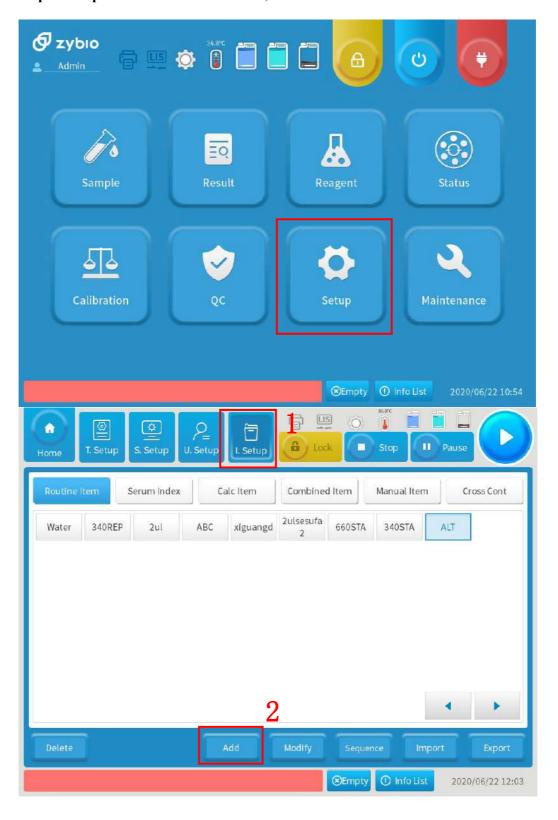


1



2. Item Setup

2.1 Click **Setup-I. Setup-Add** to add a new test item;





2.2 Fill in item parameters according to reagent instructions. Take ALT as an example:

1) **Ite Abb:** Abbreviation of the item: ALT;

2) FN/Ite: Full name of the item: Alanine aminotransferase;

3) **SAM TYP:** Sample type: Serum;

4) Rea O-V SL: Reagent open-vial shelf life: 30;

5) **Test M:** Test method:kinetic method;

6) R.Direc: Reaction direction: Decrease;

7) **R** Unit: Result unit: U/L;

8) **R ACC:** Result accuracy: 0.00;

9) **Dom WL:** Dominant wavelength: 340nm;

10) Sub WL: Sub-wavelength: 405nm;

11) S Vol: Sample volume: 12ul;

12) R1 Vol: Reagent 1 volume: 200ul;

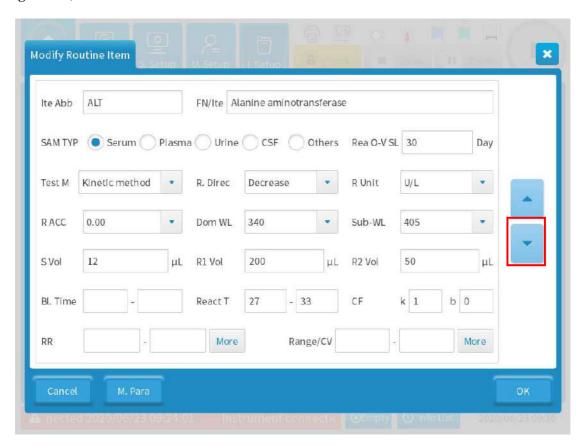
13) **R2 Vol:** Reagent 2 volume: 50ul;

14) **Bl.Time:** Blank time: /;

15) **React T:** Reaction time: 27-33; 16) **CF:** Calculate factor: K:1;B:0;

17) **RR:** Reference range: 0-40/0-28;

18) Range/CV: /;



Click the arrow key to enter the routine item interface, and fill in the related information:

19) Default Test Mode: Routine;

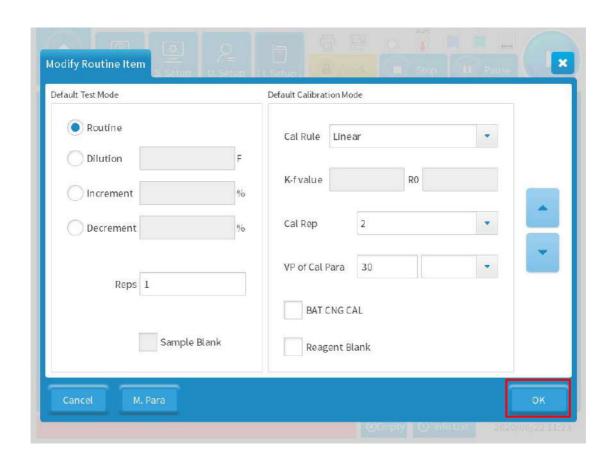
20) Default Calibration Mode:

Cal Rule: Calibration rule: Linear;

Cal Rep: Calibration repetition: 2;

Click **OK** to finish item setting.

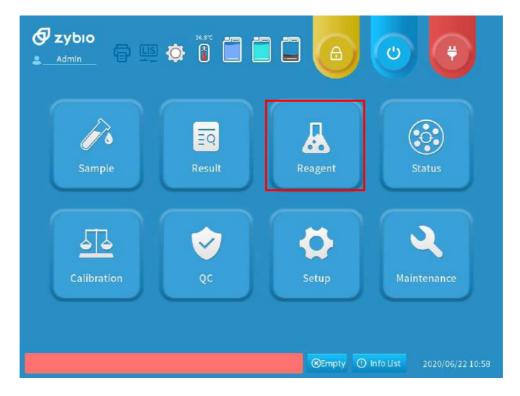




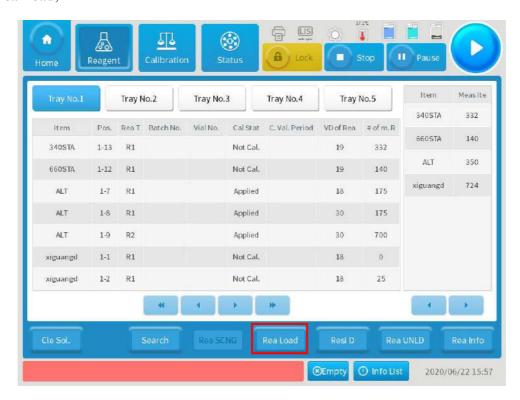


3. Reagent Loading

3.1 Back to main interface and click **Reagent** to enter the reagent setting interface;

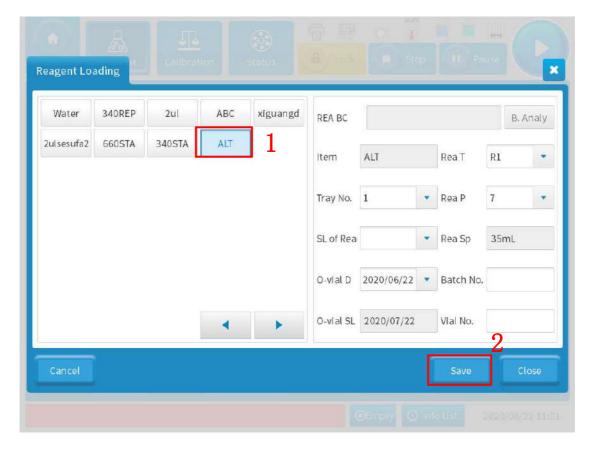


3.2 Click Rea Load;





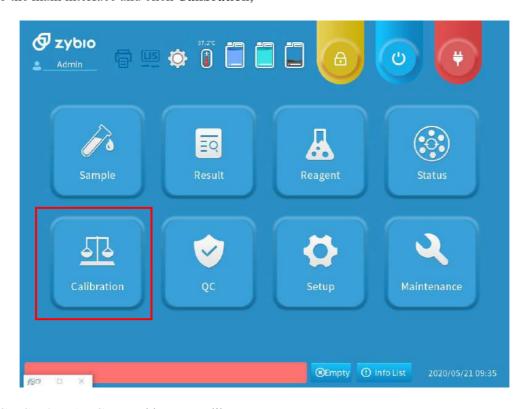
- 3.3 Choose an item and fill in the related information to load the reagent. Take ALT as an example:
- 1) Click the item to be loaded on the left of the interface: ALT;
- 2) **REA BC:** Click **B.Analy** on the right side and scan the bar-code of the reagent through scanner or input the bar-code number manually(suitable only for closed analyzer);
- 3) Rea T: Reagent type: R1/R2;
- 4) **Tray NO.:** Reagent Tray No.: Input related tray No.;
- 5) Rea P: Reagent position: Select a position for reagent. Position No.1-19 are for reagent with 35mL;
- Position No. 21-39 are for reagent with 20mL. Put the reagent into the corresponding position after selecting;
- 6) **SL of Rea:** Enter shelf life of reagent;
- 7) **Rea Sp:** Reagent specification. It will show automatically after selecting reagent position and cannot be modified;
- 8) **O-vial D:** Select open-vial date of the reagent. Default date is the day when reagent is loaded;
- 9) **O-vial SL:** Reagent open-vial shelf life. It will show automatically according to the open-vial date of the reagent and cannot be modified;
- 10) Batch No.: Reagent batch No.: Fill in it according to reagent instructions or leave it blank;
- 11) Vial No.: Reagent vial No.: Fill in it according to reagent instructions or leave it blank.
- Click **Save** at the bottom to finish the reagent loading.





4. Calibration

4.1 Back to the main interface and click **Calibration**;



4.2 Click Cal Setting-Ad Cal to add a new calibrator;





4.3 Fill in the related calibrator information, which includes the following:

1) Calibrator: Calibrator name;

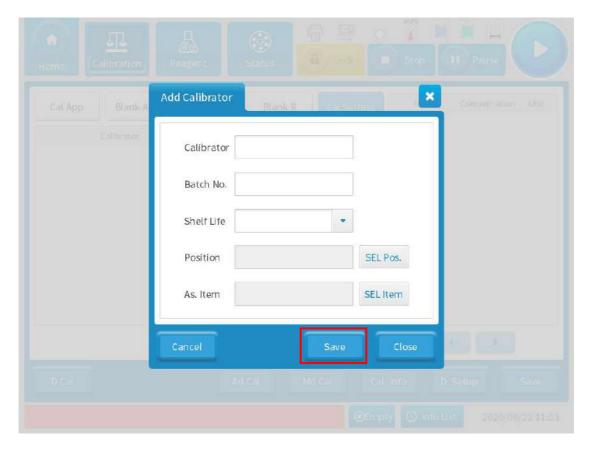
2) Batch No.: Batch No. of calibrator;

3) **Shelf Life:** Select calibrator shelf life according to instructions;

4) Position: Click SEL Pos. on the right side and choose position for calibrator in the pop-up interface;

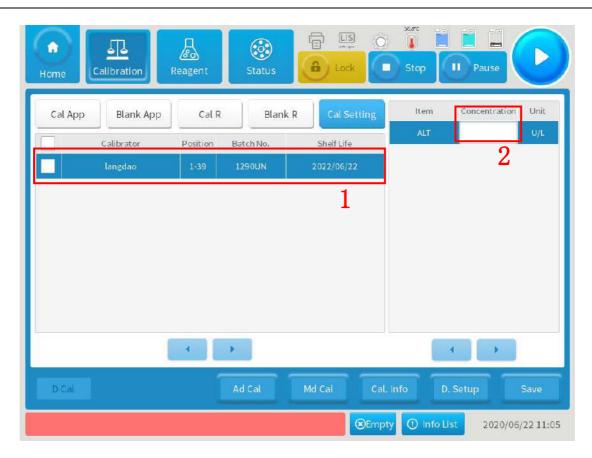
5) **As.Item:** Click **SEL Item** on the right side and choose associated item of the calibrator in the pop-up interface;

Click **Save** and put the calibrator at the corresponding position;

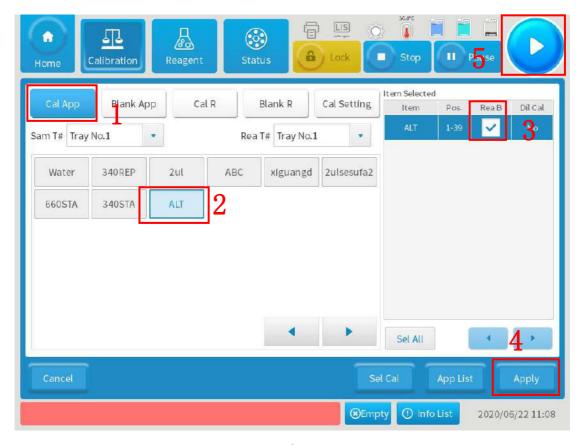


4.4 Choose the related calibrator on the left side of the interface and input the calibrator concentration on the right side;



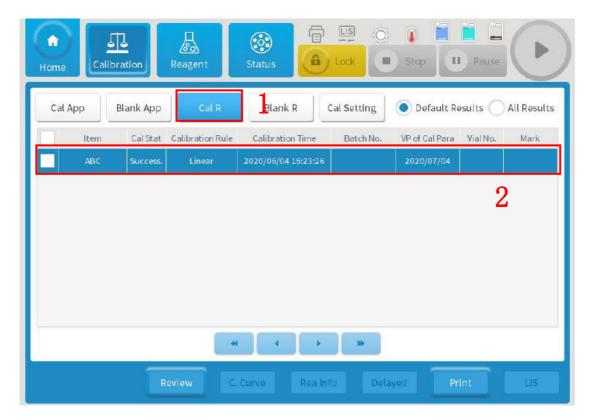


4.5 Click **Cal APP** to apply for calibration, choose related item, such as ALT and check under the **Rea B.** Put pure water in the No. 40 of the reagent-sample tray, click **Apply** at the bottom right and click the start key on the top right to start calibration;





4.6 Click **Cal R** after calibration to enter the calibration result review interface. Choose the related calibrator and check the calibration result.





5. QC

5.1 Click **QC** on the main interface to enter the QC interface;

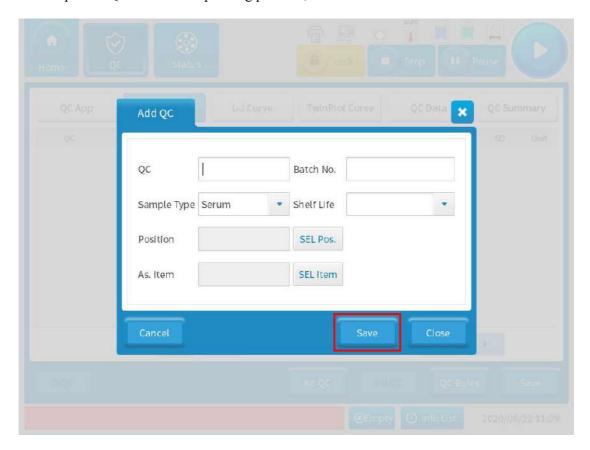


5.2 Click **QC Setting-Ad QC** to add a new QC;



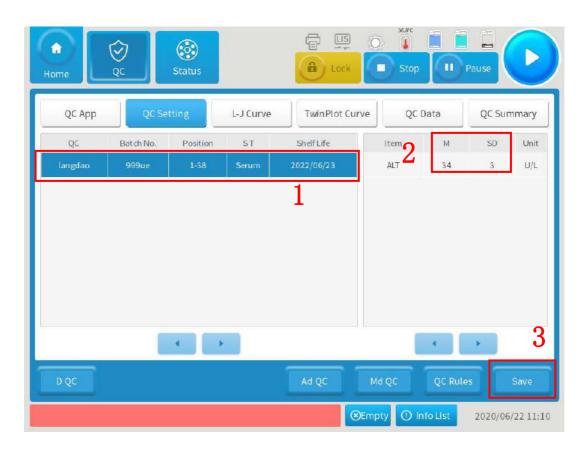


- 5.3 Fill in QC information in the pop-up interface, which includes the following:
- 1) QC: QC name;
- 2) Batch No.: Batch No. of QC;
- 3) Sample Type: Choose sample type, default sample type is Serum;
- 4) **Shelf Life:** Choose shelf life of QC;
- 5) **Position:** Click **SEL Pos.** on the right side and choose position for QC in the pop-up interface;
- 6) **As.Item:** Click **SEL Item** on the right side and choose associated item of the QC in the pop-up interface; Click **Save** and put the QC at the corresponding position;

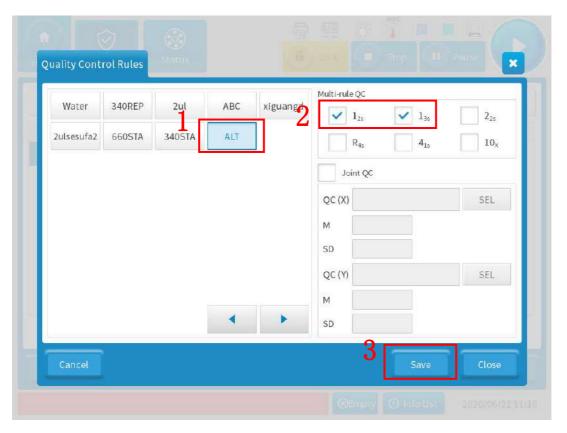


5.4 Choose the related QC on the left side of the interface and input the target QC concentration and standard deviation under the M and SD respectively on the right side, and click **Save**;



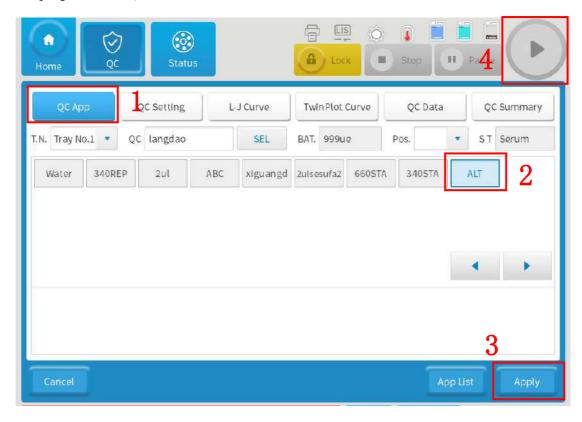


5.5 Click QC Rules to set QC rules in the pop-up interface. Choose the related QC on the left side of the interface and check 1_{2s} , 1_{3s} on the right side and click Save;

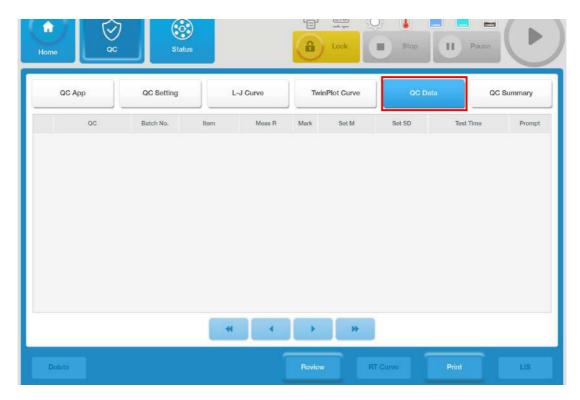




5.6 Click **QC App**, choose corresponding QC item and click **Apply** at the bottom right and then click the start key at the top right to start QC test;



5.7 Click **QC Data** to review the QC result after QC testing. Sample test can be performed once the QC result is in control.

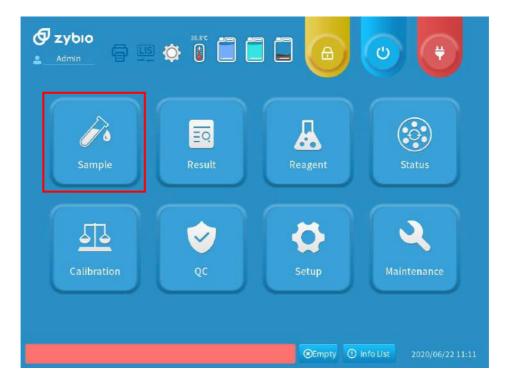




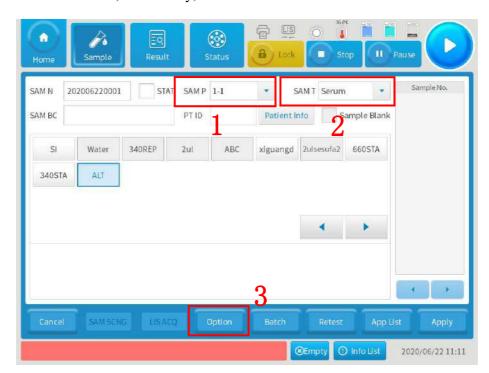
6. Sample test

Sample test can be performed after calibration and QC

6.1 Click **Sample** on the main interface to enter the sample application interface;



6.2 Choose sample position and type at SAM P and SAM T respectively. Put the sample at the corresponding position of the reagent-sample tray. Choose the test item on the interface. Click **Option** below to set the number of tests, if necessary;





6.3 As shown in the picture below, the method for filling in the parameters of the sample application setting is as follows:

SAM N: Sample number, which will show automatically and cannot be modified;

SAM BC: Sample bar-code, input it manually, fill in it through a scanner, or leave it blank;

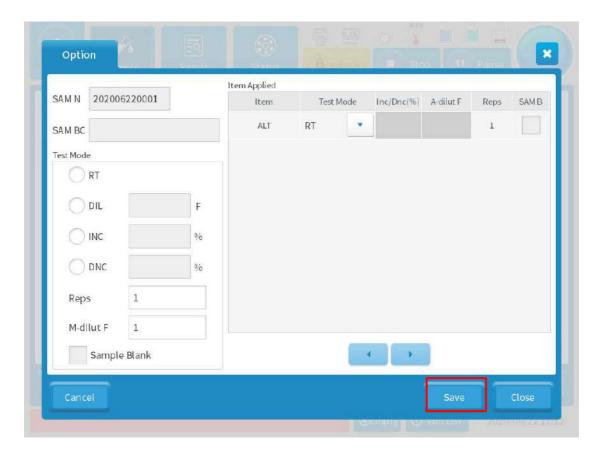
Test Mode: Test mode, which will show automatically and cannot be modified;

Reps: Enter the number of repetitions if multiple tests are required;

M-dilut F: Manually dilution ratio, default is 1;

Sample Blank: Sample blank, which will show automatically after item setting and cannot be modified;

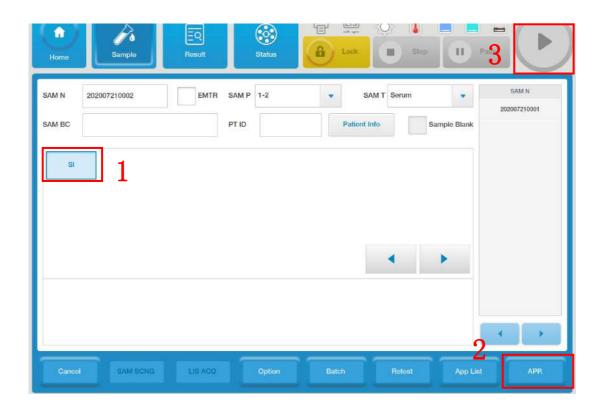
Click Save to save the sample parameters application after setting;



6.4 Choose an item and click **APP.** below to apply for the sample test, and then click the start key on the upper right corner;

Note: Make sure the reagent, sample, detergent and diluent are placed in the corresponding position in the reagent-sample tray before starting the test.

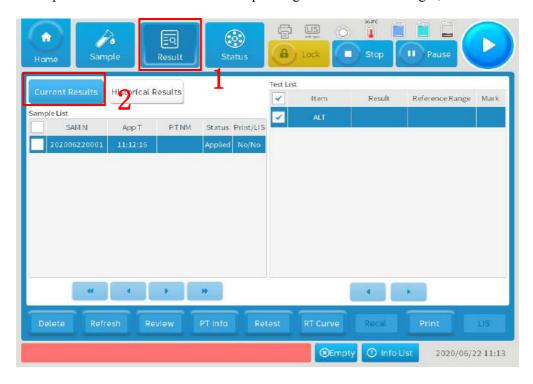




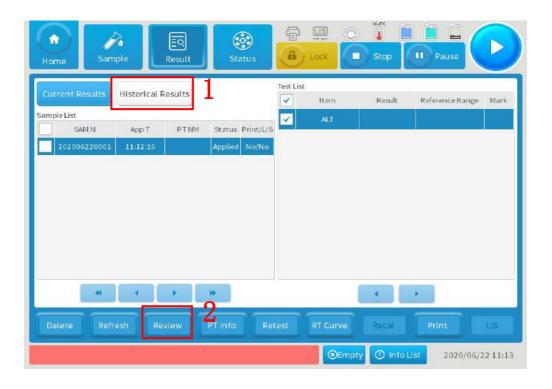


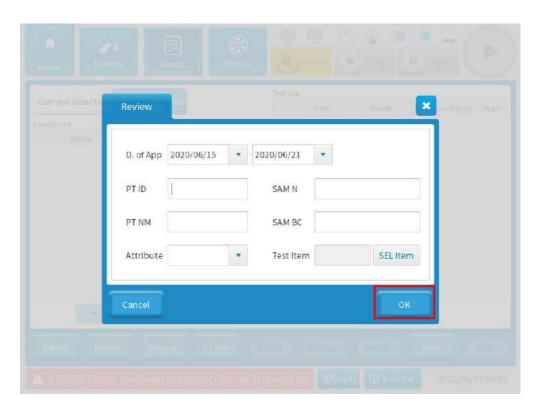
7. Review and Print of the Test Result

7.1 Click the **Result** above to view the results after the test, click **Current Results** to query the current results, and click the sample information to view the corresponding test results on the right;

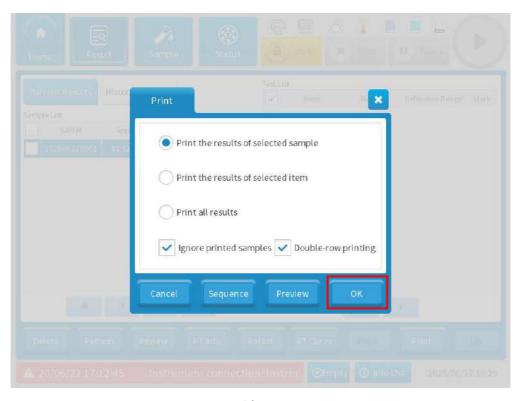


7.2 To query historical results, click **Historical Results-Review** and fill in the date range, patient ID, sample number, patient name, sample type, etc. you want to query in the pop-up interface and click **OK**;





7.3 To print the sample test results, click **Print**, select the results to be printed in the pop-up interface, choose whether to ignore the printed samples or whether to print in two columns; click **Sequence** to change the printing order, click **Preview** to preview, click **OK** to print after confirmation.



U3600 Series Urinalysis Hybrid System

Operation Manual



This device bears the CE marking in accordance with the provisions of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices and the Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

The CE marking only applies to electrical equipment which has been placed on the market as per the EU Directive mentioned above.

Unauthorized changes to this product are not covered by the CE marking.

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- Accident, neglect, misuse, relocation, unauthorized repair or modification of the instrument, whether intentional or unintentional;
- Using non-approved parts, accessories, consumables, etc.;
- Installing instruments by the personnel not authorized by Zybio or its local distributor and/or not using the instrument according to instructions in this manual; and
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E-mail: info@zybio.com

Revision history

Edition	Release date	Contents revised
01	May 10, 2022	First release

Contents

1		Gen	eral	1
1.1	_	Basic Information		
1.2	<u>)</u>	Models		3
1.3	3	Abo	ut this manual	3
1.4	ļ	Sym	bols	4
1.5	<u>, </u>	Elec	tromagnetic compatibility (EMC)	8
1.6	ò	Safe	ty precautions	8
1.7	7	Resi	dual risk	.15
2		Insta	allation	.17
2.1	-	Insta	allation requirements	.17
	2.1.	.1	Space requirements	.17
	2.1.	.2	Requirements for power supply	.18
	2.1.	.3	Environment requirements	.19
	2.1.	.4	Printer requirements	.19
	2.1.	.5	Handling requirements	.20
2.2	<u>)</u>	Syst	em connection	.20
	2.2.	.1	Computer connection	.20
	2.2.	.2	Connecting the reagent	.21
	2.2.	.3	Installation of sensor	.22
3		Instr	rument introduction	.24
3.1	-	Stru	ctural compositions	.24
	3.1.	.1	Sample processing module	.24
	3.1.	2	Optical counting cell module	.24
	3.1.	.3	Microscope camera module	.24
	3.1.	4	Auto strip-pick module	.25
	3.1.	.5	Test strip transport module	.25
	3.1.	6	Optical module	.25
	3.1.	.7	Fluidics module	.25
	3.1.	.8	Physicochemical module (optional)	.25
	3.1.	.9	Circuit control module	.26
	3.1.	.10	Data processing module	.26
	3.1.	.11	Software	.26
3.2	<u>)</u>	Арр	earance	.26
	3.2.	.1	Front view	.26
	3.2.	.2	Back view	.27
	3.2.	.3	Left side view	.28

3.	.2.4	Right side view	28
3.3	Per	formance parameter	29
3.	.3.1	Main test items and indicators	29
3.	.3.2	Main performance parameters	33
3.4	Spe	ecifications and configuration	35
3.5	Sof	tware interface	37
4	Оре	eration principles	41
4.1	Tes	t principle of urine sediment	41
4.2	Tes	t principle of strip	42
4.3	Tes	t principle of turbidity	43
4.4	Tes	t principle of color	43
4.5	Tes	t principle of specific gravity	44
4.6	Tes	t principle of conductivity	44
4.7	Cal	culation principle of osmotic pressure	45
5	Dail	y operation	47
5.1	Pre	parations before test	47
5.	.1.1	Sample preparation	47
5.	.1.2	Prepare strips and desiccants	48
5.	.1.3	Test tube requirements	49
5.	.1.4	Barcode requirements	49
5.	.1.5	Inspection before startup	50
5.2	San	nple test	51
5.	.2.1	Powering on	51
5.	.2.2	Log in onto software	51
5.	.2.1	Confirmation of instrument status	52
5.	.2.2	Sample test	53
5.	.2.3	Emergency diagnosis test	54
5.	.2.4	Modification of patient information	55
5.	.2.5	Confirmation of alarm information	56
5.3	Ret	est of sample	56
5.4	Tes	t result	57
5.	.4.1	Browsing of various test images	58
5.	.4.2	Manual classification of images	58
5.	.4.3	Sediment size browsing	60
5.5	Res	ult review	60
5.6	Que	ery for test results	61
5.7	Pre	view and printing of report	61
5.8	Del	etion of result	61

5.9	Export to LIS62		
5.10	Erythrocyte phase prompt function62		
5.11	Sleep62		
5.12	Shut down63		
6	Dat	ta query	65
6.1	Qu	ery	65
6.	1.1	Query by sample number	65
6.	1.2	Query by barcode number	66
6.	1.3	Query by patient's name	66
6.	1.4	Query by department	66
6.	1.5	Query by inspection time	67
6.2	Dat	ta query list	67
6.3	Cle	ar historical data	68
6.4	Exp	port of historical data	68
6.5	Pre	eview and printing of reports	68
6.6	LIS	export	68
7	Foo	cus	71
7.1	Мо	rphological focusing	71
8	Cal	ibrate	73
8.1	Мо	rphological calibration	73
8.2	8.2 Physicochemical unit calibration (optional unit)75		
8.2.1 Specific gravity calibration7			75
8.	2.2	Turbidimeter calibration	76
8.	2.3	Conductivity calibration	78
9	QC		81
9.1	Coi	ntrol	81
9.2	Qu	ality control settings	82
9.3	Мо	rphological quality control	82
9.	3.1	Quality control registration	82
9.	3.2	Morphological quality control testing	83
9.4	Dry	/ chemical quality control	84
9.	4.1	Quality control registration	84
9.	4.2	Dry chemical quality control testing	85
9.5	Phy	ysicochemical unit quality control(optional unit)	85
9.	5.1	Quality control registration	85
9.	5.2	Physicochemical unit quality control testing	86
9.6	Sta	ndard strip test	87
9.7	Quality control review88		

9.7.1	Morphological quality control query	88
9.7.2	Morphological quality control graph	89
9.7.3	Dry chemical quality control query	89
9.7.4	Dry chemical quality control graph	90
9.7.5	Printing	90
9.7.6	Physicochemical unit quality control query (optional unit)	91
9.7.7	Physicochemical unit quality control graph (optional unit)	91
9.7.8	LIS export	92
10 Stat	istics	93
11 Mar	nagement	95
11.1 Rea	gent management	95
11.2 Use	r management	96
11.3 Ger	der	97
11.4 Age	unit	97
11.5 Rac	e	98
11.6 Visi	t type	99
11.7 Cha	rge type	100
11.8 Deli	very department & doctor	101
11.8.1	Department	101
11.8.2	Doctor	101
11.9 Dilu	ition ratio	102
11.10 Mar	k	103
12 Sett	ings	105
12.1 Sys	tem configuration	105
12.1.1	Set language	105
12.1.2	Set result decimal precision	105
12.1.3	Device setting	105
12.1.4	Device temperature alarm range	105
12.1.5	PHYC unit setting	105
12.1.6	Reagent expiration range prompt	106
12.1.7	Alarm alert	106
12.1.8	Test mode	106
12.1.9	Set manual review	106
12.1.10	Set sleep time	107
12.1.11	Abnormal mark	107
12.1.12	LIS configuration	107
12.2 Mor	phological configuration	107
12.3 Dry	Chemical Configuration	109

12.4	Re-e	examination rule	109
12.	.4.1	Microscopic examination condition	109
12.	.4.2	Urine culture conditions	110
12.5	Auto	print	111
12.6	Auto	send to LIS	112
12.7	Auto	o review	112
13	Mair	ntenance	115
13.1	Rep	lace sheath fluid	115
13.2	Prin	ne sheath fluid	115
13.3	Gray	/	115
13.4	Emp	oty	115
13.5	Clea	ning flow pool	116
13.6	Clea	ning fluidics	116
13.7	Clea	ning physicochemical unit	117
13.8	Blar	nk test	117
13.9	Clea	ring data	117
13.10	Data	abase backup and recovery	117
14	Mair	ntenance and care	121
14.1	Clea	ning the waste strip box	121
14.2		ning the strip-transport plate	
14.3	Clea	ning waste liquid container	124
14.4		ning the scanning window of the barcode scanner	
14.5	Clea	ning the sensor	125
14.6	Clea	ning sheath fluid bottle	125
14.7	Emp	otying fluidics	126
14.8	Che	cking and replacing the tubing	126
14.9	Rep	lacement of wearing parts	127
14.10	Erro	r information and troubleshooting	127
Appen	ıdix A	Related information	163
Appen	idix E	3 Literature	166

1 General

The Urinalysis Hybrid System provides basis for clinical diagnosis through the analysis, counting and analysis on physicochemical indicators of the sediment of human urine by using the flow image analysis technology and the principles of photoelectric colorimetry, refraction method and scattering method. It features accurate analysis and convenient operation. The instrument can provide optional physicochemical indicators if corresponding modules equipped, including: color, turbidity, specific gravity and conductivity.

The Urinalysis Hybrid System covers three models: U3600, U3601 and U3602. This manual is prepared mainly for U3600, and it also applies to U3601 and U3602.

This manual aims to help users understand the structure, working principle, function, performance, operation, sample analysis, maintenance, troubleshooting and technical support of the instrument.

In this chapter, the basic information, model, manual information, symbols, electromagnetic compatibility, precautions and warnings of the instrument are mainly introduced.

Note

- Please carefully read and understand the contents of this manual before using the instrument to ensure the correct use of the instrument and the personal safety of the operator.
- The pictures in this manual are only used for illustration or example, but not for other purposes. All pictures shown are for illustration purpose only. Actual product may vary due to product enhancement.
- This manual is provided together with the instrument. Please keep this manual properly after reading for reference at any time.

1.1 Basic Information

The basic information about the Urinalysis Hybrid System is provided in this section.

Table 1-1 Basic Information

Category	Details
Product name	Urinalysis Hybrid System
Madal 0 DEF Na	U3600: REF 02-15-04-0003-00
Model & REF No.	U3601: REF 02-15-04-0004-00

Category	Details	
	U3602: REF 02-15-04-0005-00	
	The Urinalysis Hybrid System consists of a sample	
	processing module, optical counting cell module,	
	microscope camera module, automatic strip-pick	
Structure components	module, strip transmission module, fluid pathway	
	module, optical detection module, data processing	
	module, physicochemical module (optional), circuit	
	control module and software.	
	The Urinalysis Hybrid System is an automated	
	instrument, intended for quantitative and qualitative in	
Intended purpose	vitro determination of urine sediment, chemical	
	constituents and optional physicochemical parameters	
	of clinical urine specimens.	
Intended users	Medical laboratory professionals or technicians, and	
intended users	trained medical doctors or nurses.	
Intended use	Ctondordly managed laboratory	
environment	Standardly managed laboratory	
Overvoltage category	II	
Pollution degree	2	
Means of protection	Class I	
Degree of ingress	IPX0	
protection		
	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	
	Lotus NL B.V.	
EC REP	Koningin Julianaplein 10, 1e Verd, 2595AA,	
	The Hague, Netherlands.	
	See the instrument nameplate	
Service life	8 year ¹	
Contraindications	None	

Note 1: the service life of the instrument is determined based on the lifespan test performed on the device. In the process of use, the user shall maintain or repair the instrument according to the Manual. The instrument with basic safety and performance after maintenance or repair can be used normally. In the process of use, the user shall maintain and repair the product according to the requirements of the user manual. After maintenance and repair within the validity period, the products with the basic safety and effectiveness confirmed can be used normally.

1.2 Models

The Urinalysis Hybrid System covers three models: U3600, U3601 and U3602. The operation, working principle, main functions, composition structure and key components of the three models of instruments are exactly the same and only different in the amount of data stored. Refer to the following table for the difference of various instrument models

Product model	Functional difference	Software name	Software model	
U3600	Store no less than			
03600	500,000 pieces of data			
U3601	Store no less than	Urinalysis	U3600	
03001	100,000 pieces of data	0,000 pieces of data Hybrid System software		
113603	Store no less than	Suitware		
U3602	300,000 pieces of data			

Table 1-2 Model differences

1.3 About the manual

This manual is composed of 14 chapters and 2 appendices. Readers can find the correct chapters according to the information required.

Chapters	Introduction
	Introduces the basic information, model, manual
1. Introduction	information, symbols, electromagnetic compatibility,
	safety precautions of the Urinalysis Hybrid System.
2	Introduces the installation requirements and
2. Installation	precautions for use of the instrument
3. Instrument introduction	Introduces the structural compositions, parameter and
5. Instrument introduction	performance, specifications, configuration, and the

Table 1-3 Manual guide

	software requirements and interface of instrument.
4. Analysis principle and	Introduces the test principle and calculation method of
calculation method	the instrument.
5. Daily operation	Introduces the process of daily sample running.
C Data muami	Introduces the methods of data query, such as test
6. Data query	results.
7. Focus	Introduces the specific operation of daily focusing test.
O Calibrata	Introduces the main contents and operation of
8. Calibrate	calibration.
0 Quality control	Introduces the specific methods of daily standard test
9. Quality control	on control.
10 Ctatistics	Introduces the methods of workload, system log and
10. Statistics	maintenance record statistics.
11. Management	Introduces the operation and user settings of software.
12 Cottings	Introduces the operation and system settings of
12. Settings	software.
13. Maintenance	Introduces the common keys and operations in system
15. Maintenance	maintenance.
14. Maintenance and care	Introduces the contents and methods of system
14. Maintenance and care	maintenance and cleaning.
	Introduces the relevant information of the instrument,
Appendix A Related	including the information on term explanation, list of
information	accessories and reagent, cable information, training
	information, etc.
Appendix B Literature	The literature referenced is listed.

1.4 Symbols

The symbols used in the system and its manual are described in this section.

The symbols used in this manual are shown in the following table:

Table 1-4 Symbols used in the manual

Symbols	Explanation	
	Indicates a reference to substances that may be hazardous to	
	men, animals, plants, or the environment based on biological	
~	activity.	

Symbols	Explanation	
Warning	Indicates a situation that, if not avoid, could result in hazards or other serious adverse consequences from the use of an IVD medical device.	
Caution	Indicates a potentially hazardous situation which, if not avoid, could result in minor or moderate injury, or damage of the IVD medical device or incorrect results.	
Note	Indicates the important information or content that requires the attention of the operator.	

The symbols used on the instrument and its package are shown in the following table:

Table 1-5 Summary of instrument and packaging symbols

Symbols	Meaning	
•	Indicates that there are potential biological risks associated	
	with the medical device, necessary to consult instructions for	
	use for details.	
	Indicates the need for the user to consult the instructions for	
<u> </u>	use for important cautionary information (white	
	background).	
^	Indicates the need of taking care regarding the hazard	
, i	specified by the supplementary sign; the user needs to	
	consult the instructions for use (yellow background).	
	Indicates the need of taking care to avoid injury from sharp	
	elements.	
A	Indicates the need of taking care to avoid injury to hands	
	when in the vicinity of equipment with closing mechanical	
	parts.	
A	Indicates the need of taking care to avoid coming into	
	contact with electricity.	
) 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Indicates that this is a class-1 laser product, and laser	
LASER 1	radiation should be avoided.	
Do not unlock	Indicates that unlocking is strictly prohibited for lay persons.	
	<u> </u>	

Symbols	Meaning	
Waste strip box	Indicates the waste strip box.	
	Warning for disassembly. No disassembly by non- professionals is allowed.	
-	Indicates the placement of test strip.	
	Indicates the protective earth (ground).	
~	Indicates that the device is suitable for alternating current only.	
SN	Indicates the manufacturer's serial number so that a specific medical device can be identified.	
REF	Indicates the manufacturer's catalogue number so that the medical device can be identified.	
LOT	Indicates the manufacturer's batch code so that the batch or lot can be identified.	
~	Indicates the medical device manufacturer.	
سا	Indicates the date when the medical device was manufactured.	
<u> </u>	Indicates that this equipment is classified as Waste Electrical and Electronic Equipment under the European WEEE Directive. It must be recycled or disposed of in accordance with applicable local requirements.	
IVD	Indicates the instrument that is intended to be used as an in vitro diagnostic medical device.	
CE	Indicates CE marking of conformity.	
UDI	Indicates a carrier that contains unique device identifier information.	
Ţi	Indicates the need for the user to consult the instructions for use.	

Symbols	Meaning	
	Indicates the authorized representative in the European	
EC REP	Community.	
몲	Indicates the camera connection port	
	Indicates connection to the mains.	
\circ	Indicates disconnection from the mains.	
F1AL250V	Indicates the fuse specification.	
RS232	Indicates the serial port	
W2	Indicates the waste liquid outlet	
W-D	Indicates the waste liquid level sensor	
SW	Indicates the sheath fluid inlet	
SW-D	Indicates the sheath fluid level sensor	
	Indicates the maximum number of identical transport packages/items which may be stacked on the bottom package.	
	Indicates that distribution packages shall not be rolled or turned over.	
	Indicates that distribution packages shall be kept away from rain and be kept in dry conditions.	
	Indicates the correct upright position of the distribution package for transport and/or storage.	
	Indicates that contents of the distribution package are fragile therefore it shall be handled with care.	
-20°C	The temperature to be maintained for the transport package	
The humidity range to be maintained for the transport package.		

Symbols	Meaning
106.0kPa	The atmospheric pressure range to be maintained for the
50.0kPa	transport package.

1.5 Electromagnetic compatibility (EMC)

The Urinalysis Hybrid System complies with the emission and immunity requirements described in IEC 61326-2-6 and IEC 61326-1. It is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.

The instrument has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.

Do not use the instrument in close proximity to sources of strong electromagnetic radiation, as these may interfere with the proper operation. Use of the instrument in a dry environment, especially if synthetic materials are at present (synthetic clothing, carpets etc.) may cause damaging electrostatic discharges that may cause erroneous results.

1.6 Safety precautions

The special safety precautions for use of the Urinalysis Hybrid System are described in this section, so that the user can use the instrument safely and effectively. The following instructions should be followed strictly. Otherwise, inaccurate test results, instrument damage, personal injury, etc. may be caused.

Note

- The Urinalysis Hybrid System can only be operated and used by the personnel trained by Zybio or its distributors.
- The instrument should be correctly installed in the environment specified in this manual. For installation and use of the instrument in the conditions other than that specified, unreliable results and damage to the instrument may be led to. As for changing the working environment of the instrument, if required, please contact Zybio or its distributors.
- In the case that the label of the instrument is blurred or falls off, please contact Zybio for replacement.

- For incorrect analysis parameters will lead to wrong test results, please consult Zybio or its distributors.
- Before the test, carefully check the joints of each tubing for any liquid leakage, which will lead to inaccurate aspiration and dispensing capacity.
- Carefully check the reagents and samples before testing to ensure no insoluble floating matters, such as cellulose, fibrin and others. Otherwise, the sample probe will be blocked.
- Do not place reagents and samples on the top cover or workbench of the instrument to avoid liquid spilling and leakage.
- Some substances of the discarded instrument are subject to the pollution control regulations. Please follow the local regulations to handle the discarded instrument.
- Any serious incident that has occurred in relation to the instrument shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

System use

In order to use the Urinalysis Hybrid System more safely and effectively, please use according to the following regulations:

Warning

- The instrument should be used according to the relevant instructions in the manual. Improper use may lead to incorrect test results, or even system damage or personal injury.
- The protection provided by the instrument may be receded if it is not used in the manner prescribed by Zybio.
- Do not touch the rack-in module in operation to prevent scratching.
- Do not install any software and hardware other than those specified by Zybio in the system. Meanwhile, do not run other software during the system operation. Otherwise, the normal operation of the system may be hindered.
- Do not use this system for any other purposes. As the computer virus may spread through USB, program, network and other means, improper use may cause the instrument to be infected by the virus.

Near the power interface of the instrument are two fuses (specification: F1AL250V).
 If either one is blown, please replace it timely.

Note

- During the first test of the instrument, focusing and calibration should be performed at first, followed by quality control, so as to confirm that the system works normally.
- For daily use of the system, it is recommended to perform daily focusing and quality control to ensure the reliability of the results.

System maintenance

The Urinalysis Hybrid System should be maintained according to the following regulations:

Warning

- Please maintain the system according to the relevant instructions in this manual.
 Improper maintenance may lead to incorrect test results, or even system damage or personal injury.
- The hospital or institution using this instrument must properly formulate and implement a set of acceptable repair/maintenance plan to avoid failure of the instrument or threatening the personal safety.
- After the main components, such as the physicochemical components, optical components and syringe components, are replaced, calibration analysis is required.
 The replacement and maintenance of all components shall be carried out by the after-sales engineer or agent designated by Zybio.

Note

- If the instrument is out of service due to failure or other reasons and maintenance or treatment is required, please contact Zybio or its distributors in time. Meanwhile, other measures, such as using other instruments or methods, should be taken to replace the unfinished test, so as to avoid the delay of the results.
- The surface of the instrument shall be wiped with a cloth wet with 75% ethanol or water every day. Do not use strong acid and strong alkaline cleaning agents, as they may cause a hazard as a result of a reaction with parts of the instrument or with

material contained in it. If there is any doubt about the compatibility of decontamination or cleaning agents with parts of the instrument or with material contained in it, please contact Zybio or its authorized local distributor.

Sample

Prepare, store and use samples in strict accordance with the following regulations.

Note

- Please use a urine sample without any suspended solids. The suspended solids contained in the urine sample, if any, may lead to the blockage of the sample probe, which may further affect the accuracy of the test results. So, the operator should carefully observe the sample state.
- Store the samples correctly. Improper sample storage conditions may change the component content of the sample, thus affecting the accuracy of the test results.
- Do not leave the sample open for a long time to prevent the volatilization of sample. Otherwise, the accuracy of the test results may be affected.
- There might be interference factors in dry chemical tests, please refer to the instructions for use of the dry chemical reagents.
- The system has requirements for sample size of analysis. During sampling, the sample size should be determined properly according to the relevant instructions in this manual.
- Before analysis, it should be confirmed that the sample is placed at the correct place. Otherwise, the correct results cannot be obtained.

Reagent

The reagents should be stored and used in strict accordance with the following regulations.

Note

For analysis with this system, the reagents produced by Zybio shall be used.
 Otherwise, the test results will be unreliable and the instrument may be damaged.

- For the use and storage of reagent, calibration solution and control, please refer to the reagent manual.
- Attention should be paid to the validity of supporting control and test strip. It is not allowed to use the expired control and test strip. The use of expired control or test strip will lead to the unreliable test results.
- The reagent, calibration solution and control, if stored improperly, even within the validity, may lead to failure to obtain correct test results.
- If the reagent lot number varies, focusing, calibration and analysis of quality control is required. Otherwise, the accuracy of test results may be affected.
- Before the continuous test, it is necessary to confirm that the reagent is sufficient and the connection interface is correct. Otherwise, no correct test results can be obtained.

Preventing electric shock

The Urinalysis Hybrid System meets the requirements on electrical safety in IEC 61010-1, IEC 61010-2-101. To prevent electric shock, the following regulations should be observed strictly:

Warning

- The power supply must be properly grounded. Otherwise, a risk of electric shock may be led to.
- The impedance between the protective earthing and each accessible part of the instrument shall be lower than 100 m Ω . Otherwise, unstable analysis result, electric leakage of the housing, and electric shock may occur due to poor grounding.
- Before the instrument is connected to the power cord, it must be ensured that the
 voltage and frequency of the AC power supply are as required by the instrument.
 The power must be off to connect the power cord.
- The unauthorized maintenance personnel shall not open the panel of the instrument when the power is on. Avoid spilling liquid on the workbench. If any liquid enters the instrument, turn off the power immediately and contact Zybio in time.

- In case of power failure, turn off the instrument immediately, and do not open the enclosure.
- Do not touch the power switch or the cord with wet hands.
- Do not unplug the power cord if the power is not cut off.
- Do not clean the instrument if the power is not cut off.
- Do not replace the fuse if the power is not cut off.
- This instrument complies with the IEC 61010-1 standards, and repeating any tests of this standard may damage the instrument and reduce protection against danger.

Laser safety

A laser product is contained in the instrument. In order to avoid laser injury to users, please read the following information carefully:

Warning

- The built-in barcode scanner CM600_L280 is a Class-1 laser product (according to IEC60825-1:2014, publication date 2014-05-15), which is used for the identification of sample barcode. The emitting wavelength is 650 nm (red), and the pulse duration is <120 µs. Users shall not disassemble the instrument under any circumstances. Otherwise, a risk of uncontrolled laser radiation may be resulted in.
- The external handheld barcode scanner is a LED red light product, which is mainly used to scan the barcode information of samples. Therefore, never look at the beam of scanner directly when the handheld barcode scanner is used.
- During the installation, commissioning and maintenance of the instrument, the warning information on the surface of the instrument should be read carefully, so as to avoid the possible harmful laser radiation.
- The direct glare or reflection of laser rays should be avoided. Retinal injury may be caused in case of glaring at the laser rays with the naked eye for long time.

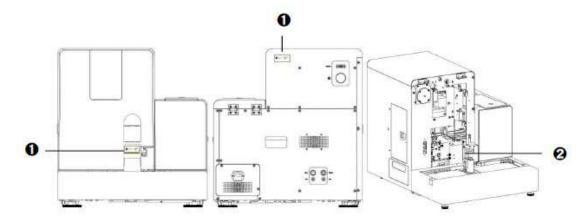


Figure 1-1 Laser label

No.	Part name	Description
		It is affixed to the emergency baffle and the back of
1	LASER	the instrument, reminding the user that there is class
	1	1 laser radiation in these areas and do not look
		directly at the laser beam.
2	Lacarindani	It is located at the back of the emergency baffle and
2	Laser window	used to scan the sample barcodes.

Biological risk

The instrument operation and disposal of waste and scrapped instrument shall be performed in strict accordance with the following regulations.



- When using the instrument, operators should take preventive measures, such as
 wearing gloves, masks, protective glasses and overalls. Otherwise, infection may
 be caused due to contact with the contaminated areas and liquids, or skins may be
 damaged by contact with corrosive liquids. If the body contacts the contaminated
 or corrosive liquid accidentally, washing with water and immediate disinfection is
 required.
- The waste liquid, mainly containing the clinical urine samples, the used reagents and the waste cleaning liquid, should be treated and discharged according to the discharge standard for biological risks.

- Users are required to complying with the relevant regional and national regulations on the discharge and treatment of reagents, waste liquid, waste samples, consumables, etc.
- When the instrument reaches its service life, it is recommended to stop using and dispose of it according to the requirements of the local environmental authority, but not to treat and discard as general waste.

1.7 Residual risk

The Urinalysis Hybrid System is a dedicated medical device, the safe and effective operation of the instrument requires the correct use of hardware and software system, as well as appropriate operating conditions.

The instrument shall be operated by persons obtained necessary trainings, and having a good knowledge of its intended use and the safety warnings and precautions for its usage.

Despite risk mitigation measures are implemented to minimize verities of hazards as far as possible, risks including but not limited to biological hazards, and electromagnetic compatibility cannot be completely excluded.

The instrument is used together with matched reagents as a detection system to provide test results of clinical samples. The reagents shall be chosen and used according to the instructions for use to ensure the accuracy of results.



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2 Installation

The installation information of the instrument is mainly introduced herein, including the installation requirements, system connection, sensor installation and precautions for use, etc.

It is noted that the instrument should be strictly tested before delivery. In order to avoid impact during transportation, the instrument should be carefully packed before transportation. When the instrument arrives, the packaging should be carefully checked for any physical damage. In case of any damage, Zybio or its distributors should be notified immediately.

Warning

Unpacking and installation by personnel not authorized or trained by Zybio may cause personal injury or instrument damage. Do not unpack and install the instrument without the presence of authorized personnel of Zybio.

Note

- During transportation, the moving components are fixed with clamps/binding ties before shipment to avoid damage to the sampling components. Hence, the clamps/binding ties must be removed before using the instrument.
- After unpacking, the instrument should be carefully inspected visually and checked according to the attached packing list. In case of any damage caused during transportation or incomplete configuration, Zybio or its distributors should be notified immediately.

2.1 Installation requirements

Before installation, the operator must ensure that the following space, power supply, environment and fuse requirements are met preferably.

2.1.1 Space requirements

The instrument dimensions are: 687 mm (Length) ×512 mm (Width) ×530 mm (Height)

In order to provide space for repair and maintenance and to ensure the heat dissipation and normal operation of the instrument, the following conditions shall be satisfied during the installation of instrument:

- The workbench surface should be smooth (with an inclination less than 1/200);
- The workbench can bear a weight of at least 150kg;

- The distance from the left and right sides of the instrument to the wall shall not be less than 500 mm, and the distance to other instruments shall not be less than 1000 mm.
- The distance from the back plate of the instrument to the wall shall not be less than 500 mm.
- The distance from the front of the instrument to other instruments shall not be less than 1000 mm.
- Do not place the device in a position where it is difficult to operate the disconnecting device.

The instrument should be installed according to the space requirements as shown in the figure below.

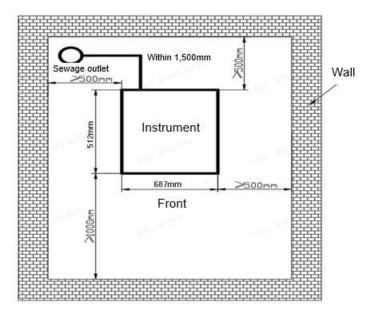


Figure 2-1 Space requirements for installation

2.1.2 Requirements for power supply

- 100 V 240 V, 50/60 Hz, with the main supply voltage fluctuation within $\pm 10\%$.
- The power socket shall be properly grounded, the voltage to ground shall be less than 5V, and the grounding resistance shall be less than 100 m Ω . If permitted, the instrument shall be connected to a special power cord.
- Input power: 150 VA. The hospitals are recommended to equip online UPS over 2000 VA.

Warning

- The instrument must be used under correct and good grounding conditions. Incorrect grounding may cause electric shock and instrument damage.
- The input voltage must meet the requirements of the instrument.

2.1.3 Environment requirements

The environmental requirements for instrument installation are mainly described herein.

- The environment should be as free as possible from dust, mechanical vibration, large noise source and power interference.
- It is recommended to evaluate the electromagnetic environment of the laboratory before the device is put into operation.
- The environment should be well ventilated, and ventilation equipment can be used, if necessary, but the direct air flow to the instrument should be avoided.
- Avoid direct sunlight or placement in front of heat source and wind source.
- Do not get close to the brushed motor, the flashing fluorescent lamp and the electrical contact devices that are normally on and off.
- No corrosive and combustible gas.
- Indoor use.

Warning

The instrument cannot be used in the flammable and explosive environment.

Note

- If the room temperature is higher than the normal working temperature range of the instrument, the instrument temperature may be out of limit, and the test results will be unreliable.
- If the instrument is in a dusty environment for a long time, the performance of the instrument may be degraded.

2.1.4 Printer requirements

The USB external printer is required to connect to the USB interface of the computer. For printer connection, please refer to the instructions for use of the related printer.

Note

Zybio does not provide printer, and users shall prepare the required printer.

2.1.5 Handling requirements

Never move the instrument installed and put into normal operation without authorization, so as to avoid vibration and damage to the high-precision components and wearing parts therein, which will affect the normal operation of the instrument.

To handle the instrument, if required, please contact Zybio or its distributors.

Warning

Never move the instrument without authorization. Otherwise, instrument failure or personal injury may be caused, for which Zybio will not undertake any liability.

2.2 System connection

The main information on system connection is described herein, including computer connection, reagent connection, sensor installation, and precautions during installation.

2.2.1 Computer connection

Refer to the following diagram to connect the computer with the instrument by a serial port cable and a network cable. Specifically, the network port is connected with that of the independent network card in computer, and the serial port is connected with that of the independent serial port card of the computer.

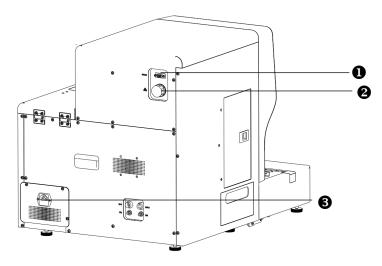


Figure 2-2 Electrical connection diagram

No.	Components
1	RS-232 interface
2	Network port
3	Power interface

2.2.2 Connecting the reagent

Please refer to the following diagram to connect the sheath fluid inlet pipeline and waste liquid tube of the instrument.

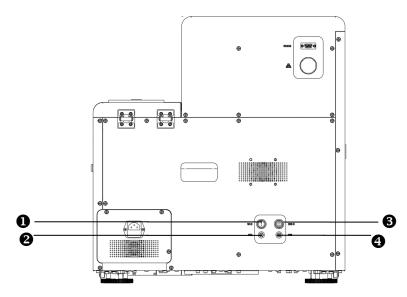


Figure 2-3 Reagent connection diagram

No.	Components
1	Waste liquid sensor
2	Waste liquid interface
3	Sheath fluid sensor
4	Sheath fluid interface



- Users are required to complying with the relevant regional and national regulations on the discharge and treatment of reagents, waste liquid, waste samples, consumables, etc.
- The reagents are irritant to eyes, skin and mucous membranes. Users exposed
 to the relevant articles in the laboratory should abide by the safe laboratory
 operation specifications and wear personal protective equipment (such as
 the protective clothing, gloves, masks, etc. for laboratory).

Caution

- The panel joint of the pipelines should be tightened, so that the whole pipeline is closed to prevent liquid leakage and seepage caused by siphon.
- The sheath fluid must be provided by Zybio or its distributors. Otherwise, the accuracy of the test results may be affected.

2.2.3 Installation of sensor

The installation of sensors is mainly introduced in this section, with the specific contents as follows:

- Installation of sheath fluid level sensor
- (1) Press and open the circular cardboard with a dotted line for cutting on the upper side of the sheath fluid tank to expose the round hole.
- (2) Pull up the container lid so that the cardboard around the round hole sticks to the container neck on the lower side of the lid to prevent it from sinking.
- (3) Rotate to open the container lid (with the lid retained) and prohibit any foreign matter from entering the container.
- (4) Install the sheath fluid level sensor in the accessory package. The sensor should be kept upright as far as possible during installation, and the container lid of the sheath fluid level sensor should be tightened.

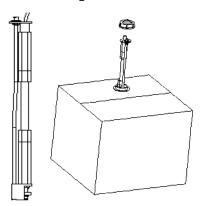


Figure 2-4 Installation of sheath fluid sensor

Replacement of sheath fluid

The replacement process of sheath fluid is similar as the installation of sensor. The empty container and lid of sheath fluid should be reserved for backup.

Note

The shelf life of sheath fluid at room temperature is 30 days after being uncovered.

• Installation of waste liquid level sensor

Take a waste liquid container (with an empty container equipped in the packing box or replaced by an empty sheath fluid container. Pull the nozzle of the sheath fluid container out of the box for exposure), and open the lid. Install the waste liquid level sensor in the accessory package. During installation, the waste liquid sensor should be kept upright as far as possible, and the container lid of the sensor should be tightened to prevent the waste liquid from overflowing.

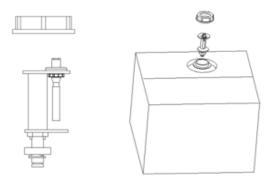


Figure 2-5 Installation of waste liquid level sensor

Note

- The liquid level sensor used in this device is only applicable to the waste liquid container provided by our Company or the waste liquid container of same specification and model (such as the sheath fluid container used by this instrument).
- For the connection of waste liquid tube, never fold or flatten the drain.



- Please make sure to wear gloves, masks, work clothes, and safety goggles during operation to prevent infection
- The waste liquid, mainly containing the clinical urine samples, the used reagents and the waste cleaning liquid, should be treated and discharged according to the discharge standard for biological risks.

3 Instrument introduction

The structure, parameter performance, specification, configuration, and the software requirements and interface of instrument are introduced in this chapter. It is noted that the graphics, settings or data in the illustration may not be completely consistent with the actual instrument due to different model and version.

3.1 Structural compositions

The instrument consists of a sample processing module, optical counting cell module, microscope camera module, auto strip-pick module, test strip transport module, fluidics module, optical module, data processing module, physicochemical module (optional), circuit control module and software.

3.1.1 Sample processing module

It is mainly composed of sample rack, rack-in assembly, and sample extraction assembly.

Rack-in assembly: its main function is to scan the sample barcode and transfer the sample to be tested, a single sample rack can hold 10 samples.

Sample aspiration assembly: it is designed to drive the sample probe to the aspiration position and cleaning position.

Fluidics assembly: with the pressurized gas and fluid as the medium, it is designed for fluid supply, sample mixing, sample aspiration, laminar flow in the flow cell, sample probe cleaning, and drainage of liquid waste, etc.

3.1.2 Optical counting cell module

It is mainly composed of a flow cell and a flow cell holder. After the instrument collects the sample, the sample to be tested and the sheath fluid entering the instrument are adjusted by the fluidics module and enter the flow cell at the preset flow rate and ratio. The sample forms a flat laminar flow in the flow cell, which is captured by the microscope camera module.

3.1.3 Microscope camera module

It is mainly composed of optical assemblies. Its function is to take a picture of the sample when the sample flows through the shooting area of the optical counting cell

module, and transmit it to the data processing module.

3.1.4 Auto strip-pick module

It is mainly composed of strip-pick assemblies. Its function is to supply the test strips in the test strip chamber according to the specified quantity and direction.

3.1.5 Test strip transport module

It is mainly composed of the toothed plate, cam, bedplate, toothed plate fixing plate, vertical guide rail, limit shaft, rolling bearing, motor bracket, horizontal guide rail, connecting rod, fixed shaft and side plate. Its function is to transport the test strips selected by the strip-pick assembly to the sample dropping position and the test position according to the specified direction and time.

3.1.6 Optical module

The optical module is mainly composed of optical detector, LED, data acquisition board, support structure, guide rail, motor, synchronous belt, and zero-position optocoupler. The optical detector and LED are connected to the data acquisition board and fixed on the surface of the support structure. The motor drives the synchronous belt and the linear guide rail to drive the support structure to collect the information of the test strip at the test position of the test strip transport.

3.1.7 Fluidics module

The fluidics module is mainly composed of the syringe assembly, liquid storage assembly, cleaning assembly, pump, valves, pipeline and joints. It works on the principle that in a closed circuit (system), the pressurized gas and liquid are used as the media by the air pump, hydraulic pump and syringe to realize water replenishment, sample bubble mixing, sample extraction and sample cell cleaning, sample dropping, laminar flow in the flow cell, outer wall cleaning of sample probes, and liquid waste emptying during the transport of the device.

3.1.8 Physicochemical module (optional)

The physicochemical module is used to detect the color, turbidity, specific gravity, and conductivity of the samples. The sample color is obtained according to the R, G and B values; the specific gravity is obtained by testing the sample's ability to refract light; the conductivity value is obtained by testing the conductivity of the sample.

3.1.9 Circuit control module

It is mainly composed of the main control board, rack-in control board, and switching power supply. It is powered by the switching power supply, and the CAN bus realizes the communication between the modules.

3.1.10 Data processing module

The data processing module performs image segmentation on the sediment targets in the captured images, extracts the features of the target image in terms of morphology, statistics, frequency domain and texture, and normalizes these features as the input of the classifier for classification and calculation through the recognition algorithm of the data processing module. Finally, it is presented in the software interface through data transmission, and the user can audit it.

3.1.11 Software

The software has such functions as sample testing, data query, focusing, calibration, quality control, statistics, system management, system maintenance, shutdown, and fault prompt. If the device is equipped with a physicochemical module, the software supports setting of the physicochemical module to test specific gravity, color, turbidity, and conductivity.

The software can perform operations such as sample application test, result query, online status check of test, focusing application test, calibration application test, quality control application test, device setting and maintenance.

3.2 Appearance

This section mainly introduces front view, back view, the left side view and the right side view of the instrument.

3.2.1 Front view

The structure and relevant important components on front of the instrument are introduced in this section. See the figure below for details:

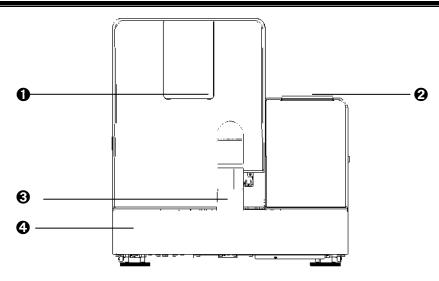


Figure 3-1 Front view of instrument

No.	Parts	Description	
1	Status indicator lamp	The working status of instrument (Blue: working	
1	Status indicator tamp	and standby mode; orange: instrument failure)	
2	Ctrip pick cover	Open the strip-pick cover to put in or take out the	
2	Strip-pick cover	test strip	
3	Emergency site	Site for sample testing in priority	
4	Rack-in module	For transfer of tube rack	

3.2.2 Back view

The structure and relevant important components on back of the instrument are introduced in this section. See the figure below for details:

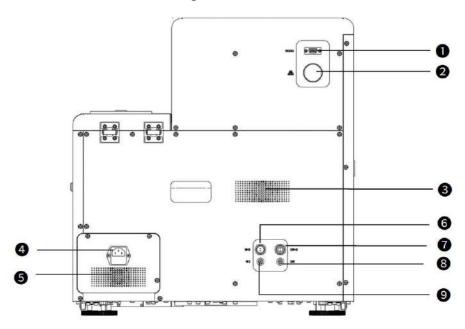


Figure 3-2 Back view of instrument

No.	Parts	Description	
1	RS-232 interface	Used to connect the computer for data transmission	
2	Network port	Used to connect the computer for image transmission	
3	Fan of the whole	Used for heat dissipation of the instrument	
J	device		
4	Power socket	Connection point of power input line	
5	Power supply fan	For heat dissipation of power supply.	
	Waste liquid sensor	Used to connect the waste liquid sensor	
6	interface		
7	Sheath fluid sensor	Used to connect the sheath fluid sensor	
1	interface		
8	Sheath fluid tube	Used to connect the sheath fluid tube.	
0	nozzle	Osed to connect the sheath itulu tube.	
9	Waste liquid tube	Used to connect the waste liquid tube.	
ן פ	nozzle		

3.2.3 Left side view

The structure and relevant important components on left side of the instrument are introduced in this section. See the figure below for details:

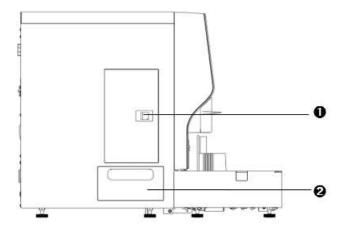


Figure 3-3 Left side view of instrument

No.	Parts	Description	
1	Left door	Open the cabin door of sheath fluid buffer bottle	
2	Waste strip box	Collect the waste strip after use.	

3.2.4 Right side view

The structure and relevant important components on right side of the instrument are introduced in this section. See the figure below for details:

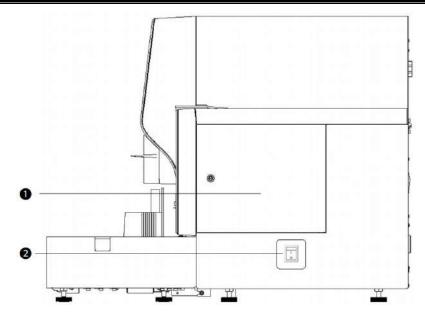


Figure 3-4 Right side view of instrument

No.	Parts	Description	
1	Right side door	Used to open the strip-pick door for maintenance of	
1	Right side door	strip-pick structure.	
2	Dawarawitah	Main power switch of instrument (press "I" to start up	
2	Power switch	and "O" to shut down)	

3.3 Performance parameter

The performance parameter information of instrument is mainly described in this section, including the main test items and indicators, and the main performance parameters.

3.3.1 Main test items and indicators

The main test items and indicators of instrument are mainly introduced in this section. Besides, the test items and sample pictures are shown in the following table:

Table 3-1 Main test items and indicators

Items	Description		
	Red blood cells (RBC), white blood cells (WBC), white blood		
	cell clump (WBCC), phagocyte (PHCY), squamous epithelial		
Test items of	cells (SQEP), non-squamous epithelial cells (NSE), budding		
sediment	yeast (BYST), yeast with pseudo hyphae (HYST), bacillus		
	(BACI), suspected coccus (SUCO), sperm (SPRM), mucus		
	(MUCS), hyaline cast (HYAL), unclassified casts (UNCC), fat,		

Items	Description			
	amorphous (AMOR), magnesium ammonium phosphate			
	crystal (MAPH), calcium oxalate monohydrate (COM), calcium			
	oxalate dihydrate crystal (COD), uric acid crystal (URIC),			
	ammonium urate crystal (AUCR), tyrosine crystal (TYRO),			
	calcium phosphate crystal (CAPH), unclassified crystal			
	(UNCX), an	d the unclassified (U	NCL).	
	Urobilinog	en (URO), bilirubin (E	BIL), ketone body (KET), occult	
	blood (BLI	D), protein (PRO), n	nitrite (NIT), white blood cell	
Dry chemical test	(WBC), glud	cose (GLU), specific g	ravity (SG), pH, Vitamin C (VC),	
items	microalbur	min (MALB), creatin	ine (CRE) and calcium (Ca),	
	urine prote	ein/creatinine ratio	(P:C), urine microalbumin to	
	creatinine ratio (A:C)			
Physicochemical	Specific gravity (SG) (optional), turbidity (optional), color			
test items	(optional),	conductivity (option	onal), and osmotic pressure	
(optional)	(reported v	vhen conductivity co	onfigured)	
Emergency	Emergency	diagnosis test is sup	pported	
function				
Identification of				
abnormal red	The function of prompting abnormal red blood cells.			
blood cells				
	120 tests/hour for urine sediment only			
Test speed	240 tests/hour for dry chemical only			
	120 joint tests/hour			
	Urine	Minimum size: 3 mL non-centrifugal urine		
	sediment	Suction volume: Ab	J	
	mode	Suction volume: AL	JOUL 1.0IIIL	
		Without the	Minimum volume: 3 mL non-	
Sample size	Dry m chemical w mode W	Without the physicochemical module	centrifugal urine	
			Aspiration volume: About	
			1.6mL	
		With physicochemical	Minimum volume: 3 mL non-	
			centrifugal urine	
			Aspiration volume: About	
		module 1.6mL		

Items	Description		
	Urine		
	sediment		
	+	Minimum volume: 3 mL non-centrifugal urine	
	Dry	Aspiration volume: About 1.6mL	
	chemical		
	mode		
Size of sample to	60 samples		
be tested	ou samples		
Capacity of test	200 strips		
strip cabin	300 strips		
Capacity of waste	200 strips		
strip box	300 strips		

Note 1: the reference intervals of urine protein/creatinine ratio (P:C), urine microalbumin to creatinine ratio (A:C), and the osmotic pressure are 0-200mg/g, 0-30mg/g, and 600-1000mOsm/kgH $_2$ O respectively. For the reference intervals of the 14 items of dry chemical, please refer to the instructions for use of the Urinalysis Strip (Dry Chemistry Method).

Note 2: the osmotic pressure is only used as the research parameter but not as the basis for judging the clinical test results.

Table 3-2 Test items and sample pictures

Category	Abbreviation	Sample pictures
Red blood cell	RBC	
White blood cell	WBC	®
White blood cell clump	WBCC	
Phagocyte	PHCY	

Squamous epithelial cells	SQEP	
Non-squamous epithelial cells	NSE	
Budding yeast	BYST	and the second
Pseudomycelium yeast	HYST	<i>y</i>
Bacillus	BACI	
Suspected coccus	SUCO	
Sperm	SPRM	
Mucus	MUCS	
Hyaline casts	HYAL	
Unclassified casts	UNCC	
Fat	FAT	
Amorphous	AMOR	1. 李
Magnesium ammonium phosphate crystal	МАРН	

Calcium oxalate monohydrate	СОМ	o o o
Calcium oxalate dihydrate crystal	COD	*
Uric acid crystal	URIC	
Ammonium urate crystal	AUCR	
Tyrosine crystal	TYRO	*
Calcium phosphate crystal	САРН	

Note

- A single particle that cannot be classified according to the above 23 categories is regarded as an unclassified name.
- In order to distinguish and identify the unclassified crystals, unclassified casts, and the unclassified, the operator must review the image and manually identify the image through the operation software to confirm the classification.

3.3.2 Main performance parameters

Table 3-3 Performance parameters of instrument

Name		Description		
Repeatability of urine sediment				Coefficient
		Sediment	Concentration/	of
		name	(pcs/μL)	variation
				(CV, %)
		Red blood	50	≤ 15.0
		cell	200	≤ 8.0
Identification	Coincidence	Sediment	Coincidence rate/%	
rate of urine	rate of single	name		

Name		Description	
sediment	result with	RBC	≥ 70
test	microscopic	WBC	≥ 80
	examination result	Cast	≥ 50
	False negative rate of urine sediment		ative rate of the test results of nt shall not be greater than 3%.
Stability of urine sediment		The coefficient of variation (CV) of cell count results shall not exceed 15% within 8 hours after the instrument is started.	
Carryover of urine sediment		The carryover of instrument to cells shall not be greater than 0.05%.	
Repeatability of urine dry chemical test items		The coefficient of variation (CV,%) of reflectance test results of instrument shall be ≤ 1.0 .	
Accuracy of matching with test strip for urine analysis		The difference between the test result and the indicated value of the reference solution in the same direction shall not exceed one order of magnitude, and no reverse difference is allowed. No negative test result can be obtained from the positive reference solution, while no positive result can be obtained from the negative reference solution.	
Stability of urine dry chemical test items		reflectance to	nt of variation (CV, %) of est results within 8 hours after nt is started shall be ≤ 1.0.

Name	Description
	The positive samples with the highest
	concentration results of all test items except
Carryover of urine dry chemical	the specific gravity and pH should be tested,
test items	and the negative sample shall also be tested.
	No positive is allowed for the negative
	sample.

3.4 Specifications and configuration

The specifications and configuration as well as the working specifications of the instrument are described in this section.

Specifications and configuration

See the following table for the specifications and configuration of the instrument.

Table 3-4 Specifications and configuration

Items	Description
Dimensions (Length×Width×Height)	687 mm×512 mm×530 mm
Weight (kg)	Gross weight: 90 kg; net weight: 55 kg
Input/output device	Printer (configured by user)Handheld barcode scanner
Communication interface	 RS232 communication interface (DB9 female) Network port (RJ45 network port socket)
Power	 Voltage: 100V - 240 V~ Power: 150 VA Frequency: 50/60 Hz
Fuse	F1AL250V
Pollution degree	2
Classification of laser product	Class 1
Noise level	<66 dB
Minimum computer configuration	 CPU: Dominant frequency 2.8 GHz Memory capacity: 8 GB Hard disk: 500 GB Screen: Screen resolution: 1,920 × 1,080 Graphics card: Support CUDA 10.1

Items	Description
	Memory capacity of graphics card: 6 GB
Software name	Urinalysis Hybrid System software
Software model	U3600
Version	V1
Software running	64-bit operating system Windows 10 and its compatible
environment	version
	Network type: LAN
	Broadband: No requirement
Network conditions	Note: to avoid cyber-attack, it is suggested not to
	connect the computer installed with the software to
	Internet.
	Name: Windows Defender
	Model and specification: Windows Defender
	• Full version: 4.12.1625.15 and its compatible version
	Supplier: Microsoft (Microsoft Corporation)
Security software	Requirements for operating environment: Windows
Security software	10, 64-bit operating system. The users are
	recommended to scan and remove the computer virus
	at least once a month.
	• Update: It can be updated by user to the latest version,
	if necessary.
	Connect to the LIS through the network interface or
Interface	serial port to transmit data in dual ways; Data
	transmission protocol is HL7 or ASTM.
	Login password is required by the software of
	instrument for user identification. The software is
User access control	equipped with a control system for user access,
osci access control	including the identification method (user name and
	password), type and authority (administrator, operator
	and reviewer) of the user.

Environmental specifications

The environmental specification of instrument is shown in the following table:

Table 3-5 Environmental specifications

Items	Working conditions	Storage and transportation conditions
Ambient	10°C - 30°C	-20°C - +55°C
temperature	(Temperature fluctuation < 2 °C/H)	-20 C - +33 C
Relative	Not more than 80% (no frost)	Not more than 93%
humidity	Not more than 80% (no nost)	Not more than 95%
Atmospheric	70.0 kPa - 106.0 kPa	50.0 kPa - 106.0 kPa
pressure	10.0 KPa - 100.0 KPa	50.0 KPa - 100.0 KPa
Altitude range	Below 3,000 m	\

Note

The instrument must be used, stored and transported under the specified environmental conditions.

3.5 Software interface

The relevant information on software interface of the instrument is introduced herein. As shown in the figure below, the operation interface of software mainly comprises the toolbar, the status bar, and the functional area.



Figure 3-5 Operation interface of software

Toolbar

The toolbar icons and functions are shown in the table below:

Table 3-6 Toolbar icons and functions

Icons	Description
D	The user triggers the start button to start the sample test.
	The user triggers the stop button, and thus the instrument stops
	working to stop the test item.
	The user triggers the emergency button, and the emergency
<u> </u>	samples can be tested.
	The user triggers the reset button and the instrument acts for
	resetting.
	The user triggers the shutdown button and the instrument enters
	the process of shutdown.
	Displaying the instrument connected currently.
22℃ [[Displaying the current ambient temperature.
Ø LIS	Displaying the connection status of LIS. For the LIS symbol, red is
	for disconnection while green for connection.

Status bar

- Status display area
 - Displaying the current status of instrument, as shown in the following example:
 - Standby;
 - "Dry CHM. + Morphology" test, "Morphology" test and "Dry CHM." test.
 - Alarm display area

System status: Click "system status" to view the detailed status of the instrument.

Instrument alarm: If the instrument contains any error information or fails, the error or alarm information will be displayed in the bottom information bar, and the "instrument alarm" button at the bottom of the software interface will also flash. Then, click the flashing "instrument alarm" button to enter the alarm information page.

Account:

• Account display area

Displaying the name of the current login user, such as "admin".

Software version

Click the drop-down box button on the left of "admin" to view the current version of software.

Functional area

Multiple function buttons are contained, which are mainly used to open various functional pages of the instrument, mainly including the following modules:

Sample testing: Sample registration can be performed and the test results of the day can be displayed.

Data query: The sample test results can be reviewed, including the historical results.

Focusing: The registration, deletion and execution of focusing can be performed.

Calibration: Test can be performed for morphological calibration and the calibration of physicochemical units (optional).

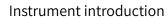
Quality control: The QC information setting, application for QC test and querying of QC results can be operated.

Statistics: The workload, login information and maintenance records can be counted.

System maintenance: The unit module reset, instrument priming, manual triggering of daily and routine maintenance, and diagnostic operation can be performed.

System management: The following settings can be made, including user management, reagent management, gender, age, race, type of visit, cost type, inspection department and doctor, sample type, dilution ratio and exception identification.

System settings: The language selection, IP setting, instrument setting, and report setting of the instrument can be performed.



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4 Operation principles

The operation principles of the Urinalysis Hybrid System, including the routine test of urine, and the qualitative and quantitative counting of urine sediment, is described in this chapter.

4.1 Test principle of urine sediment

The urine sediment test of the instrument is based on the principle of flow microscopy imaging.

The hydrodynamic system of the instrument is composed of a special flow cell in shell structure. After sampling by the instrument, the sample enters the flow cell, and the injection pump works to pump the sheath fluid into the flow cell, so that the sample entering the shell structure of the flow cell is wrapped by the sheath fluid. Under the action of sheath fluid, the sample liquid flows through the shell structure of the flow cell in a single layer of cells. Meanwhile, the high-frequency light source, shaped by the lighting component, illuminates the shooting area of sediment at strobe frequency. Then, adjust the imaging component by magnification. The camera takes photos at the same frequency, and transmits the captured image data of sediment to the computer software. The computer software will perform the image segmentation to the sediment target on the image, extract the features of the target image in terms of morphology, statistics, frequency domain and texture, and thus normalize these features as the input of the classifier. Then, through the classification and calculation by the identification algorithm of the computer software, the tested urine sample will be discharged into the waste liquid container. As shown in the figure below:

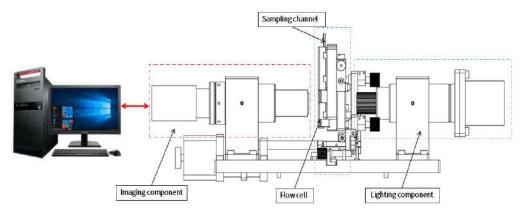


Figure 4-1 Schematic diagram of imaging principle

The sheath flow technology, high-speed camera technology and image

identification technology for tests by the instrument are described as follows:

- Sheath flow technology: The sheath fluid used by the instrument for test is an isotonic, particle-free buffer solution, capable of ensuring that the sediment in the urine sample always flow in a single-layer manner. The flow cytometry technology is adopted to ensure that each sediment is photographed and imaged at high speed by flowing in front of the microscope lens and CCD camera within the focus range of the microscope lens. In addition, the urine flows in a diffused way, which can also effectively avoid the accumulation of sediment.
- High-speed camera technology: The urine sample enters the flow cell in the wrap of sheath fluid and flows in front of the objective lens in a flat laminar flow, with its thickness and position just within the focus of the microscope. According to the sheath flow principle, any particle passing through will directly aim at the lens with the maximum cross-sectional area. When the visual field of each microscope is illuminated by LED light source, the sediment passing through is photographed instantaneously. The CCD camera takes an image containing sediment for each sample within a specific period of time. As shown in the figure below:

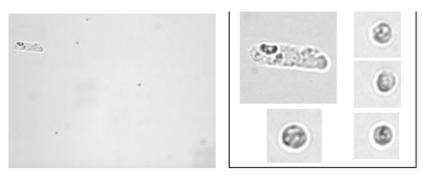


Figure 4-2 Images of sediment

Image identification technology: The automatic identification software of sediment and the image identification technology can quickly extract the images of sediment particles, and identify and classify them according to the characteristics, such as morphology, texture and frequency domain, of the captured "particles".

After classification by the automatic software of sediment, the concentration of sediment is calculated according to the number of captured "particle" images and the volume of scanned urine samples. The result unit can be expressed in the number per microliter or in the number per high/low power field.

4.2 Test principle of strip

The Urinalysis Hybrid System analyzes the content of biochemical components in urine through the color change caused by the reaction of the reagent block on the test strip with the biochemical components in urine according to the principle of photoelectric colorimetry.

When the test strip soaked with urine sample is transmitted to the test area and further by the synchronous belt to the place right below the optical detector for test. After the reagent blocks on the test strip subjected to the chemical reaction are irradiated by the light source, the reflected light is received by the detector. Each reagent block in the test strip reacts independently with various elements of the urine to show different colors. The depth of color is proportional to an element in the urine. The darker the color of the reacted reagent block, the greater the amount of absorbed light, the smaller the amount of reflected light, and the smaller the reflectivity. On the contrary, the lighter the color, the smaller the amount of absorbed light, the larger the amount of reflected light, and the greater the reflectivity. In other words, the depth of color is positively correlated with the concentration of an element in the urine sample.

4.3 Test principle of turbidity

The light from the luminescent tube on the turbidimeter passes through the sample and detects how much light is scattered by the particles in the sample in the direction of 90° of the incident light. This measurement method of scattered light is called the scattering method. Generally, the turbidity of urine is divided into four gradients: "clear", "slight turbid", "turbid" and "very turbid".

The formula for measuring the turbidity by scattering method is:

T = (SS/TS - SW/TW)/K

Where:

T: Turbidity level

SS: Scattering luminosity grade of urine sample

TS: Emission luminosity grade of urine sample

SW: Scattering luminosity grade of wash solution

TW: Emission luminosity grade of wash solution

K: Coefficient

4.4 Test principle of color

The sample color is tested by RGB color sensor. Specifically, the sample is irradiated by white light-emitting diode, of which the R, G and B values are detected by the color sensor after transmission. Then, the sample color is obtained according to the R, G and B values.

4.5 Test principle of specific gravity

The light of the light-emitting diode becomes a beam through a gap and lens device. Besides, the light passes through a prism tank containing urine and then radiates on the detector. The refractive index varies according to the specific gravity of urine in the prism tank, and thereby the light angle related to the detector also varies.

The calculation formula of refractive hydrometer method is:

$$SG_X = (SG_H - SG_L) (K_X - K_L) / (K_H - K_L) + SG_L$$

Where:

SG_X	Specific gravity of sample solution		
SG _H	Specific gravity of high-concentration		
	solution		
SGL	Specific gravity of low-concentration		
	solution		
K _X	Position coefficient of sample solution		
K _H	Position coefficient of high-		
	concentration solution		
K _L	Position coefficient of low-concentration		
	solution		

The specific gravity of sample solution changes with the temperature of the urine sample. The specific gravity changes by 0.001 for every 3 °C change in temperature.

4.6 Test principle of conductivity

The conductivity unit is designed with 2 electric corrosion-resistant conductive joints to test the conductivity of electrolyte solution in urine. The temperature sensor is designed in the instrument.

The calculation formula of conductivity is:

Conductivity before temperature compensation: Condnotemp=9.994/R

Where:

Condnotemp	Conductivity before temperature
	compensation
R	Corrected resistance
Canadhanan	Conductivity after temperature
Condtemp	compensation
Temper	Temperature value

4.7 Calculation principle of osmotic pressure

The osmotic pressure is of linear correlation with the conductivity, and the regression equation of osmotic pressure to conductivity is:

$$Y = A + BX$$

Where:

A, B	Coefficient
Х	Conductivity results



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5 Daily operation

This chapter mainly introduces specific procedures of daily test operations, including pre-test preparations, viewing, modifying, printing, reviewing, and re-examination of test results, as well as precautions during the test.

Note

- When connecting the drain, be careful not to fold or flatten it.
- If the foam in the sample is higher than 5 mm, the foam in the sample shall be reduced through settlement to less than 5 mm before the test.
- Avoid put any viscous sample under the test to prevent clogging the sample probe.
- The waste liquid container connected to the instrument shall be placed on the ground, and the waste liquid tube shall be as vertical as possible to the ground to ensure the smooth flow of the waste liquid.

Caution

• The operator shall stay away from the sampling position of the sample probe to avoid injury.

5.1 Preparations before test

This section mainly introduces preparations before the test, including sample preparation, test tube requirements, barcode usage requirements, and pre-test checks, etc.

5.1.1 Sample preparation

Considerations when preparing samples are as follows:

- Collect urine in clean or sterilized utensils.
- Use fresh urine samples which shall be kept out of direct sunlight. If the test cannot be performed within 1 hour after collection, please seal the urine and store it in the refrigerator under 2°C–8°C. The test shall be completed within 2 hours. The sample shall be returned to room temperature before the test.
- Do not add preservatives, disinfectants and cleaning agents to the urine sample.
- Do not centrifuge the sample, and mix the urine sample thoroughly before the test, or otherwise the sensitivity of the test result will be affected.
- When testing the sample, the instrument must be used for the test in the required

operating environment. If the temperature exceeds the range, the accuracy of the test result may be affected.

• The instrument requires a test sample volume of no less than 3 mL.

Note

- If the sample volume is 3 mL, it is necessary to use a pointed test tube. It is recommended that the test tube not be fully filled with the sample during the test to avoid the liquid overflow when the instrument automatically mixes and sucks the sample.
- If the concentration of urine sample is high, dilute the sample before performing an analysis.

5.1.2 Prepare strips and desiccants

Prepare strips and desiccants according to the requirements below.

Note

- The strips prepared must be consistent with the settings in the instrument. To ensure the reliability of the test results, check the strip type first before use.
- The strip chamber is capable of holding up to 300 strips, and the strips cannot be left in the strip chamber for more than 24 hours. The damped strips will affect the accuracy of the test results, so please put the strips in the strip chamber back into the strip vial and cap the vial tightly after all the tests are over.
- When placing the strips, ensure that the black end of the strip is in the same direction as the label affixed to the strip chamber to avoid failure to select the strip.
- Please use the desiccants in the strip vial.
- Strips

Open the strip-pick cover **1** at the right side of the instrument, adjust the black end direction of the strip in accordance with the label **3** affixed to the strip chamber **4**, and feed the strips to the strip chamber.

Desiccant I

Open the strip-pick cover **1** at the right side of the instrument, place the desiccant on the desiccant area **2**, and ensure that the strip-pick cover is properly closed.

Desiccant II

There is also a desiccant chamber at the side of the strip-pick module, and the desiccant can be replaced when cleaning the strip-transport plate (see chapter 14.2). To open this

desiccant chamber, twist the hand screw **6** (flat side down) of the fixed desiccant chamber **6**.

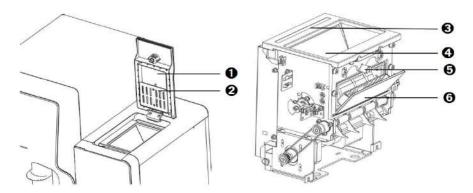


Figure 5-1 Strip and desiccant placement illustration

No.	Part name
1	Strip-pick cover
2	Desiccant area
3	Label for the strip placement
4	Strip chamber
5	Hand screw
6	Desiccant chamber

5.1.3 Test tube requirements

The test tube requirements are as follows:

- Sample tube specifications: The outer diameter of the tube is 14–15 mm, and the length is 90–110 mm. The shape of the test tube shall be regular, and there shall be no extrusion deformation. Test without the cover opened can be achieved with the test tube sealed with aluminum foil and tin foil of same specification. For the specific test tube types for the without the cover opened, please contact Zybio.
- Tube rack specifications: Use the tube rack that came with the instrument.

5.1.4 Barcode requirements

This section mainly introduces the types, specifications, and specific use requirements of barcodes.

- Barcode type: Accepted barcodes are Code 39, Code128, EAN128, Code 93, Codebar, Interleaved 2 of 5.
- Barcode specifications



Figure 5-2 Barcode specifications illustration

The specific requirements on barcode specifications are as follows:

Barcode height: d ≤ 20 mm

Barcode label width: a ≤ 45 mm

Blank space on both sides of barcode: $b \ge 3$ mm, $c \ge 3$ mm

 The barcode shall be flat, wrinkle-free, pollution-free, and the lines shall not be printed with imperfections, or otherwise the barcode cannot be read correctly.

When pasting the barcode, the lower edge of the barcode shall be positioned more than 25 mm from the bottom of the tube to ensure the barcode can be scanned correctly. At the same time, during the process of putting the test tube into the tube rack, ensure that all barcode labels can be seen from the longitudinal notch of the tube rack, , and make sure the test tube is placed vertically, and closely against the base.

When the barcode type is Code 39, Code 128, Code 93, the characters can be used including letter, digit, -, blank space, +, /, %, and \$.

• The numbers of digits for different types of barcodes are shown in the table below:

Sample barcode typeCode number identificationCode394-12Code1284-25Code934-16Codabar4-15Interleaved 2 of 54-22

Table 5-1 Table of numbers of digits of barcode types

5.1.5 Inspection before startup

Please perform inspection according to the following requirements before powering on the instrument to ensure that the instrument is ready.

 Check the power supply: The power supply is correctly grounded and provides the correct voltage.

- Check the power cord: The power cord is firmly and tightly connected.
- Check the strips: The test strips have been correctly placed in the strip chamber.
- Check the sheath fluid: Keep enough sheath fluid in the sheath fluid container.
- Liquid waste: Keep the liquid waste bucket empty.
- Check the tubing: The tubing is not kinked, broken, or poorly connected.
- Check the waste strip box: There is enough space in the waste strip box for waste strips.
- Check Printer: Check whether the power cable and data cable to the printer are connected correctly, and whether the printing paper used by the printer is in sufficient stock.

5.2 Sample test

This section mainly introduces the main process of test on sample, including powering on, software login, instrument status confirmation, test on sample, emergency diagnosis test, patient's information modification, alarm information confirmation, etc.

5.2.1 Powering on

Before the test, turn on the following power sources:

- Power on the computer and the monitor, respectively.
- Turn on the printer's power switch (if configured), and mount the printing paper.
- Turn on the power switch of the instrument.

5.2.2 Log in onto software

The steps for software login are as follows:

(1) Enter the username and password in the "Login" dialog box, and click on "Login".

Note

The default user name of the system administrator is "admin", and the default password is "admin". It is recommended to change the password when using it for the first time to prevent others from tampering with the rights of the administrator. If the operator forgot the password, Zybio or the local distributor shall be contacted.

(2) After the login is successful, the instrument performs the startup initialization test. After the instrument calibration is carried out automatically, and if the power-on self-check result is normal, and the main interface of the operating software will be successfully entered. At this point, the startup process is over.

5.2.1 Confirmation of instrument status

After logging in onto the software, please confirm the status of the instrument first. The specific confirmation information is as follows:

Status confirmation

Click "System status" at the bottom of the main interface of the software to enter the "System status" interface, as shown in the figure below.

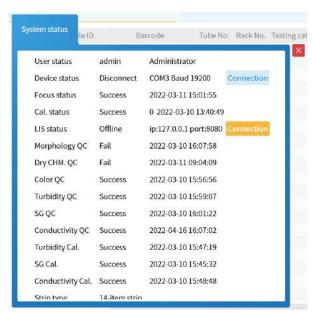


Figure 5-3 "System status" interface

Alarm confirmation

When an alarm sets off in the instrument, in addition to the flashing alarm icon "Device alarm", if a buzzer sound prompt is also needed, click on "Settings" in the main button area on the left side of the interface to enter the "Settings" interface, and set the "Alarm tone" to "On" and click on "Save". In this way, the instrument will have double prompts during the alarm.

- Morphological focusing, calibration
- Focus: Operate according to "7.1 Morphological focusing", and execute it once a day when the instrument is turned on.
- Calibrate: Operate following "8.1 Morphological calibration", at least once a month.
- Physicochemical unit calibration

Hydrometer, turbidimeter: Operate following "8.2.1 Specific gravity calibration", "8.2.2 Turbidimeter calibration" and "8.2.3 Conductivity calibration", at least once a month.

• Dry chemical calibration

Test strip test: Operate according to "9.6 Standard strip test". 9.6Standard strip test

Quality control

Operate following "9.3.2 Morphological quality control testing", "9.4.2 Dry chemical quality control testing", "9.5.2 Physicochemical unit quality control testing", and execute it once a day when the instrument is turned on.

Replenish

The instrument needs to consume sheath fluid when performing "Focus", "Calibrate", "QC" and "Test" When the remaining sheath fluid is insufficient, it should be replenished, or otherwise the test cannot be performed normally. See Chapter 11.1 for the method of sheath fluid replenish.

Note

The instrument shall be carried out in the order of "Focus", "Calibrate" and "QC". When calibration is not required, it shall be carried out in the order of "Focus" and "Calibrate".

5.2.2 Sample test

This section mainly introduces the main information on the test on sample. The main steps of the test on sample are as follows:

- (1) Place the barcoded tube with the urine sample on the tube rack, keeping the tube perpendicular to the rubber base.
- (2) Place the tube rack on the right side of the rack-in module of the instrument.
- (3) Click "Start" in the shortcut key area at the top of the main interface, and the "Test Info." interface will pop up.
- (4) Select the test mode on the "Test Info." interface (Dry chemical, Morphological, Dry chemical and Morphological). Enter the initial sample number. Click "OK", and the tube rack is automatically transferred to the sample suction position of the instrument for the test. Click "Register sample" at the upper left of the "Test" interface to display the information on the sample under tested.
- (5) Click "Test result" at the top right of the "Test" interface to display a list of results after the test is completed.

Note

- This "Test result" interface only display the results of tests completed on that day and the results that have not been released.. If a historical result needs to be queried, click"Data query" in the main button area of the interface. For specific operations, please refer to "6 Data query".
- If the test sample needs to be diluted, please use a diluent that applies to the model of this product and is with a registration certificate. Before the test, pull down the options and select the set dilution ratio in the "Dilution ratio" box on the "Test" interface.

5.2.3 Emergency diagnosis test

As shown in Figure 5-3, pull out the emergency diagnosis rack **1** to the outside. Put the emergency diagnosis sample tube **2** into the round hole on the emergency diagnosis rack.

Push the diagnosis rack back to its original position.

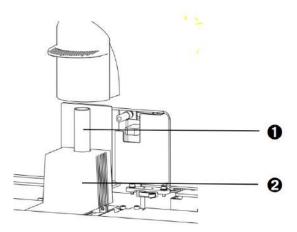


Figure 5-4 Emergency diagnosis sample placement

No.	Part name
1	Emergency diagnosis rack
2	Emergency diagnosis sample test tube

Click "Emergency" in the shortcut button area at the top of the interface. The sample probe will automatically move to the emergency diagnosis position to suck the sample. After the test is completed, the result will be displayed in the "Test result" list in the "Test" interface. For emergency diagnosis samples, the sample number is displayed as En (e.g. E1, E2) in the work list, and the rack/tube number of an emergency diagnosis sample is displayed as null.

5.2.4 Modification of patient information

This section mainly introduces the modification of patient information.

Note

Editing of patient's information can be done during and after the test on sample before the re-examination.

Before or after the sample test, if the LIS is connected, "LIS import" will be displayed at the lower right corner of the "Register sample" and "Test result" interfaces of "Test". Click "LIS import" to import the relevant LIS information to the sample registration interface, and the sample barcodes scanned by the built-in barcode scanner will correspond to the imported information. Basic sample test information can also be manually registered on the left side of the sample registration interface. To delete and modify the sample information that has been registered, click "Delete" or "Modify" at the bottom of the interface.

In the "Test result" interface, click on the page-turning button at the bottom left of the interface to turn pages, and click on the result in the list to select the sample.

Enter the barcode number, patient name, age unit, medical record number, bed number, and note in the patient's information column; select the patient's gender, age unit, race, visit type, charge type, department, delivery doctor, sample type, dilution ratio and other information (mnemonic symbols can be used during registration), click "Modify" to complete the information editing and modification of patient's information, and the patient's information is automatically displayed in the result list.

- Age unit: Enter the age in the input box and select the appropriate age unit in the drop-down list box. This function is set in the "Management" window of the main button area. For specific operation, please refer to "11.4 Age unit".
- Gender: Select an appropriate gender from the drop-down list box. This function is set in the "User settings" window of the main button area. For specific operations, please refer to "11.3 Gender".
- Race: Select an appropriate race from the drop-down list box. This function is set in the "User settings" window of the main button area. For details, please refer to "11.5 Race".
- Visit type: Select an appropriate type of visit from the drop-down list box. This function is set in the "User settings" window of the main button area. For details,

please refer to "11.6 Visit type".

- Type of fee: Select an appropriate type of fee from the drop-down list box. This function is set in the "User settings" window of the main button area. For details, please refer to "11.7 Charge type".
- Department: In the drop-down list box, select the department category to which the sample submitted for inspection belongs. This function is set in the "User settings" window of the main button area. For specific operations, please refer to "11.8.1 Department".
- Inspection doctor: Select the doctor's name in the drop-down list box. This function is set in the "User settings" window of the main button area. For specific operations, please refer to "11.8.2 Doctor".
- Dilution ratio: Select an appropriate type from the drop-down list box. This function is set in the "User settings" window of the main button area. For specific operations, please refer to "11.9 Dilution ratio".
- Mark: Enter a customized abnormality mark in Name. This function is set in the "User settings" window of the main button area. For specific operations, please refer to "11.10 Mark".

5.2.5 Confirmation of alarm information

If a fault occurs during the test, the software will send an alarm prompt, and an alarm icon for "Device alarm" will flash in the shortcut key bar in the lower right corner of the screen. Click the "Instrument alarm" in the lower right corner of the interface to display brief descriptions such as the number of alarms, alarm codes, alarm levels, time of alarm, etc.

Note

When an alarm occurs, please refer to the alarm handling method to deal with it. If the fault still cannot be cleared, please contact Zybio.

5.3 Retest of sample

This section mainly introduces the specific operations of the retest of sample.

(1) Before starting retest

After the initial test is over, if the sample needs to be retested, select the sample to be retested in the result list on the test result interface.

(2) Initiation of retest

Click "Retest", select the test mode, place the sample to be reviewed on the tube rack, and place the tube rack on the right side of the rack entry module of the instrument. Click "OK" on the interface to retest the sample.

(3) Viewing of retest result

The retest result is displayed on the "Test" interface. The retest results (if the retest sample number is 10, the retest result will be displayed in the list with the sample number as 10#1) are displayed in the list, and the retest sample number is selected. Click "Review comparison" to display the comparison result before and after the retest. Click "Replace" to replace the test result before the retest with the result after it.

Note

- Retest can only be carried out for the test result on the same day.
- To retest the sample, "Retest" must be clicked on to send the retest command.

5.4 Test result

In the "Test result" interface list, double-click on the selected sample information after the test to view the test result.



Figure 5-5 "Test result" interface

 The right side of the interface displays the urine dry chemical and physiochemical results of the corresponding sample and the total number of particles detected in

- morphological detection, among which "*P: C", "*A: C" and "Osmotic pressure" are research parameters.
- Results of sediment are displayed on the left side. Each sediment can be viewed in the result and is with a reference value range. A result in the normal range is green; a result in the abnormal range is red, and it is displayed in red in the display area where it exceeds the standard.
- If there are too many sediment in the sample test result, scrolling down can be down along the list.
- Click "Previous sample" or "Next sample" to browse other test results.

5.4.1 Browsing of various test images

Click on the button with a representation of the cell in the result of the sediment, and the image of the particle will be displayed in an enlarged form. For example, double-click "Red Blood Cells", and the result is shown in the figure below.



Figure 5-6 Sediment image browsing interface

5.4.2 Manual classification of images

In case of misidentification, the image can be reclassified as follows:

 Select the image that does not match the name of the sediment in the sediment image interface. Click the corresponding category button on the right side of the screen to complete the reclassification. Click "Back", return to the "Test result" interface, then click on "Save", and the above modification can be saved and confirmed.

The followings are three ways to select particle pictures on the sediment image interface:

- Click the image directly to select it or cancel the selection;
- Hold down the left mouse button and drag the mouse, a rectangular box will be displayed. After releasing the button, all images in the rectangular box will be selected;
- Click the particle name button, all particle images on the current page will be selected, click the button again to deselect the images.
- If the manual classification has been completed and the operation is found to be with errors, before clicking on "Save", "Cancel" can be clicked on the test result interface for cancellation and re-classification.

The following categories can be automatically identified:

Erythrocytes, leukocytes, leukocyte masses, phagocyte, squamous epithelial cells, non-squamous epithelial cells, budding yeasts, pseudohyphae, bacilli, cocci, sperms, mucus filaments, hyaline casts, pathological casts, fat, amorphous, magnesium ammonium phosphate crystals, calcium oxalate monohydrate, calcium oxalate dihydrate crystals, uric acid crystals, ammonium urate crystal, tyrosine crystals, calcium phosphate crystals, unclassified crystals, and the unclassified.

The following categories can be manually identified:

Table 5-2 Categories can be manually identified

Cell	Cast	Crystallization	Others
Normal erythrocyte	Red blood cell	Amorphous	Trichomonas
Normal erytmocyte	cast	phosphate crystal	
Other poikilocyte	White blood cell	Sodium urate	Oval fat body
Other polkhocyte	cast	crystal	
Erythrocyte mass	Granular cast	Calcium	Artifact
Erytinocyte mass		carbonate crystal	
Large red blood cell	Broad cast	Cystine crystal	/
Microcyte red blood cell	Waxy cast	Leucine crystal	/
Polymorphonuclear	Renal tubular	/	/
Leukocyte	epithelial cast		

Cell	Cast	Crystallization	Others
/	Fatty casts	/	/

5.4.3 Sediment size browsing

Enter the sediment image interface, select the image of the sediment of the test item, move the mouse to the top of the sediment to display the diameter of the sediment, and make judgments for clinicians more intuitive, as shown in the figure below.



Figure 5-7 Sediment size browsing interface

5.5 Result review

To review a sample result, select a test result in "Test result" on the "Test" interface. Click "Review" at the bottom of the interface. "Yes" is displayed under the corresponding "Review" in the list. The reviewer is the current logged-in user by default. The review time is the current time. And this indicates that the review is completed. If batch review is to be performed, click on "Batch review" at the bottom of the "Test result" interface of the "Test" interface, a prompt box will pop up. Select the date and the starting and ending sample numbers to be reviewed in the prompt box. Click "OK". "Yes" is displayed under the "Review" corresponding to the selected sample result in the list. The reviewer is the currently logged-in user by default. The review time is the current time. And this indicates that the review is completed.

After review, a prompt to confirm whether release the reviewed test results is displayed, then click "Confirm" to release. The released test results are cleared in the result list,

and can be viewed in the "Historical data." Click "Cancel" to give up release.

Click to select the reviewed test results, and click "Cancel review" to cancel the review.

5.6 Query for test results

Click "Search" in the "Test result" interface to enter the corresponding interface. Enter the query conditions (sample number, barcode, patient name, emergency diagnosis or not, medical record number, test time, etc.). Click "OK". And the result of the sample that meet the conditions will be displayed on "Test result" interface.

5.7 Preview and printing of report

The printed report can display up to 16 particle images. Select the image in the "Browse sediment size" interface, right click on it to select "Add flag", and the flagged image will display a green dot at the upper right corner. Go back to the result search interface, click "Save" to save the flag or click "Cancel" to cancel the flag. After the particle image is successfully flagged, it can be displayed on the printed report.

Report preview and printing operations are as follows:

- Report preview and printing of single sample result: Select a test result in "Test result" on the "Test" interface. Click "Print" to preview the result record to be printed. If the report needs to be printed, click on "Print" again.
- Report preview and printing of batch samples: To print reports in batches, click on "Batch print", and enter the starting and ending sample numbers for batch printing in the "Sample ID" input box, and then click on "Print".

Note

The starting sample number for batch printing must be less than or equal to the ending sample number.

5.8 Deletion of result

The operation of sample result deletion is as follows:

• Delete the single sample result: If a sample result is to be deleted, select a test result in "Test result" on the "Test" interface, click on "Delete" at the bottom of the interface. A prompt box will pop up showing "Do you confirm to delete the selected data?" Click "OK", and a prompt box showing will pop up showing "Deleted successfully!", indicating that the deletion is successful.

Delete the sample results in batches: If deletion in batches is to be done, select
multiple or all the checkboxes in front of the serial numbers, click on "Delete", and
a prompt box will pop up showing "Do you confirm to delete the selected data?"
Click "OK", and a prompt box showing will pop up showing "Deleted successfully!",
indicating that the deletion is successful.

5.9 Export to LIS

Export of test results to LIS: Check one or more pieces of sample information in "Test result" on the "Test" interface, and click on "LIS export" to upload the test results to the LIS.

5.10 Erythrocyte phase prompt function

This section mainly introduces the erythrocyte phase prompt function.

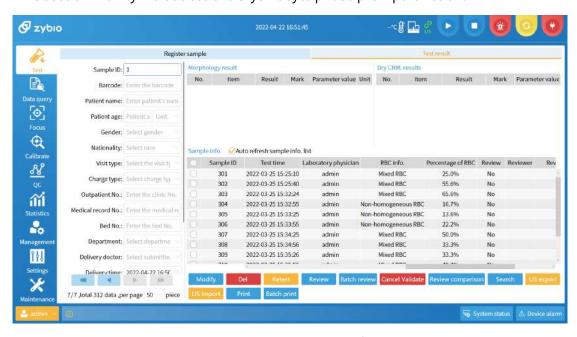


Figure 5-8 "Test result" interface

In the test result list, detailed information on the erythrocytes of the sample after the test is displayed. If the number of normal erythrocytes in the sample is less than 30%, heterogeneous erythrocytes and the detailed proportion will be displayed. If the number of normal erythrocytes in the sample is between 30% and 70%, mixed erythrocytes and the detailed proportion will be displayed. If the number of normal erythrocytes in the sample is greater than 70%, homogeneous erythrocytes and the detailed proportion will be displayed.

5.11Sleep

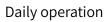
When the sleep time setting is enabled in the system configuration interface, if the fluidic-related operations have stopped for the time period preset by the operator, the Urinalysis Hybrid System will enter the sleep mode.

When the Urinalysis Hybrid System is in sleep mode, any reset or any analysis can wake up it. After a reset, it will enter the standby mode. And an analysis can be performed only after it is woken up. During the sleep, the sample probe will be immersed in the cleaning pool and the syringe will be pulled down, which is intended to protect them from any damage. Please note that these will not happen for the standby mode.

5.12Shut down

After all the tests are over, follow the steps below to shut down the instrument.

- (1) Click "Shut down" button on the right side of the toolbar, a dialog box will be displayed. There are 3 options including "Exit", "Exit after cleaning", and "Cancel" on the dialog box.
- (2) Click "Exit" to exit the software; click "Cancel" to cancel the shutdown operation; click "Exit after cleaning", the information "Please put the test tube containing the wash solution on the sample rack, and then click Confirm." will be displayed.
- (3) After the tube with wash solution is placed properly, click "Confirm" and the instrument will perform cleaning automatically. The information "The cleaning is done. Please turn off the instrument, and the program will be shut down in 30s" will be displayed.
- (4) Press the switch to "O" to turn off the instrument. The software will be shut down after counting down or click "Shut down" to exit directly.



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6 Data query

This chapter mainly introduces the relevant content of data query. Users can select query conditions according to actual needs, view the data query list, and perform operations such as clearing and exporting of historical data.

6.1 Query

Click "Data query" on the main interface for the query, export, upload to LIS, and printing of the test result, as shown in the following figure:

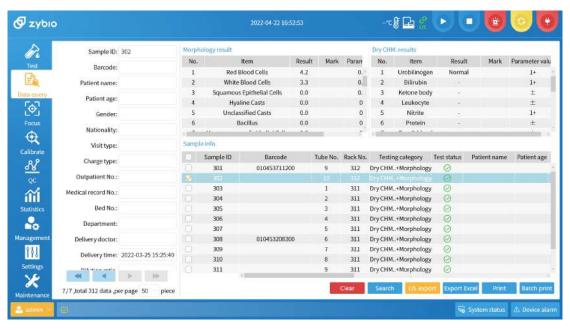


Figure 6-1 "Data query" interface

On the "Data query" interface, click "Search" at the bottom, and the "Result query" dialog box will pop up.

6.1.1 Query by sample number

The steps to make the query by sample number are as follows:

(1) On the "Result query" interface, enter the starting sample number in the sample number input box. The ending sample number must be greater than or equal to the starting sample number. At the same time, select the test time (the default is 0:00 to 24:00 on that same day). For example: The starting sample number is 1, the ending sample number is 3, and the inspection time is selected from March 3, 2021 to 24:00 on March 4, 2021.

(2) After entering the information, click on "Confirm", and all historical records with sample numbers 1 to 3 from March 3, 2021 to March 4, 2021 at 24:00 will be displayed in the data query list. Click "Cancel" after entering the information, and no query for historical records will be made.

6.1.2 Query by barcode number

The steps to query by barcode number are as follows:

- (1) Enter the complete barcode number or a part of the barcode number in the barcode number input box on the "Result query" interface, and select the inspection time (the default is 0:00 to 24:00 on that same day), for example: The barcode number is "123456", and the inspection time is selected from March 3, 2021 to 24:00 on March 4, 2021.
- (2) After the input, click "OK", and all the historical records including 123456 in the barcode number from March 3, 2021 to March 4, 2021 at 24:00 will be displayed in the data query list; Click "Cancel" after entering the information, and no query for historical records will be made.

6.1.3 Query by patient's name

The steps to make a query by a patient's name are as follows:

- (1) Enter the patient's full name or a part of the patient's name in the patient's name input box on the "Result query" interface, and select the test time (the default is 0:00 to 24:00 on that same day), for example: The patient's name is "Wang", and the test time is selected from March 3, 2021 to 24:00 on March 4, 2021.
- (2) After the input, click "OK", and all historical records with "Wang" in the patient's name from March 3, 2021 to March 4, 2021 at 24:00 will be displayed in data query list; Click "Cancel" after entering the information, and no query for historical records will be made.

6.1.4 Query by department

The steps to make a query by department are as follows:

(1) Click "Data query", and then click "Search" to select the corresponding department name from the drop-down box of the department on the "Result query" interface. Select the name of the department and select the inspection time (the default is 0:00 to 24:00 on that same day), for example: The name of the

- department is "Internal Medicine", and the inspection time is selected from March 3, 2021 to 24:00 on March 4, 2021.
- (2) After inputting, click "OK", and in the data query list, all the historical records submitted by the internal medicine department from March 3, 2021 to March 4, 2021 at 24:00 will be displayed; Click "Cancel" after entering the information, and no query for historical records will be made.

6.1.5 Query by inspection time

The steps to make a query by inspection time are as follows:

- (1) Click "Data query", and then click on "Search". Click the inspection time on the test result query interface for a drop-down box, and set the inspection start time for the query (the default is 0:00 to 24:00 on that same day). The ending time shall be greater than or equal to the starting time, and the ending time cannot exceed 24:00 of the day. For example: The inspection time is selected from March 3, 2021 to 24:00 on March 4, 2021.
- (2) After the input, click on "OK", and all historical records from March 3, 2021 to March 4, 2021 at 24:00 will be displayed in the data query list; Click "Cancel" after entering the information, and no query for historical records will be made.

The inspection time query condition can be used alone, or in conjunction with the sample number, barcode number, patient's name, and department information for the query.

6.2 Data query list

According to the description in Section 6.1, query for all historical data that meets the conditions during the inspection period from 2021.01.01 to 2021.03.03, and the data query list will be returned after the query is successful.

On the "Data query list" interface, select a piece of data and double-click on it to enter the "Detailed data" interface. The left side of the "Detailed data" interface is the morphological result, and the displayed items include morphology component, concentration, upper limit, normal range, abnormal range, out of limits. The sample information on the upper right side of the interface includes the sample ID, inspection time, and total number of particles; bottom right is a list of dry chemical results.

Click "Previous sample" and "Next sample" to view the detailed data interface of other samples; click on "Back", and the page will return to the "Data query list" interface.

6.3 Clear historical data

Click "Clear" on the "Data query list" interface, and all data in the current list will be cleared.

6.4 Export of historical data

Click "Export Excel" on the "Data query list" interface, and the "Export path" pop-up box will pop up. After setting the path, click on "Save", and the list will be exported to the corresponding path and saved.

6.5 Preview and printing of reports

The preview and printing of the report includes the preview and printing of a single sample, as well as the preview and printing of batch samples.

- Report preview and printing for a single sample: Select a piece of sample information from "Sample Info." on the "Data query" interface, and click on "Print" to preview the result record to be printed. If the report is to be printed, click on "Print" again. Click "Cancel", the report will not be printed. See Appendix B for the inspection report template.
- Report preview and printing of batch samples: If the reports are to be printed in batches, click on "Batch print", enter the starting and ending sample numbers for batch printing in the "Sample ID" input box, or select the inspection time interval of different dates for batch printing. Click "OK" to print in batches; click on "Cancel" to not print the reports.

6.6 LIS export

The "LIS export" function will upload the flagged images on "Browse sediment image" to the LIS. Select one or more pieces of sample information on the "Data

query" interface, click on "LIS export", and upload the test result to the LIS.



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7 Focus

In order to have the sediment of urine clearly photographed and imaged when it passes through the focusing plane of the microscope, focusing shall be performed for the instrument once a day, and then the sample test can be conducted.

7.1 Morphological focusing

Follow the steps below for morphological focusing.

(1) Preparations before focusing

Pour about 7 mL of well-mixed sediment focusing fluid into a clean test tube, and place the tube at the front of the tube rack.

Note

The sediment focusing fluid needs to be mixed by turning upside down and again for 1 min to 3 min.

- (2) Considerations for focusing
- Please use the focusing fluid designated by our company.
- Focusing shall be performed once the instrument is powered up for the first time each day.
- (3) Focusing test
- 1) Place the tube rack on the right side of the rack-in module.
- 2) Click "Focus" in the main button area on the left side of the main interface to enter the "Focus" interface.
- 3) On the right side of the focusing interface, enter the lot number, name, and manufacturer according to the description information of the focusing fluid, and select the validity period in the drop-down calendar (Barcode registration: click on the input box after the barcode number. Use an external barcode scanner to scan the barcode of sediment analysis focusing fluid, or manually enter the barcode number in the input box after the barcode number. The lot number, name, manufacturer, and validity period of the focusing fluid will be displayed automatically). Click "Register", the input focusing information will be displayed in the focusing registration list on the left. After clicking on this information, click on

"Run focus", the sample probe will perform sample suction action. After the focusing test is over, the interface will pop up a "Pass" or "Failed" prompt. Whether the focusing has passed the test is displayed in the focusing result list below the "Focus" interface, and the focusing time and focusing result will be displayed on the "System status" interface.

- 4) If the focusing is successful, " "will be displayed in the status bar at the bottom of the interface, and the instrument will automatically enter the standby mode.
- 5) If focusing is unsuccessful, " \otimes " will be displayed in the status bar at the bottom of the interface. Do not perform the sample test at this time. Perform the focusing again. If it is still unsuccessful, please contact Zybio or its distributor.

(4) Focusing result query

Click "Search" under the focusing result, and the "Focus result" interface will pop up. Enter the focusing lot number, name, manufacturer, and focusing status in the window; after selecting the focusing time, click on "OK", and the focusing result interface will display all corresponding focusing results.

(5) Printing of focusing result

Select a piece of information in the focus result list and click "Print" to preview the focus record to be printed. If printing is to be done, click on "Print" again.

(6) LIS export

Export of focusing results to LIS: Select one or more focus results on the "Focus" interface. Click "LIS export", and upload the test results to the LIS.

(7) Deletion of focusing result

Check a single or multiple focusing results that need to be deleted. Click "Delete", and a prompt will pop up showing "Do you confirm to delete selected data?" Click OK, and a prompt will pop up showing "Deleted Successfully". Check to see that the checked information has been deleted.

8 Calibrate

In order to obtain accurate measurement results, it is necessary to determine the calibration coefficient for the urine analysis bias under the specified conditions through calibration. In order to obtain accurate urine analysis results, please periodically calibrate the instrument according to the procedure in this chapter.

Note

Users shall use Zybio's calibration solution, and store and use it in strict accordance with the required environment.

8.1 Morphological calibration

This section mainly introduces the content of morphological calibration, including calibration solution storage, calibration frequency, calibration operation, and query for and printing of calibration results.

- (1) Storage of calibration solution
- The calibration solution is a solution containing aldehydated erythrocytes, and the number of particles contained is indicated on the label of each bottle of reagent.
- The calibration solution shall be stored at 2°C–8°C. It should not be frozen. It shall be equilibrated to room temperature before use.
- (2) Calibration frequency

Calibration shall be performed at least once a month. Focusing shall be performed before calibration.

- (3) Preparations before calibration
- 1) Turn the calibration solution bottle upside down. Shake it vigorously for 5 times, and then invert it upside down and again for a total of 5 times. Mix it for 1–3 minutes. Use it after the bubbles disappear.
- 2) The calibration solution can be used immediately after opening, and is for a single time of use only. The rest cannot be used. Calibration solutions of different batches cannot be mixed for use.
- Mix and pour the calibration solution from the same bottle into 5 clean test tubes (≥ 8 mL each).

- 4) Place the 5 test tubes on the tube rack.
- (4) Calibration test
- 1) Place the tube rack on the right side of the rack-in module.
- 2) Click "Calibrate" in the main button area on the left side of the main interface to enter the "Calibrate" interface.
- 3) On the right side of the "Calibrate" interface, enter the calibration lot number, calibration name, manufacturer, and calibration target value according to the instructions on the calibration solution, and select the validity period in the dropdown calendar for the validity period (Barcode registration: Click the input box after the barcode number. Use an external barcode scanner to scan the barcode on the calibration solution bottle of Zybio, or manually enter the barcode in the input box after the barcode number. The calibration lot number, calibration name, manufacturer, validity period, and calibration target value will be displayed after the code scanning is done.) Click "Register", and the entered calibration information, click on this information will be displayed in the calibration registration list on the left. Click "Run calibration", and the sample probe will perform a suction action. Each test tube is tested twice and the test is done for a total of ten times. After the five test tubes are completely tested, the interface will pop up a prompt showing "Pass" or "Failed", calibration status related information will be displayed in the calibration result list at the bottom of the "Calibrate" interface, and at the same time the calibration time and calibration factor will be displayed on the "System status" interface.
- 4) If the calibration is successful, the status bar at the bottom of the interface will display "Pass", and the instrument will automatically enter the standby mode.
- 5) If the calibration fails, the status bar at the bottom of the interface will display "Failed". At this time, the calibration solution shall be replaced with another batch and the calibration shall be performed again. If it is still unsuccessful, please contact Zybio or its agent.
- (5) Query for calibration result
- 1) Click "Search" at the bottom right of the calibration interface, and the "Calibration result" interface will pop up.
- 2) Enter the calibration lot number and calibration status in the window, select the calibration date, and click on "OK". And all corresponding calibration results will be

displayed on the calibration result interface.

(6) Printing of calibration result

Select a piece of information in the calibration result list, and click on "Print".

(7) LIS export

Export of calibration results to LIS: Check one or more calibration results on the "Calibrate" interface, and click on "LIS export" to upload the test results to the LIS.

(8) Deletion of calibration result

Check a single or multiple calibration results to be deleted, click on "Delete", and a prompt will pop up showing "Do you confirm to delete selected data?" Click OK, and a prompt will pop up showing "Deleted Successfully". Check to see that the checked information has been deleted.

8.2 Physicochemical unit calibration (optional unit)

On the "Calibrate" interface, click on "PHYC unit Cal." to enter the "PHYC unit Cal." interface.

Note

Specific gravity, turbidity, and conductivity shall be calibrated monthly.

8.2.1 Specific gravity calibration

This section mainly introduces the specific operation of specific gravity calibration, which is as follows.

- (1) Calibration solution preparation
- 1) Take three test tubes. Pour no less than 3.5 mL of Level 3 specific gravity calibration solution into the first test tube. Pour no less than 3.5 mL of Level 2 specific gravity calibration solution into the second test tube. Pour no less than 3.5 mL of Level 1 specific gravity calibration solution into the third test tube.
- 2) Place the Level 3, Level 2, and Level 1 specific gravity calibration solutions at the first, second, and third positions of the tube rack, respectively.
- 3) On the "Physicochemical Unit Calibration" interface, select the hydrometer for the calibration type, enter the calibration lot number, calibration name, and manufacturer according to the instructions on the calibration solution, select the validity period in the drop-down calendar for the validity period, enter the Level 3

specific gravity value in the high calibration value box, enter the specific gravity value of Level 2 in the middle calibration value box, and enter the specific gravity value of Level 1 in the low calibration value box (barcode registration: Click the input box after the barcode number. Scan the barcode of the calibration solution with an external barcode scanner, or manually enter the barcode number in the input box after the barcode number. After scanning the barcode, the calibration lot number, calibration name, manufacturer, expiration date, and the three horizontal target values will be displayed automatically.) Click "Register", and the entered calibration information will be displayed in the calibration registration list on the left.

- 4) Place the tube rack on the right side of the rack-in module. Click "Calibrate" to perform hydrometer calibration, and a prompt will automatically pop up showing "Passed" or "Failed" after the calibration is completed.
- (2) Query for calibration result
- 1) Click "Search" below, and the "Calibration result" interface will pop up.
- 2) Enter or select the calibration result in the window, select the calibration date, click on "OK", and all corresponding calibration results will be displayed in the calibration list.
- (3) Printing of calibration result

Select a piece of information in the calibration result list, click on "Print", and the printing of the selected result information will be achieved.

(4) Transmission of calibration result to LIS

When the system is connected to the LIS, select a piece of information in the calibration result list, click on "LIS", and the selected information will be uploaded to the LIS.

(5) Deletion of calibration result

Select a single or multiple pieces of information in the calibration result list, click on "Delete", and a prompt will pop up showing "Do you confirm to delete the selected data?" Click OK, and a prompt will pop up showing "Deleted Successfully". Check to see that the checked information has been deleted.

8.2.2 Turbidimeter calibration

This section mainly introduces the specific operation of turbidimeter calibration, which is as follows.

- (1) Calibration solution preparation
- Take two test tubes. Pour Level 2 turbidity calibration solution (≥ 3.5 mL) into the first tube as a high turbidity calibration solution. Pour Level 1 turbidity calibration solution (≥ 3.5 mL) into the second tube mL) as a low turbidity calibration solution.
- 2) Place the high and low turbidity calibration solutions at the first and second positions of the tube rack respectively.
- 3) On the "PHYC Unit Cal." interface, select the turbidimeter for the calibration type, enter the calibration lot number, calibration name, and manufacturer according to the instructions on the calibration solution, select the validity period in the drop-down calendar for the validity period, enter the Level 2 turbidity value in the high calibration value box, enter the Level 1 turbidity value in the low calibration value box (barcode registration: Click the input box after the barcode number. Scan the barcode of the calibration solution with an external barcode scanner, or manually enter the barcode number in the input box after the barcode number. After scanning the barcode, the calibration lot number, calibration name, manufacturer, expiration date, and the two level target values will be displayed automatically.) Click "Register", and the entered calibration information will be displayed in the calibration registration list on the left.
- 4) Place the tube rack on the right side of the rack-in module. Click "Calibrate" to perform turbidimeter calibration, and a prompt will pop up automatically showing "Pass" or "Failed" after the calibration is completed.
- (2) Calibration query
- 1) Click "Search" below, and the "Calibration result" interface will pop up.
- 2) Enter the calibration result in the window, select the calibration date, click on "OK", and all corresponding calibration results will be displayed in the calibration list.
- (3) Printing of calibration result

Select a piece of information in the calibration result list, click on "Print", and the printing of the selected result information will be achieved.

(4) Transmission of calibration result to LIS

When the system is connected to the LIS, select a piece of information in the calibration result list, click on "LIS", and the selected information will be uploaded to the LIS end.

(5) Deletion of calibration result

Select a single or multiple pieces of information in the calibration result list, click on "Delete", and a prompt will pop up showing "Do you confirm to delete the selected data?". Click OK, and a prompt will pop up showing "Deleted Successfully". Check to see that the checked information has been deleted.

8.2.3 Conductivity calibration

This section mainly introduces the specific operation of conductivity calibration, which is as follows.

- (1) Calibration solution preparation
- 1) Take three clean empty test tubes. Pour ≥ 3.5 mL of Level 3 conductivity calibration solution into the first test tube.
- 2) Pour \geq 3.5 mL of Level 2 conductivity calibration solution into the second tube.
- 3) Pour \geq 3.5 mL of Level 1 conductivity calibration solution into the third test tube. Place them at the first, second and third positions on the same tube rack in sequence.
- 4) On the "PHYC Unit Cal." interface, select the conductivity for the calibration type, enter the calibration lot number, calibration name, and manufacturer according to the instructions on the calibration solution, select the validity period in the drop-down calendar for the validity period, enter the Level 3 conductivity value in the high calibration value box, enter the conductivity value of Level 2 in the middle calibration value box, and enter the conductivity value of Level 1 in the low calibration value box (barcode registration: Click the input box after the barcode number. Scan the barcode of the calibration solution with an external barcode scanner, or manually enter the barcode number in the input box after the barcode number. After scanning the barcode, the calibration lot number, calibration name, manufacturer, expiration date, and the three horizontal target values will be displayed automatically.) Click "Register", and the entered calibration information will be displayed in the calibration registration list on the left.
- 5) Place the tube rack on the right side of the rack-in module, select the "Conductivity" option, and click on "Calibrate" to perform conductivity calibration. After the calibration is completed, a prompt will appear automatically showing "Passed" or "Failed".
- (2) Query for calibration result

- 1) Click "Search" below, and the calibration result interface will pop up.
- 2) Enter the calibration result in the window, select the calibration date, click on "OK", and all corresponding calibration results will be displayed in the calibration list.
- (3) Printing of calibration result

Select a piece of information in the calibration result list, and click on "Print".

(4) Transmission of calibration result to LIS

When the system is connected to the LIS, select a piece of information in the calibration result list, click on "LIS", and the selected information will be uploaded to the LIS end.

(5) Deletion of calibration result

Select a piece of information in the calibration result list, click on "Delete", and a prompt will pop up showing "Do you confirm to delete the selected data?" Click OK, and a prompt will pop up showing "Deleted Successfully". Check to see that the checked information has been deleted.



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9 Quality control

The function of the quality control (QC) program is to verify and test for the correctness of the analysis of the instrument through the test on the urine control and the collection of quality control data. The purpose of quality control testing is to ensure the accuracy and repeatability of the test results.

9.1 Control

Quality control materials

- A control is used for the quality control of the measurement result of the instrument; Positive control is used as abnormal quality control, and negative control is used as normal value quality control, both of which are used to test for whether the instrument can measure and count correctly.
- The sediment positive control is a solution containing a fixed number of erythrocytes in an ionically balanced fluid. For cell counts, see Particle Counts under the Positive Control tab.
- The sediment negative control is a particle-free solution.
- A control must be kept refrigerated but never frozen, and equilibrated to the room temperature before each use.

Quality control frequency

- To ensure the accuracy of the test result for the sediment, positive and negative controls for sediment shall be performed at least once a day or as per the standards in the laboratory quality control procedure manual, and a focusing shall be performed before the quality control.
- In order to ensure the accuracy of the dry chemical test result, Zybio's positive and negative urine analysis controls can be used for the quality control testing in the following situations.
 - At the start of the test each day;
 - At replacement with a new tube of test strips;
 - When changing the operator;
 - When the test result is in doubt.

- In order to ensure the accuracy of the test result of the physicochemical unit (optional unit), a quality control testing can be carried out with the matched specific gravity, turbidity, color, and conductivity controls in the following situations (when the physicochemical unit is selected for equipment).
 - Perform test once a month;
 - Perform test when the test result is in doubt.

9.2 Quality control settings

This section mainly introduces the main contents of quality control settings, including the morphological alarm range and dry chemical quality control settings.

Morphological alarm range

Click "QC" in the main button area on the left side of the main interface, and then click on "Set QC" to enter the quality control settings interface.

Select "Exceed ± 1 SD", "Exceed ± 2 SD", "Exceed ± 3 SD", indicating that the positive quality control result is judged by deviation limits as per SDs of 5%, 10%, and 15% respectively. Select the common alarm range, click on Save, and a confirmation dialog box will pop up; click OK to save the set quality control range of morphological quality control.

Dry chemical control settings

By selecting each quality control item displayed in the dry chemical quality control list at the bottom of the "Set QC" interface, the upper and lower limits of each quality control item can be set; by checking whether the negative target value and the positive target value are enabled, clicking on "Save", the quality control settings are saved.

9.3 Morphological quality control

On the "QC" interface, click on "Morphology QC" to enter the "Morphology QC" interface.

9.3.1 Quality control registration

Morphological quality control registration includes the addition and deletion of quality control items. The details are as follows:

Addition of quality control items

Method 1: Manual registration

Enter the corresponding information in the input boxes after the quality control lot number, quality control name, manufacturer, and target value according to the instructions on the control. Select "Negative" or "Positive" for the control information description. Click "Register" after entering all the information, and the entered quality control information will be displayed in the quality control registration list on the left. (The negative control target value is 20 by default and cannot be modified).

Method 2: Barcode registration

Click the input box after the barcode number. Scan the barcode of the control with an external barcode scanner, or manually enter the barcode number in the input box after the barcode number. The quality control lot number, quality control name, quality control type, manufacturer, validity period, and quality control target value will be displayed automatically after the code scanning is done. Click "Register", and the input quality control information will be displayed in the quality control registration list on the left. Barcode registration supports registration of multiple quality controls and a single quality control.

- Deletion of quality control items
- (1) Select the quality control item to be deleted in the quality control registration list on the "Morphology Quality Control" interface.
- (2) Click "Delete", and a confirmation dialog box will pop up; click "OK", and the selected quality control item will be deleted.

9.3.2 Morphological quality control testing

The main steps of the morphological quality control testing are as follows:

(1) Use of control

Shake it well before use: Mix the sediment control (positive) by turning it upside down and again, and use it after the bubbles disappear.

Note

Since the sediment control (negative) does not contain particles, it is not necessary to be shaken well before use.

- (2) Quality control testing considerations
- In order not to affect the quality control result, please use the control designated by Zybio.

- (3) Preparations before quality control testing
- 1) Pour about 5 mL of sediment control (positive) and 5 mL of sediment control (negative) into two test tubes.
- 2) Place the two tubes on the tube rack in the order where they are listed in the quality control registration.
- (4) Quality control testing
- 1) Place the tube rack on the right side of the rack-in module. Select the quality control registration column to be tested in the quality control registration table on the "Morphology QC" interface. Click "Run QC", and the sample probe will automatically perform the suction action. Wait for the test tubes on the tube rack are done testing, the quality control related information and quality control status will be displayed in the quality control result list area on the screen.
- 2) If the quality control fails, "S" will be displayed in the "QC status" column of the quality control result. At this time, the control shall be replaced with one o of another lot number and the procedure shall be executed again. If it is still unsuccessful, please contact Zybio or its distributor.

9.4 Dry chemical quality control

Click "Dry CHM. QC" on the "QC" interface to enter the "Dry CHM. QC" interface.

9.4.1 Quality control registration

The dry chemical quality control registration includes the addition and deletion of quality control items, and the details are as follows:

• Addition of quality control item

Method 1: Manual registration

On the quality control registration interface on the right, select "Negative" or "Positive" in the quality control items according to the instructions on the control, enter the quality control lot number, quality control name, manufacturer, select the validity period in the drop-down calendar for validity period, click on "Register" after entering all the information, and the input quality control information will be displayed in the quality control registration list on the left.

Method 2: Barcode registration

On the quality control registration interface on the right, click on the input box after the

barcode number, use an external barcode scanner to scan the barcode of the control, or manually enter the barcode number in the input box after the barcode number, and the quality control item, quality control lot number, quality control name, manufacturer, and validity period will be displayed automatically after code scanning is done. Click "Register", and the input quality control information will be displayed in the quality control registration list on the left. Barcode number registration supports registration of multiple quality controls and a single quality control.

Deletion of quality control item

Select the quality control item to be deleted in the quality control registration list of the "Dry CHM. QC" interface, click "Delete", and the selected quality control item will be deleted.

9.4.2 Dry chemical quality control testing

The main steps of dry chemical quality control testing are as follows:

- (1) Pour the matched urine dry chemical control (negative) and urine dry chemical control (positive) into two test tubes respectively.
- (2) Put the test tubes containing the urine dry chemical control (negative) and the urine dry chemical control (positive) on the tube rack in turn, and place the tube rack on the right side of the rack-in module.
- (3) On the quality control registration interface, click to select the registered negative and positive controls in turn; then click on "Run QC", and the sample probe will automatically perform the suction action. After the testing is done, the quality control result will be displayed in the data column of the current chart, and the instrument will automatically enter the standby state.
- (4) If the quality control fails, "S" will be displayed in the "QC status" column of the quality control result. At this time, the control shall be replaced with one of another lot number and the procedure shall be executed again. If it is still unsuccessful, please contact Zybio or its distributor.

9.5 Physicochemical unit quality control (optional unit)

On the "QC" interface, click on "PHYC unit QC" to enter the "PHYC unit QC" interface.

9.5.1 Quality control registration

The physicochemical unit quality control registration includes the addition and

deletion of quality control items. The details are as follows:

Addition of quality control item

Method 1: Manual registration

On the "QC" interface, click "PHYC unit QC" and select the "Color", "Turbidity", "SG", and "Conductivity" items in the quality control item column of the quality control registration area. Enter the quality control lot number, quality control name, manufacturer according to the instructions on the control of the selected item. Select the quality control level. Select the validity period in the drop-down calendar for the validity period. The target value for each level needs to be entered for specific gravity and conductivity items according to the instructions on the control. After all information is completely input, click "Register", and the input quality control information will be displayed in the quality control registration list on the left.

Method 2: Barcode registration

Click the input box after the barcode number, scan the barcode of the quality control with an external barcode scanner, or manually enter the barcode number in the input box after the barcode number. The quality control lot number, quality control name, quality control type, manufacturer, validity period, and quality control target value will be displayed automatically after the code scanning is done. Click "Register", the input quality control information will be displayed in the quality control registration list on the left. Barcode registration supports the registration of multiple quality controls and a single quality control under a quality control item.

Deletion of quality control item

Select the quality control item to be deleted in the quality control registration list of the "PHYC unit QC" interface. Click "Delete", and the selected quality control item will be deleted.

9.5.2 Physicochemical unit quality control testing

The main steps of the physicochemical unit quality control testing are as follows:

- (1) Pour the matching color, turbidity, specific gravity, and conductivity controls with different levels into the corresponding test tubes according to the registered quality control type.
- (2) Place the test tubes containing the corresponding color, turbidity, specific gravity, and conductivity controls with different levels on the tube rack, and place the

tube rack on the right side of the rack-in module.

- (3) On the quality control registration interface, click to select the registered information; then click to execute quality control, and the sample probe will automatically perform the sample suction action. After the test is completed, the quality control result will be displayed in the quality control result data column below, and the instrument will automatically enter the standby state.
- (4) If the quality control fails, "S" will be displayed in the "QC status" column of the quality control result. At this time, the control shall be replaced with one of another lot number and the procedure shall be executed again. If it is still unsuccessful, please contact Zybio or its distributor.

9.6 Standard strip test

This section mainly introduces the main content of standard strip test, including dry chemical standard strip test and test result query.

- Dry chemical standard strip test
- (1) Empty the test strip cabin, take out the random standard strip, and put them into the test paper compartment according to the marked direction.
- (2) Empty the waste strip bin, and place dry, clean white paper in the waste strip bin.
- (3) Click "Standard strip test" on the QC interface to enter the Standard Strip Test interface. In the test registration area on the right, enter the barcode number and manufacturer; or click on input box after the barcode number, scan the standard barcode with an external barcode scanner, then manually enter the manufacturer, click on "Register" after all information are input. Check the information to be tested in the left test information area and click on "Start", and the instrument will execute the test on the standard strip. The results will be displayed in the data list in turn on the "Standard strip test" interface.
- (4) The standard strips for which the test has been completed will be transferred to the waste strip bin. Put standard strips in the standard strip bin.
- (5) If the standard strip test is unsuccessful, " \otimes " will be displayed in the status column of the test result, and the test needs to be done again. If it is still unsuccessful, please contact Zybio or its distributor.

Note

- Never test the standard strip after it is dipped in water (or other liquid).
- Please use the standard strip specified for the instrument.
- If the surface of the standard strip is contaminated or damaged, please contact the supplier. Do not continue to use the standard strip for testing.
- To guarantee correct test results, it is recommended that the instrument be tested with a standard strip every 1 to 2 weeks.
- Standard strip test result query

Click "Standard strip test" to enter the Standard Test interface. Select the test status and time for the query. Click "Search" to display the standard test result that meets the conditions. Click "Reset" to clear the query conditions.

Deletion of standard strip test result

On the standard test result interface, select one or more test results, click on "Delete", and a prompt will pop up showing "Do you confirm to delete selected data?" Click OK, and a prompt will pop up showing "Deleted Successfully". Check to see that the checked information has been deleted.

Printing of standard strip test result

On the standard test result interface, select one or more test results, and click on "Print" to print the results of the selected information.

9.7 Quality control review

Click "QC review" on the "QC" interface to enter the "QC review" interface, where the query for the quality control information for which the test has been done.

Select "Morphology QC", "Dry CHM.", "PHYC unit" to switch to display the "Morphology QC", "Dry CHM.", "PHYC unit" quality control review interfaces.

9.7.1 Morphological quality control query

On the "QC review" interface, click on "Morphology QC" to enter the "Morphology QC review" interface.

- Quality control query review
- (1) Select the quality control button to switch to the query of the corresponding quality control type, and enter different operators to make the query for the quality control information under such a user.

- (2) Enter the corresponding parameters in the input boxes after the quality control lot number and quality control name.
- (3) Click the drop-down menu after "QC status" and "QC time", and click on "Search" to display the morphological quality control query result.
- (4) Click "Reset" to clear the quality control query condition.
- Deletion of quality control results
- (1) On the "Morphology QC" interface, select the quality control result to be deleted in the quality control list, click on "Delete", and a confirmation dialog box will pop up.
- (2) Click "OK", and the selected quality control results will be deleted.

9.7.2 Morphological quality control graph

Click "QC graph" on the "QC" interface to enter the QC graph interface.

About quality control graph

- The horizontal axis of the quality control graph represents the date or time of the quality control, and the vertical axis represents the quality control line.
- Each point in the quality control graph corresponds to a quality control result, and the points are connected by line segments.

Query and printing of quality control graph

- Select "Morphological QC" on the "QC graph" interface.
- Select the corresponding parameters in the drop-down boxes for quality control lot number, quality control name, and quality control manufacturer, select the starting time, ending time, and the quality control type, and click on "Search" to display the morphological quality control graph.
- Click "Print" to preview the result record to be printed.
- If the quality control graph is to be printed, click on "Print" again, and the printing will be done.
- Click "Reset", and the query condition will be reset.

9.7.3 Dry chemical quality control query

Click "Dry CHM." on the "QC review" interface to enter the "Dry CHM. QC review"

interface, where the query for the negative or positive quality control record within a certain time range can be made.

- Quality control query review
- (1) Select the quality control button to switch to the query of the corresponding quality control type, and enter different operators to make the query for the quality control information under such a user.
- (2) Enter the corresponding parameters in the input boxes after the quality control lot number and quality control name.
- (3) Click the drop-down menu after "QC status" and "QC time", select the corresponding query parameters, click on "Search", and the dry chemical quality control query result will be displayed.
- (4) Click "Reset" to clear the quality control query condition.
- Deletion of quality control results
- (1) On the "Dry CHM. QC" interface, select the row of the quality control result to be deleted in the quality control list.
- (2) Click "Delete". Click "OK" in the pop-up dialog box, and the selected quality control results will be deleted.

9.7.4 Dry chemical quality control graph

Click "Dry CHM." on the "QC graph" interface to enter the "Dry CHM. QC graph" interface.

- (1) Negative or positive quality control records within a certain time range can be queried for.
- (2) Select the corresponding parameters from the drop-down boxes for quality control date, quality control type, quality control lot number, quality control name, and manufacturer, click on "Search", and the dry chemical quality control graph will be displayed. Click "Reset" to clear the quality control query condition.
- (3) Click "Print" to preview the result record to be printed. If the quality control graph needs to be printed, click on "Print" again, and the printing will be done.

9.7.5 Printing

Click "Print", and the printing of the quality control information will be done.

9.7.6 Physicochemical unit quality control query (optional unit)

Click "PHYC unit" on the "QC review" interface to enter the "PHYC unit QC review" interface, where the query for the quality control records on color, turbidity, specific gravity, and conductivity within a certain time range can be made.

- Quality control query review
- (1) Check "Color", "Turbidity", "SG" and "Conductivity" in the drop-down boxes for the quality control items, and enter the corresponding parameters in the input boxes after the quality control lot number and quality control name.
- (2) Click the drop-down menus after "QC status", "QC time", and "QC level", click on "Search", and the query results of physicochemical unit quality control will be displayed.
- (3) Click "Reset" to clear the quality control query condition.
- Deletion of quality control results
- (1) On the PHYC unit QC search interface, select the row of the quality control result to be deleted in the quality control list, and click on "Delete".
- (2) Click "OK" in the pop-up dialog box, and the selected quality control results will be deleted.

9.7.7 Physicochemical unit quality control graph (optional unit)

Click "PHYC unit" on the "QC graph" interface to enter the "PHYC unit QC graph" interface, where the query for the quality control records on color, turbidity, specific gravity, and conductivity within a certain time range can be made.

- (1) Select the corresponding parameters from the drop-down boxes for quality control date, quality control lot number, quality control name, quality control level, manufacturer, and quality control items, click on "Search", and the quality control graph of the physicochemical unit will be displayed.
- (2) Click "Reset" to clear the quality control query condition.
- (3) Click "Print", and the printing of the quality control graph will be done.

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Click "LIS export" to export the quality control results through the LIS system.

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10 Statistics

This section mainly introduces the statistical functions.

- Workload statistics
- (1) Click "Workload statistics" on the workload statistics interface.
- (2) After entering the statistical information, click "Search" to make the query in statistical results.
- (3) Click "Print" to print the statistical results, and click "Reset" to reset the statistical information.
- System log
- (1) Click "System log" to enter the system log interface.
- (2) After entering the log information, click on "Search" to make the query in system log.
- (3) After checking the system log results, click on "Export" to export the checked logs, and click on "Reset" to reset the log information.
- Maintenance record
- (1) Click "Maintenance record" to enter the maintenance record interface.
- (2) After entering the system maintenance information, click on "Search" to make the query in system maintenance records.
- (3) After checking the maintenance record, click on "Print" to print the maintenance record, and click on "Reset" to reset the maintenance information.



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11 Management

This chapter mainly introduces the management of the Urinalysis Hybrid System. Users may conduct settings like user management, gender, age, race, visit type, charge type, department, sample type, dilution ratio, mark, etc. on the "Management" interface.

Note

- Only users with administrator permission are accessible to the management interface.
- Reagent replenishment can only be performed in the standby state.

11.1Reagent management

Click "Management" on the main interface to directly enter the reagent management interface. On the "Reagent management" interface, you can view reagent residual, sheath fluid replenishment, strip replenishment, query reagent consumption information, view replenishment records and set reagent residual reminder.

• Sheath fluid replenishment

In the reagent information column, click "CPU card replenishment" on the right side of "Sheath fluid", and a dialog "Insert the CPU card into the card reader!" will pop up. Insert the CPU card for sheath fluid into the computer card reader according to the prompt, and then click "Confirm". After replenishing, the residual and use-by date will be displayed in the current reagent information list.

• Strip replenishment

In the reagent information column, click "Strip replenishment" on the right side of the "Strip residual", and the barcode information dialog will pop up. After entering the barcode number, click "Confirm" to replenish, and the residual and use-by date will be displayed in the current reagent information list.

Query of reagent consumption information

You may view the reagent consumption per "This day" or per "By date".

Set reagent residual reminder

You may set the warning value for sheath fluid or strip residual.

Reagent replenishment record

You may query reagent replenishment records per "This year", per "This month" or per "By date".

11.2User management

On the "Management" interface, click "User management" to enter the user management interface.

- Adding a new user
- (1) The user name, permission and password of the new user can be set in the input box on the right of the user management interface.
- (2) You may enter the user's name in the input box after the User name, however inside the name input box, there must not be the following characters: [,], 'or numbers.
- (3) Enter the mnemonic symbols for the user name in the input box after the Mnemonic symbols, but the entered mnemonic symbols must not be brackets, punctuation or special symbols.
- (4) In the input box after Permission, the user can select the permission, which may be: administrator, operator or viewer. Of which the viewer only has the permission of data query; The operator is provided with all test and edit capacities, but does not have system management or system setup permissions; The administrator is permitted to all test, edit and setup capacities of the software (including system management, system setup and user management).
- (5) Enter and set the login passwords in the input box after Password and Confirmation respectively. The two login passwords must be consistent.
- (6) Click "Add", the dialog of "Added successfully!" will pop up, and then click "Confirm" to complete the new user addition.
- Deleting the user
- (1) On the "User management" interface, select an operator to be deleted, and click "Delete" to prompt a dialog "Do you confirm to delete the selected data?"
- (2) Click "Confirm" and the selected user will be deleted; If you click "Cancel", the user will be remained.

The default administrator of the system is permitted to add, modify and delete other users, but not permitted to delete its own account.

- Modifying the user
- (1) After selecting one piece of user information on the "User management", and you may modify the user name, mnemonic symbols, permission or password.
- (2) Click "Modify", and the "Modify successfully!" dialog will pop up. Click "Confirm" to complete the modification.

11.3Gender

On the "Management" interface, click "Gender" to enter the "Gender" interface.

- Adding the gender
- (1) Enter the added gender in the Gender input box on the right.
- (2) Enter the mnemonic symbols for the added gender in the input box after the mnemonic symbols.
- (3) Click "Add", and the dialog "Added successfully!" will pop up.
- (4) Click "Confirm" and the added contents will be included in the gender list.
- Modifying the gender
- (1) Select the item to be modified in the gender list, and enter the modified content in the input box after the corresponding item on the right.
- (2) Click "Modify" to pop up the dialog box of "Modify successfully!", and click "Confirm" to save the modified contents.
- Deleting the gender
- (1) Select the item to be deleted in the gender list, click "Delete", and the dialog box "Do you confirm to delete the selected data?" will pop up.
- (2) Click "Confirm" to delete the selected item; Or click "Cancel" to remain the original settings.

11.4Age unit

On the "Management" interface, click "Age unit" to enter the age unit interface.

- Adding the age unit
- (1) Enter the unit of the added age in the input box on the right of the age unit interface.
- (2) Enter the mnemonic symbols for the added age unit in the input box after the mnemonic symbols.
- (3) Click "Add", and the dialog "Added successfully" will pop up.
- (4) Click "Confirm", and the added contents will be included in the age unit list and arranged in the last row corresponding to its sequence number.
- Modifying the age unit
- (1) Select the item to be modified in the age unit list, and enter the modified content in the input box after the corresponding item on the right.
- (2) Click "Modify" to pop up the dialog box of "Modify successfully!", and click "Confirm" to save the modified contents.
- Deleting then age unit
- (1) Select the item to be deleted in the age unit list, and click "Delete".
- (2) The dialog "Do you confirm to delete the selected data?" pops up. Click "Confirm" to delete the selected item; Or click "Cancel" to remain this setting.

The default age unit in the list is year, year old, month and day, and the mnemonic symbols by default is the full spelling of the age unit.

11.5Race

On the "Management" interface, click "Race" to enter the "Race" interface.

- Adding a race
- (1) Enter the race in the input box on the right side of the "Race" interface.
- (2) Enter the mnemonic symbols for the added race in the input box after the mnemonic symbols.
- (3) Click "Add", and the dialog "Added successfully!" will pop up.
- (4) Click "Confirm", and the added contents will be included in the race list and arranged in the last row corresponding to its sequence number.

- Modifying the race
- (1) Select the item to be modified in the race list, and enter the modified contents in the input box after the corresponding item on the right.
- (2) Click "Modify" to pop up the dialog box of "Modify successfully!", and click "Confirm" to save the modified contents.
- Deleting the Race
- (1) Select the item to be deleted in the race list, click Delete, and the dialog box "Do you confirm to delete the selected data?" will pop up.
- (2) Click "Confirm" to delete the selected item; Or click "Cancel" to remain the original settings.

The names of 56 races are defaulted in the list, and the mnemonic symbols are the initials of ethnic names by default.

11.6Visit type

On the "Management" interface, click the "Visit type" to enter the "Visit type" interface.

- Adding a visit type
- (1) Enter the visit type to be added in the input box on the right of the "Visit type" interface.
- (2) Enter the mnemonics symbols for the added type of visit in the input box after the mnemonics symbols.
- (3) Click "Add", and the dialog "Added successfully!" will pop up.
- (4) Click "Confirm", and the added contents will be included in the visit type list and arranged in the last row corresponding to its sequence number.
- Modifying the visit type
- (1) Select the item to be modified in the visit type list, and enter the modified content in the input box after the corresponding item on the right.
- (2) Click "Modify", and the dialog "Modify successfully!" will pop up. Click "Confirm" to save the modified contents.

- Deleting the visit type
- (1) Select the item to be deleted in the visit type list. Click "Delete" and the dialog "Do you confirm to delete the selected data?" will pop up.
- (2) Click "Confirm" to delete the selected item; Or click "Cancel" to remain the original settings.

There are two default settings in the list, Outpatient and Inpatient, and mnemonics symbols default to the initials of the name in pinyin.

11.7Charge type

On the "Management" interface, click "Charge type" enter the "Charge type" interface.

- Adding a charge type
- (1) Enter the charge type to be added in the right input box.
- (2) Enter the mnemonics symbols for the added charge type in the input box after the mnemonics symbols, Click "Add", and the dialog "Added successfully" will pop up.
- (3) Click "Confirm", and the added contents will be included in the charge type list and arranged in the last row corresponding to its sequence number.
- Modifying the charge type
- (1) Select the item to be modified in the charge type list, and enter the modified content in the input box after the corresponding item on the right.
- (2) Click "Modify" to pop up the dialog box of "Modify successfully", and click OK to save the modified contents.
- Deleting the charge type
- (1) Select the item to be deleted in the charge type list, click "Delete", and the dialog "Do you confirm to delete the selected data?" will pop up.
- (2) Click "Confirm" to delete the selected item; Or click "Cancel" to remain the original settings.

There are two default settings in the list, Out-of-Pocket and Medical Insurance. The mnemonics symbols default to the initials of the name in pinyin.

11.8Delivery department & doctor

On the "Management" interface, click "Delivery department & doctor" to enter the corresponding interface.

11.8.1 Department

This section mainly introduces the main information of the delivery department settings, including the addition, modification and deletion of the delivery department.

- Adding a department
- (1) The delivery department settings are on the left side of the "Delivery department & doctor" interface, and the name of the added delivery department can be entered in the input box below.
- (2) Enter the mnemonic symbols for the added department in the input box after the mnemonic symbols, click "Add", and the dialog "Added successfully" will pop up.
- (3) Click "Confirm", and the added contents will be included in the department list and arranged in the last row corresponding to its sequence number.
- Modifying the department
- (1) Select the item to be modified in the department list, and enter the modified content in the input box after the corresponding item on the right.
- (2) Click "Modify" to pop up the dialog box of "Modify successfully", and click "Confirm" to save the modified contents.
- Deleting then department
- (1) Select the item to be deleted in the department list, click "Delete", and the dialog "Do you confirm to delete the selected data?" will pop up.
- (2) Click "Confirm" to delete the selected item and the doctors contained in the selected item; Or click "Cancel" to remain the original settings.

11.8.2 Doctor

This section mainly introduces the main information of the "Doctor", including the

addition, modification and deletion of the doctor.

- Adding a doctor
- (1) The department settings are on the left side of the "Doctor" interface. Once selecting a record of the department on the left, the name of the doctor of the corresponding department, as well as its mnemonic symbols will be displayed on the right.
- (2) Enter the name of the submitter in the input box below, and enter the added mnemonic symbols for the submitter in the input box after the mnemonic symbols.
- (3) Click "Add", and the dialog "Added successfully!" will pop up.
- (4) Click "Confirm", and the added contents will be included in the doctor list and arranged in the last row corresponding to its sequence number.

Likewise, add the names of doctors of other departments and their mnemonic symbols.

- Modifying the doctor
- (1) Select the item to be modified in the doctor list, and enter the modified content in the input box after the corresponding item on the right.
- (2) Click "Modify" to pop up the dialog box of "Modify successfully", and click "Confirm" to save the modified contents.
- Deleting the doctor
- (1) Select the item to be deleted in the doctor list, click "Delete", and the dialog"Do you confirm to delete the selected data?" will pop up.
- (2) Click "Confirm" to delete the selected item; Or click "Cancel" to remain the original settings.

11.9 Dilution ratio

On the "Management" interface, click Dilution ratio to enter the "Dilution ratio" interface.

- Adding a dilution ratio
- (1) Enter the dilution ratio to be added in the right input box, and enter the added dilution ratio mnemonic symbols in the input box after the mnemonic symbols.
- (2) Click "Add", and the dialog "Added successfully!" will pop up.

- (3) Click "Confirm", and the added content will be included in the dilution ratio list and arranged in the last row corresponding to its sequence number.
- Modifying the dilution ratio
- (1) Select the item to be modified in the dilution ratio list, and enter the modified content in the input box after the corresponding item on the right.
- (2) Click "Modify" to pop up the dialog box of "Modify successfully", and click "Confirm" to save the modified contents.
- Deleting the dilution ratio
- (1) Select the item to be deleted in the dilution ratio list, and click "Delete" to pop up the dialog "Do you confirm to delete the selected data?".
- (2) Click "Confirm" to delete the selected item; Or click "Cancel" to remain the original settings.

11.10 Mark

On the "Management" interface, click "Mark" to enter the abnormal mark interface.

- Adding an Abnormal Mark
- (1) Enter the abnormal mark to be added in the right input box, and enter the mnemonic symbols for the added abnormal mark in the input box after the mnemonic symbols.
- (2) Click "Add", and the dialog "Added successfully!" will pop up.
- (3) Click "Confirm", and the added content will be included in the abnormal mark list and arranged in the last row corresponding to its sequence number.
- Modifying the mark
- (1) Select the item to be modified in the mark list, and enter the modified content in the input box after the corresponding item on the right.
- (2) Click "Modify" to pop up the dialog box of "Modify successfully", and click "Confirm" to save the modified contents.
- Deleting the mark
- (1) Select the item to be deleted in the mark list, click "Delete", and the dialog "Do you confirm to delete the selected data?" will pop up.
- (2) Click "Confirm" to delete the selected item; Or click "Cancel" to remain the

original settings.

12 Settings

This chapter mainly introduces how to setup the instrument, including system configuration, morphology configuration, dry chemical configuration, re-examination rules, auto printing, automatically send to LIS, auto review and so on.

12.1System configuration

Click the "System configuration" on the main interface of the software to enter the "System configuration" interface.

12.1.1 Set language

Select the language in the language setting area of the "System configuration" interface.

For example: Click the drop-down box of "Language", select English and then click "Save" at the bottom of the screen. Then the language in other interfaces will be shifted to English.

12.1.2 Set result decimal precision

In the "System configuration", you can set the decimal precision of the result, for example, enter 2 for decimal places, click "Save" at the bottom of the screen, and it will jump to the sample result interface, where you can see the results with two decimal places.

12.1.3 Device setting

In the "Device setting" box of the "System configuration" interface, the serial port number to be set should be the serial number for the communication between the instrument and the computer. This can be set by the user as appropriate.

12.1.4 Device temperature alarm range

The temperature range should be set within the alarm range of the instrument temperature (10 \sim 30°C by default). In case the ambient temperature exceeds this range, a prompt alarm will be given.

12.1.5 PHYC unit setting

The user can set the PHYC unit on the "System configuration" interface. Select

SG (if the PHYC unit is configured) to enable specific gravity components and test results. Select turbidity (if the PHYC unit is configured), and enable turbidity components and test results. Select color (if the PHYC unit is configured) to enable the color components and test results. Select conductivity (if the PHYC unit is configured) to enable the conductivity components and test results.

12.1.6 Reagent expiration range prompt

Set the prompt of reagent expiration range, so that the user can be prompted when the reagent expiration is shorter than the set range.

12.1.7 Alarm alert

When the instrument gives an alarm, if a buzzer prompt is needed in addition to the flashing alarm icon, select "On" in the alarm tone of the "System configuration", so that there will be double prompts when the system alarms.

If "No test tube rack alarm in the area to be tested" is selected, a prompt will be given when there is no tube rack in the pending test area during the test. Cancel the selection if it is not required.

12.1.8 Test mode

The test mode can be set on the "System configuration" interface: When "Manual" is selected, the sample number is allowed to be edited manually when sending the test; When "Automatic" is selected, the sample number is the "current maximum sample number +1" by default when sending the test, and not allowed to be modified.

12.1.9 Set manual review

Check "Name" after the review conditions. When performing manual review on the "Test" > "Test result" screen, it is necessary to identify whether "Sample Info." > "Name" is blank. If it is blank, the review result will be "Fail", and a prompt will pop up in the upper right corner of the Main Interface. If it is not checked, no judgment will be made.

Check "Barcode" after the review conditions. When performing manual review on the "Test" > "Test result" screen, it is necessary to identify whether the "Sample Info." > "Barcode" is blank. If it is blank, the review result will be "Fail", and a prompt will pop up in the upper right corner of the main interface. If it is not checked, no judgment will be made.

12.1.10 Set sleep time

Check "Enable" and select the sleep time from the drop-down menu on the right side of "Sleep time", then the instrument will enter sleep state after the selected time.

12.1.11 Abnormal mark

The abnormal mark can be set on the "Settings" interface. In the "Set abnormal mark" area, click the drop-down box of the "Abnormal mark", select the required mark, click "Save", and the selected mark will be displayed on the test report is the test result is abnormal.

12.1.12 LIS configuration

If the instrument is connected with other LIS, LIS configuration should be made.

LIS configuration is connected via the network:

- Select "LIS network" in the "System configuration", simultaneously selecting the "Automatic connection to LIS server when software starts", and then the connection of LIS network port will automatically be enabled at startup.
- IP address: Refers to the IP address of the server in the LIS.
- Port number: Refers to the port number of the server in the LIS.

LIS configuration is connected via the serial port:

- Select the option "Automatic connection to LIS server when running software" in the "System configuration", and then the serial port connection of LIS will automatically be enabled when the software starts.
- Serial port No.: Select the communication serial port number. The user may set it as appropriate.
- Data bits, stop bits and parity check are all default values, which cannot be modified by users. But users are allowed to modify the baud rate.

12.2Morphological configuration

Click "Morphology configuration" on the "Settings" interface to enter the "Morphology configuration" interface.

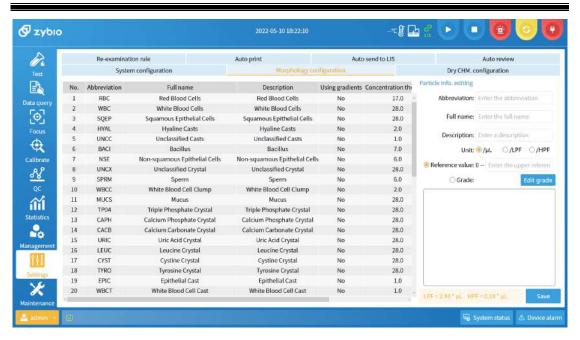


Figure 12-1 Morphology configuration interface

Particle information editing

After selecting the item to be edited in the list box on the "Morphology configuration", enter the corresponding information in the right particle information editing box:

- Abbreviation: Enter the abbreviation of this item in the printed report (either texts or numbers are OK).
- Full name: Enter the name of the item (either texts or numbers are OK).
- Description: Enter the description of this item.
- Unit: Check the commonly used unit.
- If reference value is used, please edit the upper limit of reference value in the reference value input box.
- If this item is graded, check the radio box before Grade.

Edit grade

Click "Edit grade" in the "Morphology configuration" to enter the "Edit grade" interface, and the sediment grading setup interface will be displayed. (Any starting value and its corresponding user-defined grade name can be edited according to the reference value range)

• Adding a grade: Click "Add" after entering the starting value and grade name, and then the new content will be shown in the grade edit list.

- Modifying the grade: Select a grade, modify its starting value position and grade name position in turn, and click "Modify" to show the modified contents in the list.
- Deleting the grade: Select a record in the list and click "Delete", and then the dialog "Do you confirm to delete the grade?" will pop up. Click "Confirm" to delete it, or Click "Cancel" to not delete the content.

12.3Dry Chemical Configuration

Click "Dry CHM. configuration" on "Setting" interface to enter the "Dry CHM. configuration" interface.

Edit the unit system and negative expression of the dry chemical part on the "Dry CHM. configuration" interface (this function is limited to the administrator).

- Unit systems: There are three systems of units including international system (IS), conventional system, and symbolic system of units. They are divided into the following combination check methods. Users may check the following unit forms based on needs:
 - Check "International" only.
 - Check both "International" and "Using plus system".
 - Check "Conventional" only.
 - Check both "Conventional" and "Using plus system".
 - Check "Plus system".
- Negative representation: Neg and –.

Note

There are 3 types of dry chemical strips: 11 items, 12 items, and 14 items. If changing the strip type is required, please contact Zybio.

12.4Re-examination rule

Click "Re-examination rule" on the "Setting" interface to enter the re-examination rule setting interface.

12.4.1 Microscopic examination condition

This section mainly introduces the main operations about microscopic examination

condition, as follows:

- Adding a microscopic examination condition: Click "Add" on the "Microscopy Condition" on the left side of the "Re-examination rule", that is, a new row will be added to the microscopic examination conditions table. When clicking a cell, the drop-down box options for this item will be shown, for example: Select RBC+ and click "Save" to add a set of microscopic examination judgment conditions.
- Delete: In case there is no need to set the microscopic examination conditions or urine culture conditions, they can be deleted. Click the line in the list box where the microscopic examination conditions are located, and then click "Delete".
- Restore default: Click "Restore default", and click "Confirm" in the pop-up dialog box to restore the microscopic examination condition information to default.

Note

After the microscopic examination conditions are deleted, there will be no prompt no matter what the test results are, and the manual microscopic examination should be performed.

12.4.2 Urine culture conditions

Urinary tract infection is caused by direct invasion of bacteria (in a few cases invaded by fungi, protozoa and viruses).

Urinary tract infection is divided into upper urinary tract infection and lower urinary tract infection. Upper urinary tract infection refers to pyelonephritis, and lower urinary tract infection includes urethritis and cystitis. Pyelonephritis, consisting of acute pyelonephritis and chronic pyelonephritis, is more common in women. Items like red blood cells, white blood cells or proteins may be included in routine urine examination, so the instrument can provide rapid screening report for urinary tract infection. As shown in the table below, urine culture examination is recommended if the prompt conditions of urinary tract infection are met.

Table 12-1 Prompt conditions of urinary tract infection

Item Conditions	1	2	3	4	5	6
RBC (sediment)	-	+	-	-	-	+

	1	ı	1	1	1	1 1
BLD (dry chemical)	-	+	+	+	+	+
WBC (sediment)	+	+	+	-	+	-
WBC (dry chemical)	-	+	-	-	-	-
NIT (dry chemical)	+	+	+	+	+	+
BACT (sediment)	+	-	-	+	+	-

- Add: Click "Add" to add a new row in the urine culture condition table. Click a cell
 to show the drop-down box options for this item, for example: Select RBC+ and
 click "Save" to add a set of urine culture judgment conditions.
- Delete: If urine culture conditions do not need to be set, click on the cell where the urine culture judgment conditions are located to delete it.
- Restore default: Click "Restore default", and click "Confirm" in the pop-up dialog box to restore the microscopic examination condition information to default.

Once the urine culture conditions are deleted, there will be no prompt no matter what the test results are.

12.5Auto print

Click "Auto print" on the "Settings" interface to enter the "Auto print" interface.

On the "Auto print" interface, the user can set the dry chemical and morphological conditions for automatic printing, which may be enabled separately or simultaneously. Either or both of them is allowed to be enabled.

- On the left side of the interface is the condition "Auto printing of Dry CHM. results is performed when the following conditions are met" and on the right side is the condition "Auto printing of Dry CHM. results is performed when the following conditions are met at the same time". Right after each item, the user can modify the conditions by selecting a drop-down box option. After modification, check "Enable function" or "Right". Click "Save" to automatically print the qualified test results.
- When NONE is selected for all conditions, unconditional automatic printing will be performed.
- Cancel the selection of "Enable function" if automatic printing is not needed. At this time, no matter what conditions the results meet, automatic printing will not

be performed.

• To modify the print template, click "Set print" on "Auto print" interface to change or customize the print template.

12.6Auto send to LIS

Click "Auto send to LIS" on the "Settings" interface to enter the "Auto send to LIS" interface.

On the "Auto send to LIS" interface, the user can set the conditions for performing automatic sending to LIS in dry chemical or morphology that may be enabled separately or simultaneously.

- On the left side of the interface is the condition "Automatically send to LIS when dry chemical results meet the following conditions" and on the right side is the condition "Automatically send to LIS when morphological results meet the following conditions". Right after each item, you can modify the conditions by selecting a drop-down box option, check "Enable function" after modification, and click "Save" to automatically send the qualified test results to LIS.
- When NONE is selected for all conditions, unconditional automatic sending to LIS will be performed.
- If "Auto send to LIS" is not needed, cancel the selection of "Enable function", and the automatic sending to the LIS will not be performed no matter what conditions the results meet.

12.7Auto review

Click "Auto review" on the "Setting" interface to enter the "Auto review" interface.

On the "Auto review" interface, the user can set the conditions for performing automatic review, in dry chemical or morphology that may be enabled separately or simultaneously.

On the left side of the interface is the condition "Auto review performed when Dry CHM. results meet the following conditions" and on the right side is the condition "Auto review performed when morphology results meet the following conditions".
 Right after each item, the user can modify the conditions by selecting a drop-down box option. After modification, check "Enable function" or check "With barcode" and "With name". Click "Save" to automatically review the qualified test

results.

- When NONE is selected for all conditions, unconditional auto review will be performed.
- Cancel the selection of "Enable function" if auto review is not needed. At this time, no matter what conditions the results meet, auto review will not be performed.

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13 Maintenance

Click "Maintenance" on the left side of the main interface, and the user can perform operations such as priming the fluidics, replacing sheath fluid, gray adjustment, emptying, cleaning the flow cell, cleaning the fluidics, cleaning physicochemical unit, blank test, database backup, database recovery, and data clearing.

13.1Replace sheath fluid

When there is no sheath fluid in both the buffer bottle and the container, remove the empty container connected to the instrument at the back, replace it with a new sheath fluid container, and connect with the instrument. Click "Replace sheath fluid", and the instrument will perform the replacement operation to re-prime the tubing with sheath fluid.

13.2Prime sheath fluid

When there are air bubbles in the tubing or replacing the sheath fluid, click Prime Fluidics in the System Maintenance, and the bubbles in each tubing will be discharged, so as to avoid the influence of bubbles on the test results.

Note

- Before stopping using the instrument, first empty the fluidics, then prime the fluidics with distilled water for multiple times, and finally empty the fluidics again.
- When the instrument is not used for a period of time, prime the fluidics prior to using it again.

13.3Gray

When the focus fault occurs in the instrument, it is used to guide after-sales engineers to repair and debug.

13.4Empty

Before the system transports for analysis, empty the fluidics first.

(1) Click "Empty" on the "Maintenance" interface, and then "Empty sheath fluid buffer bottle, plug sheath fluid tube out from sheath fluid container, click OK" will pop up. Do as prompted and then click "Confirm". Pull out the sheath fluid

supply tubing interface and sensor plug at the back of the instrument.

(2) Click "Confirm" in the software prompt box to start the emptying operation.

Note

- When emptying fluidics, do not unplug the waste liquid tubing interface and the waste liquid sensor plug. When the instrument is in the Standby state after emptying, remove the waste liquid tubing interface and the waste liquid sensor plug.
- Before moving the instrument, please split it into two parts: the instrument and the rack-in module.

Before stopping using the instrument, first empty the fluidics, then prime the fluidics with distilled water for multiple times (just replace the sheath fluid in the sheath fluid bottle with distilled water), and finally empty the fluidics again.

Note

Before emptying the fluidics, the sheath fluid tube should be separated from the instrument interface.

13.5Cleaning flow pool

To prevent the residual artifact in the flow pool from affecting the accuracy of the test results, the flow cell should be cleaned once a day. The cleaning method is as follows:

- (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) Click "Clean flow pool" on the "Maintenance" interface, and the test tube rack will be automatically pushed to the sample aspiration position, where the sample probe will aspirate about 2 mL of urine sediment wash solution. After soaking the flow cell for about 3 minutes, repeat the operation of cleaning the flow cell.

13.6Cleaning fluidics

When there are air bubbles in the wash solution tubing or the instrument alarms "Clean fluidics", click "Clean fluidics" on the "Maintenance" interface, and the bubbles in the wash solution tubing will be discharged, so as to avoid the influence of bubbles on the test results.

13.7Cleaning physicochemical unit

Note: Physicochemical unit includes conductivity and specific gravity. As the conductivity, specific gravity, and turbidity are in the same loop in the fluidics system, they can be cleaned at the same time and in the same step.

To avoid the residual artifact in the physicochemical unit affecting the accuracy of the test results of the instrument, it is necessary to clean the physicochemical unit when the calibration specific gravity, turbidity and conductivity fail. The cleaning method is as follows:

- (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) Click "Clean PHYC unit" on the "Maintenance" interface, and the tube rack will be automatically pushed to the sample aspiration position, and the sample probe will aspirate about 2 mL of urine sediment wash solution. After soaking the physicochemical unit for about 3 minutes, repeat the cleaning operation of it.

13.8Blank test

When the startup blank test of the instrument fails or the instrument is in maintenance, click "Blank test" on the "Maintenance" interface to perform the blank test.

- Once the blank test passed, the information that prompts the blank test passed will be displayed.
- In case the blank test fails, the information that prompts the blank test passed will be displayed. At this time, the operations of "Clean fluidics" and "Clean flow pool" should be repeated. If it still fails, please contact customer service.

13.9Clearing data

Click "Clear data" and select the data type to be cleared in the pop-up window. Click "Confirm" to clear it.

13.10 Database backup and recovery

The instrument has the function of data backup, permitting operations of backup reminder setup and backup path setup of the database.

Users are recommended to back up the database regularly to prevent data loss caused by unexpected circumstances. Backup and restore the database in standby mode.

• Auto backup reminder of database

Click "Database backup" on the "Maintenance" interface, select manual backup or set the time of scheduled backup.

- Backup path of database
- The default path is in drive D. Click "Database backup" to set the backup path.
- Database recovery

In case of any data loss for some reasons, the user can use the backed-up database file to restore the previous data.

Click "Database recovery" on the "Maintenance" interface to open next interface. Select the backed-up file and click "Open". When the dialog "Database recovery succeeded" pops up, click "Confirm."

Clearing Data

Click "Clear data" on the "Maintenance" interface, and the prompt box will pop up, as shown in Figure 13-3. Check the items to be cleared and click Delete. When the prompt box of "Deleted data cannot be recovered, do you want to delete it?" pops up, click "Confirm" to clear the data.

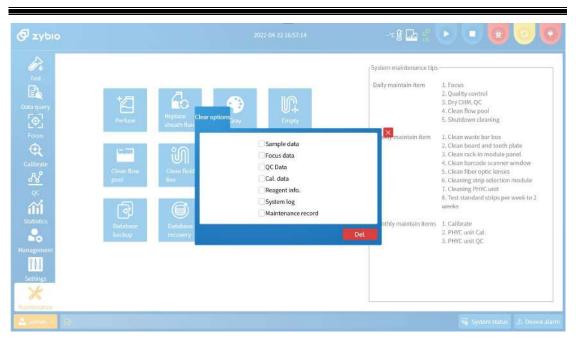


Figure 13-1 Clear options interface



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14 Maintenance and care

To ensure the accuracy and precision of the instrument, the operator must strictly follow the requirements of this manual and regularly maintain the instrument. Only in this way can the instrument provide reliable results and ensure its service life.

Warning

- Do not spill water, reagents, sheath fluid and other liquids on the mechanical or electrical parts of the instrument, so as to avoid damage to the instrument.
- When the instrument is running, do not touch the sample probe, otherwise there is a risk of infection or injury.
- When using the instrument, operators should take preventive measures, such as wearing gloves, masks, protective glasses and overalls. Otherwise, infection may be caused due to contact with the contaminated areas and liquids, or skins may be damaged by contact with corrosive liquids. If the body contacts the contaminated or corrosive liquid accidentally, washing with water and immediate disinfection is required.
- If the accessories used in the instrument are not provided or recommended by the manufacturer, or the instrument is not used in the way specified by the manufacturer, the protection provided by the instrument may be weakened.
- During maintenance, attentions should be paid to finding potential dangers caused by the failure of any hose or parts containing liquid.

Note

- Before stopping using the instrument, first empty the fluidics, then prime the fluidics with distilled water for multiple times, and finally empty the fluidics again.
- When the instrument is not used for a period of time, prime fluidics prior to using it again.

Before maintaining the instrument, please prepare the following tools: cotton swab, gauze.

14.1Cleaning the waste strip box

This section mainly introduces the method of cleaning the waste strip box and cautions when cleaning.

• A waste test strip box can hold up to about 300 test strips and should be cleaned once a week.



- Urine is potentially infectious. Protective measures must be taken when cleaning.
- Please dispose of the discarded test strips in accordance with the clinical laboratory regulations.

The method of cleaning a waste strip box is as follows:

- (1) Take out the waste strip box as shown in the figure below, and discard the test strips inside the waste strip box.
- (2) Rinse the waste strip box with pure water.
- (3) Wipe or air-dry the waste strip box.
- (4) Install the cleaned waste strip box to the original position.

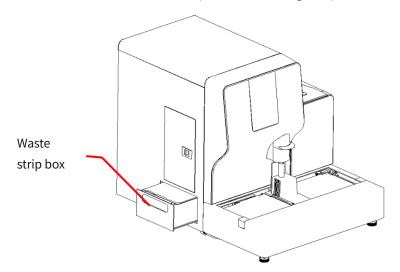


Figure 14-1 Ways to take out the waste strip box

14.2Cleaning the strip-transport plate

To ensure the cleanness of the bedplate, the bedplate and the strip-transport toothed plates should be cleaned at the end of each weekly test. The method is as follows:

Step 1: Press the button on the strip-pick cover to open the strip-pick cover, press the button, and open the front hood component.

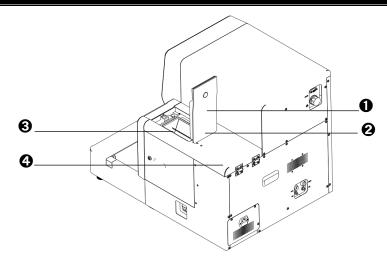


Figure 14-2 Clean the strip-transport plate - step 1

Step 2: Use the small door key to open the latch on the right door component, and then the component is opened.

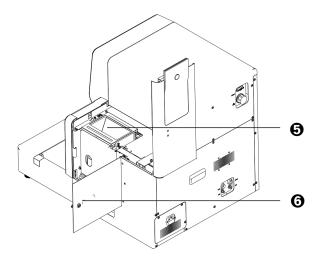


Figure 14-3 Clean the strip-transport plate - step 2

Step 3: Turn the strip-pick module outward.

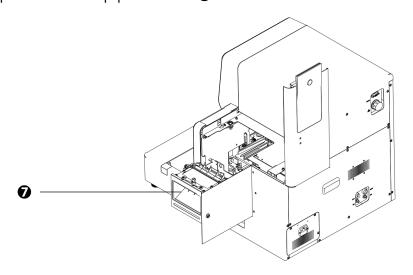


Figure 14-4 Clean the strip-transport plate - step 3

Step 4: Use your thumb to withhold the clasp on the bedplate and use your forefinger to press against the right strip-pick plate to remove the bedplate downward.

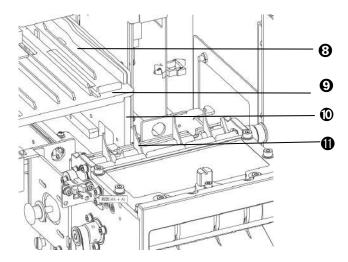


Figure 14-5 Clean the strip-transport plate - step 4

Step 5: Remove the toothed plate upward.

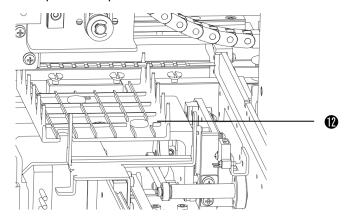


Figure 14-6 Clean the strip-transport plate - step 5

Note

When removing the bedplate, do not touch the strip-pick bar to avoid injury.

Step 6: Wipe the paper scraps of the strip-pick module with a small brush, wipe the bedplate and the toothed plate with gauze dipped with alcohol, then wash the bedplate with pure water, and put it at the vent. After the bedplate is dried, install it to its original position, and restore the instrument in a sequence from Step 5 to Step 1.

14.3Cleaning waste liquid container

When cleaning the waste liquid container, the following should be noted:

- Dispose the waste liquid in strict accordance to clinical laboratory regulations.
- Clean the waste liquid container once a week.
- Pour out the waste liquid in time when the waste liquid container is full.
- Urine is potentially infectious, and protective measures must be taken when cleaning.

14.4Cleaning the scanning window of the barcode scanner

The barcode scanner is located at the front of the emergency baffle of the rack-in module. To avoid the misreading or no reading of the barcode due to stains or dust on the scanning window, it is recommended to clean the scanning window once a week.

Cleaning method: Dip the cotton swab with 2% alkaline or neutral glutaraldehyde solution or 0.5% chlorhexidine acetate-ethanol solution barcode scanner window.

14.5Cleaning the sensor

The sensor that detecting if there is tube is located at the baffle in front of the barcode scanner of the rack-in module. To avoid the misjudgment due to dust on the surface of the sensor, it is recommended to clean the sensor once a month.

Cleaning method: wipe the sensing surface of the sensor with dry and clean cotton swab.

14.6Cleaning sheath fluid bottle

After long-term storage, the sheath fluid in the sheath fluid bottle will form a layer of fouling on the bottle wall, which will affect the quality of the sheath fluid and even the test results. Therefore, the sheath fluid bottle should be cleaned once a month. The cleaning method is as follows:

- (1) Exit the software and turn off the power switch of the instrument.
- (2) Open the small door on the right side of the instrument, unscrew the cap component, and remove the sheath fluid bottle.
- (3) Use clean self-sealing bag or plastic film to seal the bottle cap component and avoid tubing contamination.
- (4) Pour out the remaining sheath fluid from the bottle, and clean the bottle with deionized water.

(5) After cleaning, screw the bottle back into the cap component, lock the cap, put the sheath fluid bottle back in place and close the small door.

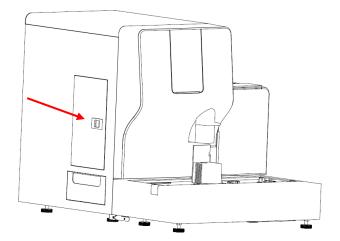


Figure 14-7 Cleaning sheath fluid bottle

Note

Do not drag the tubing or harness forcibly.

14.7Emptying fluidics

When the instrument is not used for more than one week, the liquid in the whole instrument tubing should be emptied, so as to prevent crystallization and ensure the testing accuracy of the instrument.

- (1) Refer to Section 13.4, click "Empty" to empty all liquid in the tubing of the instrument.
- (2) Insert the sheath fluid tube into the deionized water bucket, click Clean to clean the fluidics again with deionized water and ensure that there will be no residual reagent in the tubing.
- (3) After cleaning, pull out the sheath fluid tube from the deionized water, click Empty again and empty the deionized water in the instrument. Then turn off the power supply and complete the maintenance process.

14.8Checking and replacing the tubing

Please be aware of the followings when checking and replacing the tubing of the instrument:

• In the process of using the instrument, ensure that the reagent tubing (e.g., sheath fluid, liquid waste) is not kinked or weighted by heavy objects.

• During operating the instrument, if the dry strip error or full waste container error occurs while there is sufficient wash solution in the external container and enough sample in the tube, please check if the tubing leaks or poorly connected. If the leakage or poor connection is arising from bent or knikled tubing, please adjust the tubing and click Reset on the interface. If it is caused by aging or wearing of the tubing, stop operating the instrument and contact Zybio timely.

14.9Replacement of wearing parts

The information of wearing parts of the instrument is shown in the table below:

No.	Part name	Replacement cycle	Replacement method
1	Injection numn	After damage or 12	Contact Zybio or the local
1	Injection pump	months	distributor for replacement.
2	Fuse	After damage	Replace by users.

Table 14-1 Information of wearing parts

Fuse replacement

Two F1AL250V fuses are contained to protect the instrument. If the fuse is blown, replace the fuse following the steps below:

- (1) Power off the instrument and unplug the power cord.
- (2) Open the fuse holder with a slotted screwdriver, take out the fuse, and replace with a new one.
- (3) Close the fuse holder.

Warning

- For the performance and safety of the instrument, all the maintenance spare parts above shall be purchased from the manufacturer or the authorized local distributor.
- All parts other than the fuse shall be replaced by manufacturer or the authorized local distributor. Otherwise, the user shall assume all the responsibilities.

14.10 Error information and troubleshooting

During the use of the instrument, in case an abnormal condition is detected, the

instrument will display the corresponding fault prompt information. For easy search, this section will list all possible fault information displayed by the instrument, and provide possible causes and troubleshooting steps. Operators may refer to the provided steps for troubleshooting.

Table 14-2 Instrument error information and troubleshooting

Error code	Error type	Error information	Possible causes	Solutions
			1.Probe motor	
			optocoupler	
			damaged.	
			2.Probe motor	1. Reset to check if
		Probe does not	optocoupler drive	the fault is
	Stop	leave from the	chip damaged.	eliminated.
0x0103	level	cleaning	3.Probe motor	2. If the fault is not
	levei	position	optocoupler lost	eliminated, please
		optocoupler	step.	contact the after-
			4.The probe	sales personnel.
			component is	
			abnormally stuck	
			during operation.	
			1.Probe motor	
			optocoupler	
			damaged.	
			2.Probe motor	1. Reset to check if
		Probe does not	optocoupler drive	the fault is
	Stop	reach the	chip damaged.	eliminated.
0x0104	level	cleaning	3.Probe motor	2. If the fault is not
	icvei	position	optocoupler lost	eliminated, please
		optocoupler	step.	contact the after-
			4.The probe	sales personnel.
			component is	
			abnormally stuck	
			during operation.	

Error code	Error type	Error information	Possible causes	Solutions
0x0105	Stop level	Probe does not leave from the U-shaped optocoupler	1.Probe motor U-shaped optocoupler damaged. 2.Probe motor optocoupler drive chip damaged. 3.Probe motor optocoupler lost step. 4.The probe	1. Reset to check if the fault is eliminated. 2. If the fault is not eliminated, please contact the aftersales personnel.
			component is abnormally stuck during operation.	
0x0106	Stop level	Probe does not reach the U- shaped optocoupler	1.Probe motor U-shaped optocoupler damaged. 2.Probe motor optocoupler drive chip damaged. 3.Probe motor optocoupler lost step. 4.The probe component is abnormally stuck during operation.	 Reset to check if the fault is eliminated. If the fault is not eliminated, please contact the aftersales personnel.

Error code	Error type	Error information	Possible causes	Solutions
			1.Probe motor	
			optocoupler	
			damaged.	
			2.Probe motor	1. Reset to check if
		Probe does not	optocoupler drive	the fault is
	C.	leave from the	chip damaged.	eliminated.
0x0107	Stop	drop sample	3.Probe motor	2. If the fault is not
	level	position	optocoupler lost	eliminated, please
		optocoupler	step.	contact the after-
			4.The probe	sales personnel.
			component is	
			abnormally stuck	
			during operation.	
			1.Probe motor	
			optocoupler	
			damaged.	
			2.Probe motor	1. Reset to check if
		Probe does not	optocoupler drive	the fault is
	Cton	reach the	chip damaged.	eliminated.
0x0108	Stop level	sample dispense	3.Probe motor	2. If the fault is not
		position	optocoupler lost	eliminated, please
		optocoupler	step.	contact the after-
			4.The probe	sales personnel.
			component is	
			abnormally stuck	
			during operation.	
			1.Insufficient	
		Intaking air or	sample.	Check whether the
	Drompt	Intaking air or blood and urine	2.Sample	sample size of the
0x0109	Prompt level		concentration too	test tube is
	level	during the	high.	insufficient, or
		sample	3.Existent of air	hematuria.
			bubbles in fluid path.	

Error code	Error type	Error information	Possible causes	Solutions
0x010A	Stop level	Probe on the motor lost steps during vertical operation	1.Probe motor optocoupler drive chip damaged. 2.Probe motor lost step during up and down movement.	 Reset to check if the fault is eliminated. If the fault is not eliminated, please contact the after- sales personnel.
0x010B	Stop level	Master control abnormal and power off	Abnormal power failure of the whole device	 Reset to check if the fault is eliminated. If the fault is not eliminated, please contact the after- sales personnel.
0x0201	Stop level	Test tube rack transfer motor abnormal	The drive chip of the rack transfer motor is damaged.	 Reset to check if the fault is eliminated. If the fault is not eliminated, please contact the after- sales personnel.
0x0204	Stop level	Test tube rack push-out motor abnormal	The drive chip of the rack transfer motor is damaged.	 Reset to check if the fault is eliminated. If the fault is not eliminated, please contact the after- sales personnel.

Error code	Error type	Error information	Possible causes	Solutions
0x0205	Stop level	Test tube rack push out motor does not reach the optocoupler	 Sample tray pushout drive chip damaged. Sample tray pushout optocoupler damaged. Sample tray pushout motor lost step. 	 Reset to check if the fault is eliminated. If the fault is not eliminated, please contact the after- sales personnel.
0x0206	Stop level	Test tube rack push out motor does not leave from the optocoupler	 Sample tray pushout drive chip damaged. Sample tray pushout optocoupler damaged. Sample tray pushout motor lost step. 	 Reset to check if the fault is eliminated. If the fault is not eliminated, please contact the after- sales personnel.
0x0207	Stop level	Test tube rack transfer rack motor abnormal	Transfer-rack motor drive chip damaged.	 Reset to check if the fault is eliminated. If the fault is not eliminated, please contact the after- sales personnel.
0x0208	Stop level	Test tube rack transfer rack motor does not reach the optocoupler	1.Sample tray transfer-rack motor drive chip damaged. 2.ample tray transfer-rack motor optocoupler damaged. 3.ample tray transfer-rack motor lost step.	 Reset to check if the fault is eliminated. If the fault is not eliminated, please contact the aftersales personnel.

Error code	Error type	Error information	Possible causes	Solutions
0x0209	Stop level	Test tube rack transfer rack motor does not leave from the optocoupler	1.Sample tray transfer-rack motor drive chip damaged. 2.ample tray transfer-rack motor optocoupler damaged. 3.ample tray transfer-rack motor lost step.	 Reset to check if the fault is eliminated. If the fault is not eliminated, please contact the after- sales personnel.
0x020A	Stop level	Test tube rack rack-in motor abnormal	Sample tray rack-in motor drive chip damaged.	 Reset to check if the fault is eliminated. If the fault is not eliminated, please contact the after- sales personnel.
0x020B	Stop level	Test tube rack rack-in motor does not reach the optocoupler	 Sample tray rack-in motor drive chip damaged. Sample tray rack-in motor optocoupler damaged. ample tray rack-in motor lost step. 	 Reset to check if the fault is eliminated. If the fault is not eliminated, please contact the after- sales personnel.
0x020C	Stop level	Test tube rack rack-in motor does not leave from the optocoupler	 Sample tray rack-in motor drive chip damaged. Sample tray rack-in motor optocoupler damaged. ample tray rack-in motor lost step. 	 Reset to check if the fault is eliminated. If the fault is not eliminated, please contact the after- sales personnel.

Error	Error type	Error information	Possible causes	Solutions
0x020D	Stop level	Test tube rack transfer motor abnormal	Sample tray transferin motor drive chip damaged. 1. Recycling area optocoupler damaged. 2. Recycling area	1. Reset to check if the fault is eliminated. 2. If the fault is not eliminated, please contact the aftersales personnel. 1. Take away the test tube rack in the retired rack area and then continue the test. 2. Reset to check if
0x0210	level	area is full.	optocoupler blocked; 3. Recycling area is full.	the fault is eliminated. 3. If the fault is not eliminated, please contact the after- sales personnel.
0x0211	Stop level	Test tube rack transfer motor encoder abnormal	1.Sample tray transfer-rack motor drive chip damaged. 2.ample tray transfer-rack motor optocoupler damaged. 3.ample tray transfer-rack motor lost step.	 Reset to check if the fault is eliminated. If the fault is not eliminated, please contact the aftersales personnel.

Error code	Error type	Error information	Possible causes	Solutions
0x0212	Stop level	Rack-in switch signal abnormal	Rack-in optocoupler signal damaged.	 Reset to check if the fault is eliminated. If the fault is not eliminated, please contact the after- sales personnel.
0x0214	Prompt level	No test tube rack to be tested	1.Rack-in-position optocoupler signal damaged. 2.Sample test completed.	Start the test after placing the test tube rack.
0x0215	Stop level	The rack for combined use is lost	1.Transport tapeoptocouplerdamaged.2.Tube rack transporttape is taken away.	 Reset to check if the fault is eliminated. If the fault is not eliminated, please contact the after- sales personnel.
0x0216	Stop level	Transfer for combined use times out	1.Transport tape optocoupler damaged. 2.Tube rack transport tape is taken away.	 Reset to check if the fault is eliminated. If the fault is not eliminated, please contact the after- sales personnel.
0x0217	Stop level	Tube rack is moved	1.Tube rack is moved. 2.Sample tray transfer-rack motor abnormal.	 Reset to check if the fault is eliminated. If the fault is not eliminated, please contact the after- sales personnel.

Error code	Error type	Error information	Possible causes	Solutions
0x0221	Prompt level	Emergency area is not ready	1.Emergency judgment optocoupler or emergency tube in- position optocoupler damaged. 2.Emergency tube not effectively placed.	1. Check whether the emergency test tube is placed properly. 2. Reset to check if the fault is eliminated. 3. If the fault is not eliminated, please contact the after- sales personnel.
0x0301	Stop level	Strip-release motor abnormal	1. The drive chip of strip-release motor is damaged; 2. The detection optocoupler of strip-release motor is damaged; 3. Step loss during the operation of strip-release motor.	1. Reset to check if the fault is eliminated. 2. If the fault is not eliminated, please contact the aftersales personnel.
0x0302	Stop level	Strip-release motor does not reach the optocoupler	1. The drive chip of strip-release motor is damaged; 2. The detection optocoupler of strip-release motor is damaged; 3. Step loss during the operation of strip-release motor.	 Reset to check if the fault is eliminated. If the fault is not eliminated, please contact the aftersales personnel.

Error code	Error type	Error information	Possible causes	Solutions
0x0303	Stop level	Strip-pick motor anomaly	 The drive chip of strip-pick motor is damaged; The detection optocoupler of strippick motor is damaged; Step loss during the operation of strip-pick motor. 	 Reset to check if the fault is eliminated. If the fault is not eliminated, please contact the after- sales personnel.
0x0304	Stop level	Strip-pick motor does not reach the optocoupler	1. The drive chip of strip-pick motor is damaged; 2. The detection optocoupler of strippick motor is damaged; 3. Step loss during the operation of strip-pick motor.	 Reset to check if the fault is eliminated. If the fault is not eliminated, please contact the aftersales personnel.

Error code	Error type	Error information	Possible causes	Solutions
0x0305	Stop	Strip jams in the strip picker	1. Test strip stuck in strip picker.	1. Check whether there are any test strips with changed shapes in the strip picker, and if so, remove the jammed test strips. 2. Clean the strip picker with a brush. 3. Purge the debris in the strip picker with the rubber suction ball. 4. Reset to check whether the fault is cleared. 5. If the fault is not eliminated, please contact the aftersales personnel.
0x0306	Stop level	No strips in the strip picker cabin	The strips have used up	Replenish the strip and continue to test
0x0307	Stop level	Strip-pick light tracing failed	Parameter error	Start light tracing again

Error code	Error type	Error information	Possible causes	Solutions
0x0308	Stop	The strip-pick motor does not leave from the optocoupler	 The drive chip of strip-pick motor is damaged; The detection optocoupler of strippick motor is damaged; Step loss during the operation of strip-pick motor. 	 Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.
0x0309	Prompt level	Standard strip pick failed	The standard strip has not picked correctly	Place the standard strip again and continue to test
0x0401	Stop level	Strip-push motor abnormality	The drive chip of strip-push motor is damaged;	 Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.
0x0402	Stop level	Strip-push motor does not reach the optocoupler	 The drive chip of strip-push motor is damaged; The detection optocoupler of strippush motor is damaged; Step loss during the operation of strip-push motor. 	 Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.

Error code	Error type	Error information	Possible causes	Solutions
0x0403	Stop level	Strip-push motor does not leave from the optocoupler	 The drive chip of strip-push motor is damaged; The detection optocoupler of strippush motor is damaged; Step loss during the operation of strip-push motor. 	 Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.
0x0404	Stop level	Strip-transport motor abnormal	The drive chip of strip-transport motor is damaged;	 Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.
0x0405	Stop level	Strip-transport motor does not reach the optocoupler	1. The drive chip of strip-transport motor is damaged; 2. The detection optocoupler of striptransport motor is damaged; 3. Step loss during the operation of strip-transport motor.	 Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.

Error code	Error type	Error information	Possible causes	Solutions
		1. The drive chip of		
			strip-transport motor	
			1. The drive chip of strip-transport motor is damaged; 2. The detection optocoupler of striptransport motor is damaged; 3. Step loss during the operation of strip-transport motor. 1. Reset whether cleared. test motor is damaged; 1. Reset whether cleared. 2. If the damaged; 1. The drive chip of the test motor is damaged; 1. The drive chip of test motor is damaged; 2. If the damaged; 3. Step loss during the optocoupler of test whether cleared. 2. If the damaged; 3. Step loss during the elimination of sales per s	1. Reset to check
		2. The detect	2. The detection	whether the fault is
	Ston	Strip-transport motor does not	optocoupler of strip-	cleared.
0x0406	Stop level	leave from the	transport motor is	2. If the fault is not
	levei	optocoupler	damaged;	eliminated, please
		optocoupter	3. Step loss during	contact the after-
			the operation of	sales personnel.
			strip-transport	
			motor.	
				1. Reset to check
		Test motor		whether the fault is
	Stop level		The drive chip of the	cleared.
0x0407			test motor is	2. If the fault is not
	levei	abilionnat	damaged;	eliminated, please
				contact the after-
				sales personnel.
			1. The drive chip of	
			test motor is	1. Reset to check
			damaged;	whether the fault is
	Stop	Test motor does	2. The detection	cleared.
0x0408	level	not reach the	optocoupler of test	2. If the fault is not
	level	optocoupler	motor is damaged;	eliminated, please
			3. Step loss during	contact the after-
			the operation of test	sales personnel.
			motor.	

Error code	Error type	Error information	Possible causes	Solutions
0x0409	Stop level	Test motor does not leave from the optocoupler	 The drive chip of test motor is damaged; The detection optocoupler of test motor is damaged; Step loss during the operation of test motor. 	 Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.
0x040A	Stop level	Abnormal signal of the rejudge optocoupler	The rejudge optocoupler of striptransport module is damaged or abnormally blocked.	 Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.
0x040B	Stop level	Lost or overturned strip	The test strip is turned over or lost during transporting.	 Clean the bedplate. Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the aftersales personnel.
0x040C	Stop level	Strip-transport plate is not installed in place	 The bedplate is not installed in place; The switch indicating bedplate in-place installation is damaged. 	 Re-plug the bedplate. Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the aftersales personnel.

Error code	Error type	Error information	Possible causes	Solutions
0x040E	Prompt level	Waste strip box is full	1. The optocoupler determining full waste strip box is damaged; 2. The waste strip box is full.	Empty the waste box and continue the test.
0x0601	Stop level	Acquisition board light source abnormal	The light source of acquisition plate is abnormal.	 Check whether the white reference is clean. Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.
0x0602	Prompt level	White benchmark abnormal during testing	White benchmark abnormal during testing	Check whether the benchmark is cleaned in standby state.
0x0604	Prompt level	Strip slanted or no strip	The test strip is slanted or no test strip is detected in the test position.	Clean the bedplate of the strip-transport unit in standby state.
0x0605	Prompt level	Insufficient drops on strips	Insufficient drops on strips	In standby state, check whether the test tube has insufficient sample volume.
0x0606	Prompt level	Abnormal strip	Abnormal strip	Check whether it is the strip supplied by Zybio.

Error code	Error type	Error information	Possible causes	Solutions
0x0501	Stop level	SV1 valve abnormal	1.SV1 solenoid valve abnormal.2.Solenoid valve not connected or the cable disconnected.	 Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.
0x0502	Stop level	SV2 valve abnormal	1.SV2 solenoid valve abnormal.2.Solenoid valve not connected or the cable disconnected.	 Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.
0x0503	Stop level	SV3 valve abnormal	 1.SV3 solenoid valve abnormal. 2.Solenoid valve not connected or the cable disconnected. 	 Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.
0x0504	Stop level	SV4 valve abnormal	 1.SV4 solenoid valve abnormal. 2.Solenoid valve not connected or the cable disconnected. 	 Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.

Error code	Error type	Error information	Possible causes	Solutions
0x0505	Stop level	SV5 valve abnormal	1.SV5 solenoid valve abnormal.2.Solenoid valve not connected or the cable disconnected.	 Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.
0x0506	Stop level	SV6 valve abnormal	1.SV6 solenoid valve abnormal.2.Solenoid valve not connected or the cable disconnected.	 Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.
0x0507	Stop level	SV7 valve abnormal	1.SV7 solenoid valve abnormal.2.Solenoid valve not connected or the cable disconnected.	 Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.
0x0508	Stop level	SV8 valve abnormal	1.SV8 solenoid valve abnormal.2.Solenoid valve not connected or the cable disconnected.	 Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.

Error code	Error	Error information	Possible causes	Solutions
code	type	IIIIOIIIIatioii		1. Reset to check
			1.SV9 solenoid valve	whether the fault is
			abnormal.	cleared.
0x0509	Stop	SV9 valve	2.Solenoid valve not	2. If the fault is not
	level	abnormal	connected or the	eliminated, please
			cable disconnected.	contact the after-
				sales personnel.
				1. Reset to check
			1.SV10 solenoid	whether the fault is
			valve abnormal.	cleared.
0x050A	Stop	SV10 valve	2.Solenoid valve not	2. If the fault is not
	level	l abnormal	connected or the	eliminated, please
			cable disconnected.	contact the after-
				sales personnel.
				1. Reset to check
			1.SV11 solenoid	whether the fault is
		0)/11	valve abnormal.	cleared.
0x050B	Stop	SV11 valve	2.Solenoid valve not	2. If the fault is not
	level	abnormal	connected or the	eliminated, please
			cable disconnected.	contact the after-
				sales personnel.
				1. Reset to check
			1.SV12 solenoid	whether the fault is
	Cton	CV12 valva	valve abnormal.	cleared.
0x050C	Stop	SV12 valve abnormal	2.Solenoid valve not	2. If the fault is not
	level	aphormat	connected or the	eliminated, please
			cable disconnected.	contact the after-
				sales personnel.

Error code	Error type	Error information	Possible causes	Solutions
0x0510	Stop level	The sample- aspiration motor does not reach the optocoupler	1.Aspirate motor drive chip damaged. 2.Aspirate motor optocoupler damaged. 3.Aspirate motor lost step.	 Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.
0x0511	Stop level	The sample- aspiration motor does not leave the optocoupler	1.Aspirate motor drive chip damaged. 2.Aspirate motor optocoupler damaged. 3.Aspirate motor lost step.	 Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.
0x0512	Stop level	Sample-push motor does not reach the optocoupler	1.Sample push motor drive chip damaged. 2.Sample push motor optocoupler damaged. 3.Sample push motor lost step.	 Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.
0x0513	Stop level	Sample-push motor does not leave from the optocoupler	1.Sample push motor drive chip damaged. 2.Sample push motor optocoupler damaged. 3.Sample push motor lost step.	 Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.

Error code	Error type	Error information	Possible causes	Solutions
0x0514	Stop level	Sheath fluid motor does not reach the optocoupler	1.Sheath fluid motor drive chip damaged. 2.Sheath fluid motor optocoupler damaged. 3.Sheath fluid motor lost step.	 Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.
0x0515	Stop level	Sheath fluid motor does not leave from the optocoupler	1.Sheath fluid motor drive chip damaged. 2.Sheath fluid motor optocoupler damaged. 3.Sheath fluid motor lost step.	1. Reset to check whether the fault is cleared. 2. If the fault is not eliminated, please contact the aftersales personnel.
0x0516	Stop level	Internal waste pool full	1.Internal waste pool optocoupler damaged. 2.Internal waste pool full.	 Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.
0x0517	Prompt level	Sheath fluid buffer bottle is empty	1.Sheath fluid buffer bottle sensor damaged.2.Sheath fluid buffer bottle empty.	1. Check the residual of reagent in the external buffer bottle. 2. Reset to check whether the fault is cleared. 3. If the fault is not eliminated, please contact the aftersales personnel.

Error code	Error type	Error information	Possible causes	Solutions
0x0518	Prompt level	Waste liquid container full	 The float of waste liquid container is damaged; The waste liquid container is full. 	 Pour off the waste liquid; Check whether the float switch of waste liquid container is abnormal.
0x0519	Prompt level	Empty sheath fluid container	 The float of container is damaged; The sheath fluid has been used up. 	1. Replace sheath fluid 2. Check whether the float switch of the sheath fluid container is abnormal.
0x051C	Stop level	Fluid line pressure abnormal	The hydraulic sensor is damaged;	 Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.
0x0702	Stop level	Rack-in module command times out	 The sample tray module is not connected; The communication line of the sample tray module is disconnected. 	 Shut down, restart, reset and check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.

Error code	Error type	Error information	Possible causes	Solutions
			1. The strip-pick	1. Shut down,
			module is not	restart, reset and
	Ston	Strip-pick	connected;	check whether the
0x0703	Stop	module	2. The	fault is cleared.
0x0703	level	command times	communication line	2. If the fault is not
		out	of the strip-pick	eliminated, please
			module is	contact the after-
			disconnected.	sales personnel.
			1. The strip-pick	1. Shut down,
			module is not	restart, reset and
		Strip-transfer	connected;	check whether the
0x0704	Stop	module	2. The	fault is cleared.
000704	level	command times	communication line	2. If the fault is not
		out.	of the strip-transport	eliminated, please
			module is	contact the after-
			disconnected.	sales personnel.
			1. The test plate	1. Shut down,
			module is not	restart, reset and
		Test board	connected;	check whether the
0x0705	Stop level		2. The	fault is cleared.
0x0705		command times	communication line	2. If the fault is not
		out.	of the test plate	eliminated, please
			module is	contact the after-
			disconnected.	sales personnel.
			1. The	
			physicochemical	1. Shut down,
			module is not	restart, reset and
		Physicochemical	connected;	check whether the
0x0707	Stop	module	2. The	fault is cleared.
UXUTUT	level	command times	communication line	2. If the fault is not
		out	of the	eliminated, please
			physicochemical	contact the after-
			module is	sales personnel.
			disconnected.	

Error code	Error type	Error information	Possible causes	Solutions
0x0708	Stop level	Conductivity plate command timeout	1.Conductivity module not connected. 2.Communication circuit of conductivity module disconnected.	 Shut down, restart, reset and check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.
0x0802	Stop level	Focus motor does not leave from the zero position optocoupler	1.Focus motor drive chip damaged. 2.Focus motor optocoupler damaged. 3.Focus motor lost step.	 Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.
0x0803	Stop level	Focus motor does not reach zero position optocoupler	1.Focus motor drive chip damaged. 2.Focus motor optocoupler damaged. 3.Focus motor lost step.	 Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.
0x0A01	Stop level	Abnormal color light source	The color acquisition parameter is abnormal.	1. Reset to check whether the fault is cleared. 2. Re-prime the fluidics, reset and check whether the fault is cleared. 3. If the fault is not eliminated, please contact the aftersales personnel.

Error code	Error type	Error information	Possible causes	Solutions
0x0A02	Stop level	Specific gravity light source abnormal	The specific gravity acquisition parameter is abnormal.	1. Reset to check whether the fault is cleared. 2. Re-prime the fluidics, reset and check whether the fault is cleared. 3. If the fault is not eliminated, please contact the aftersales personnel.
0x0A03	Stop level	Turbidity light source abnormal	The turbidity acquisition parameter is abnormal.	1. Reset to check whether the fault is cleared. 2. Re-prime the fluidics, reset and check whether the fault is cleared. 3. If the fault is not eliminated, please contact the aftersales personnel.
0x0B01	Stop level	Conductivity self-check failed	The acquisition parameter of conductivity is abnormal.	1. Reset to check whether the fault is cleared. 2. Re-prime the fluidics, reset and check whether the fault is cleared. 3. If the fault is not eliminated, please contact the aftersales personnel.

Error code	Error type	Error information	Possible causes	Solutions
0xF001	Stop level	Grayscale adjustment failed	1.Camera failure 2.Camera not triggered 3.Camera network cable failure	 Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.
0xF002	Stop level	Waiting for an image times out prevents analysis of the current sample	1.Camera failure 2.Camera not triggered 3.Camera network cable failure	1. Check whether the network connection cable connecting the instrument to the computer is normal. 2. Check the computer system is infected with viruses and remove them. 3. Restart the computer and the instrument, if the fault is not eliminated, please contact the aftersales personnel.
0xF003	Stop level	Sample rack push times out	 Abnormal disconnection of serial port The instrument does not respond to the command Sample tray failure 	 Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.

Error code	Error type	Error information	Possible causes	Solutions
0xF004	Stop level	Reset instrument times out Mismatch between the tube rack No. of dry chemistry end and morphological end of the sample	1. Abnormal disconnection of serial port 2. The instrument sample tray and other units are not connected normally 1. Dry chemistry test device or morphology test device didn't recognize the tube number and rack number correctly. 2. After scanning of tube number and rack number by the dry chemistry device, the tube or rack positions are changed.	1. Reset to check whether the fault is cleared. 2. If the fault is not eliminated, please contact the aftersales personnel. 1. Reset to check whether the fault is cleared. 2. If the fault is not eliminated, please contact the aftersales personnel.
0xF006	Stop level	Sample rack push times out	1.Abnormal disconnection of serial port 2.Accidental disconnection of sample tray	 Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.

Error code	Error type	Error information	Possible causes	Solutions
0xF007	Stop	Failed to read or set slave computer parameters	1.Abnormal disconnection of serial port 2.Device didn't respond to the command.	 Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.
0xF008	Stop level	Sample tray reset times out	1.Abnormal disconnection of serial port 2.Device didn't respond to the command.	 Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.
0xF009	Prompt level	Device temp. is too low	1.Device temperature too low 2.Temperature sensor failure	1. Check whether the ambient temperature is in the working range. 2. Check whether the temperature displayed by the instrument matches with the ambient temperature. 3. Reset, if the fault is not eliminated, please contact the after-sales personnel.

Error code	Error type	Error information	Possible causes	Solutions
0xF010	Prompt	Device temp. is too high	1.Device temperature too high 2.Temperature sensor failure	1. Check whether the ambient temperature is in the working range. 2. Check whether the temperature displayed by the instrument matches with the ambient temperature. 3. Reset, if the fault is not eliminated, please contact the after-sales personnel.
0xF011	Prompt level	Mismatch between tube No. and rack No.	1.Dry chemistry test device or morphology test device didn't recognize the tube number and rack number correctly. 2.After scanning of tube number and rack number by the dry chemistry device, the tube or rack positions are changed.	 Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.

Error code	Error type	Error information	Possible causes	Solutions
0xF012	Stop	No physicochemical unit is detected	1. Abnormal disconnection of serial port 2. The instrument does not respond to the command 3. Whether there is any setup error in the corresponding unit of the software	 Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.
0xF013	Stop level	No conductivity unit detected	1. Abnormal disconnection of serial port 2. The instrument does not respond to the command 3. Whether there is any setup error in the corresponding unit of the software	 Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.
0xF014	Stop level	Sheath fluid replenish is exhausted, please replenish	Sheath times have been used up	Replenish sheath fluid
0xF015	Stop level	Physiochemical light tracing failed	 Abnormal light tracing parameter Physicochemical unit module failure 	 Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.

Error code	Error type	Error information	Possible causes	Solutions
0xF016	Stop level	Dry chemistry light tracing failed	 Abnormal light tracing parameter Physicochemical unit module failure 	 Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.
0xF017	Prompt level	Number of received image is 0	1. Camera failure or camera power failure 2. The camera is not triggered to take pictures 3. Camera network cable failure 4. Accidental damage of camera driver	 Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.
0x010B	Stop level	Master control abnormal and power off	1.The operator turned off the power by mistake. 2.MAINS supply power off.	 Reset to check whether the fault is cleared. If the fault is not eliminated, please contact the after- sales personnel.

Error code	Error type	Error information	Possible causes	Solutions
0xF018	Stop level	Morphology calibration failed	1. The network cable connecting the instrument and the computer is loosened or disconnected. 2. The calibrator is not shaken for mixing before calibration. 3. Calibrator expired. 4. No focusing performed before calibration.	1. Check if the network cable connection is reliable. 2. Check if the calibrator is well mixed or expired. 3. Calibrate again after reset, if the fault is not eliminated, please contact the after-sales personnel.
0xF019	Stop level	Focusing failed	1. The network cable connecting the instrument and the computer is loosened or disconnected. 2. The focusing fluid is not shaken for mixing before focusing. 3. Focusing fluid expired.	1. Check if the network cable connection is reliable. 2. Check if the focusing fluid is well mixed or expired. 3. Focus again after reset, if the fault is not eliminated, please contact the after-sales personnel.

Error code	Error type	Error information	Possible causes	Solutions
0xF020	Stop level	Morphology QC failed	 The network cable connecting the instrument and the computer is loosened or disconnected. The control is not shaken for mixing before QC. Control expired. 	 Check if the network cable connection is reliable. Check if the control is well mixed or expired. Perform QC again after reset, if the fault is not eliminated, please contact the after-sales personnel.
0xF021	Stop level	Conductivity calibration failed	 Calibrators are placed in wrong order. The calibrator is not shaken for mixing before calibration. Calibrator expired. 	 Check if the calibrators are placed in wrong order. Check if the calibrator is well mixed or expired. Calibrate again after reset, if the fault is not eliminated, please contact the after-sales personnel.

Error code	Error type	Error information	Possible causes	Solutions
0xF022	Stop level	Conductivity QC failed	 Controls are placed in wrong order. The control is not shaken for mixing before calibration. Control expired. 	 Check if the controls are placed in wrong order. Check if the control is well mixed or expired. Perform QC again after reset, if the fault is not eliminated, please contact the after-sales personnel.
0xF023	Stop level	Dry chemical QC failed	 Controls are placed in wrong order. The control is not shaken for mixing before calibration. Control expired. 	 Check if the controls are placed in wrong order. Check if the control is well mixed or expired. Perform QC again after reset, if the fault is not eliminated, please contact the after-sales personnel.

Error code	Error type	Error information	Possible causes	Solutions
0xF024	Stop level	Standard strip test failed	1. The standard strip is stained or damaged.	 Check if standard strip is stained or damaged. Check if specified standard strip is used. Perform standard strip test again after reset, if the fault is not eliminated, please contact the after-sales personnel.

Appendix A Related information

The appendix mainly introduces the information related to the instrument, covering explanation of terms, parts list, information of supporting cables, etc.

A.1 Terms

Focusing: the process of making the captured scene clearly imaged on the sensor. It is also called focusing and imaging.

A.2 Accessory and reagent list

The accessories and the reagent used of the instrument are as follows:

Table A-1 Accessory list

No.	Accessory name
1	Computer
2	Handheld barcode scanner
3	Tube rack component
4	Standard strip component with assigned value
5	Plastic waste strip box
6	Power cord
7	Serial cable
8	Network cable
9	Door key
10	Printer (prepared by users)

Table A-2 List of miscellaneous materials

No	Name
1	Protective suit
2	Surgical mask
3	Disposable latex gloves
4	Protective glass
5	75% ethanol
6	Cotton swab
7	Medical gauze

No	Name			
Note: users shall prepare the materials above and the list may not be				
exhaustive.				

Table A-3 Reagent list

No.	Reagent name	
1	Urinalysis Strip (Dry Chemistry Method)	
2	Focusing Fluid	
3	Color Control	
4	US-Calibrator	
5	Sediment Control	
6	Conductivity Control	
7	Turbidity Control	
8	SG Control	
9	Turbidity Calibrator	
10	Conductivity Calibrator	
11	SG Calibrator	
12	UDC-Control	
13	Sheath Fluid	
14	Wash solution	
15	Urinalysis Diluent	
Note: for ordering of reagents, please contact Zybio or its local distributor.		

A.3 Cable information

The cable information of the instrument is as follows:

Table A-4 Cable information

Name	Cable length	Shielded or not
Power cord (AC 250V 10A)	1.5m	No
Liquid waste sensor	2.0m	Yes
connecting cable		
Sheath fluid sensor	1.5m	Yes
connecting cable	1.5111	
Serial port cable	1.5m	Yes
Network cable	1.5m	Yes

Name	Cable length	Shielded or not

Note: before using the unspecified accessories or cables, consult Zybio or its local distributor first. External items connected to the instrument shall not reduce the safety and performance of the instrument.

A.4 Training

Zybio will send its designated after-sales service personnel or its local distributor to provide field training for users to ensure correct use and performance of the instrument. For customer training, please contact the local distributor of Zybio.

Appendix B Literature

- 1. ISO 20916:2019 In vitro diagnostic medical devices Clinical performance studies using specimens from human subjects Good study practice.
- 2. EN ISO 18113-1:2011, In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 1: Terms, definitions and general requirements.
- 3. EN ISO 18113-3:2011, In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 3: In vitro diagnostic instruments for professional use.