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

Date: Feb 17 , 2023

Zybio Inc.

Digitally signed by Monastîrschii Viorica
Date: 2024.02.01 12:07:46 EET
Reason: MoldSign Signature
Location: Moldova

zybio

Qualified

TRAINING CERTIFICATE

CERTIFICATION

To

Vitalie Goreacii

From

Sanmedico

Accomplish the training on

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

During

January 19th, 2024.

Training contents:

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

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

Trainer: Perry Jiang

Date: 2024.01.20

Cert. Code: 20240120PJP01

Validity date (2 Years)

Zybio Inc.

Declaration of Conformity

No. ZYIN2022023

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

Manufacturer

Zybio Inc.

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

EC Representative

Lotus NL B.V.

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

Product Name:

See the attachment

Specification

See the attachment

Product Classification

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

Conformity Assessment Route

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

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

General applicable directive:

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

Standards Applied:

EN ISO 13485:2016	EN ISO 18113-1:2011	EN ISO 18113-2:2011
EN ISO 14971:2019	EN 13641:2002	EN ISO 15223-1:2016
EN ISO 17511:2003	EN 13612:2002	ISO 20916:2019
EN 62366-1:2015	EN ISO 23640:2015	

CE

Place	Chongqing, China
Date of Issue	2022.5.17.
Version	02
Signature:	Rui Shao.
Name	Rui Shao
Position	RA Manager

Attachment

No.	Product Name	Specification
1	Triglyceride (TG) Kit (Enzymatic Method)	R1 30 mL × 3, R2 7.5 mL × 3 R1 48 mL × 2, R2 12 mL × 2
2	Glucose (GLU) Kit (Hexokinase Method)	R1 30 mL × 1, R2 7.5 mL × 1 R1 30 mL × 3, R2 7.5 mL × 3 R1 48 mL × 2, R2 12 mL × 2
3	Total Cholesterol (CHOL) Kit (Enzymatic Method)	R1 30 mL × 3, R2 7.5 mL × 3 R1 48 mL × 2, R2 12 mL × 2
4	Lactate Dehydrogenase (LDH) Kit (Rate Method)	R1 30 mL × 3, R2 7.5 mL × 3 R1 48 mL × 2, R2 12 mL × 2
5	Uric Acid (UA) Kit (Uricase Method)	R1 30 mL × 3, R2 7.5 mL × 3 R1 48 mL × 2, R2 12 mL × 2
6	Urea (UREA) Kit (Urease-GLDH Method)	R1 30 mL × 3, R2 7.5 mL × 3 R1 48 mL × 2, R2 12 mL × 2
7	Aspartate Aminotransferase (AST) Kit (Enzymatic Method)	R1 30 mL × 3, R2 7.5 mL × 3 R1 48 mL × 2, R2 12 mL × 2
8	Alanine Aminotransferase (ALT) Kit (Enzymatic Method)	R1 30 mL × 3, R2 7.5 mL × 3 R1 48 mL × 2, R2 12 mL × 2
9	Total Bilirubin (TBIL) Kit (Vanadate Oxidation Method)	R1 30 mL × 3, R2 7.5 mL × 3 R1 48 mL × 2, R2 12 mL × 2
10	Direct Bilirubin (DBIL) Kit (Vanadate Oxidation Method)	R1 30 mL × 3, R2 7.5 mL × 3 R1 48 mL × 2, R2 12 mL × 2
11	High Density Lipoprotein Cholesterol (HDL-C) Kit (Enzymatic 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 × 2, R2 15 mL × 2, Calibrator 1 Level × 1.0 mL × 1, Control 2 Levels × 1.0 mL × 1

12	Low Density Lipoprotein Cholesterol (LDL-C) Kit (Enzymatic 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 × 2, R2 15 mL × 2, Calibrator 1 Level × 1.0 mL × 1, Control 2 Levels × 1.0 mL × 1
13	Albumin (ALB) Kit (Bromocresol Green Method)	R 30 mL × 6 R 60 mL × 2
14	Alkaline Phosphatase (ALP) Kit (Enzymatic Method)	R1 30 mL × 3, R2 7.5 mL × 3 R1 48 mL × 2, R2 12 mL × 2
15	Total Protein (TP) Kit (Biuret Method)	R 30 mL × 6 R 60 mL × 2
16	Gamma-Glutamyl Transferase (GGT) Kit (Enzymatic Method)	R1 30 mL × 3, R2 7.5 mL × 3 R1 48 mL × 2, R2 12 mL × 2
17	Glycated Hemoglobin A1c (HbA1c) Kit (Immunoturbidimetric Method)	R1 15 mL × 2, R2 10 mL × 1, Lyse 50 mL × 2, Calibrator 5 Levels × 1.0 mL × 1, Control 2 Levels × 1.0 mL × 1 R1 15 mL × 2, R2 10 mL × 1, Lyse 50 mL × 2, Calibrator 5 Levels × 1.0 mL × 1, Control 2 Levels × 1.0 mL × 1
18	Magnesium (Mg) Kit (Xylidyl Blue Method)	R 30 mL × 6 R 60 mL × 2 R 30 mL × 6, Calibrator 1 Level × 1.0 mL × 1 R 60 mL × 2, Calibrator 1 Level × 1.0 mL × 1
19	Lipase (LPS) Kit (Colorimetric 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 × 2, R2 15 mL × 2, Calibrator 1 Level × 1.0 mL × 1, Control 2 Levels × 1.0 mL × 1
20	Calcium (Ca) Kit (Arsenazo III Method)	R 30 mL × 6 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 × 2, R2 15 mL × 2, Calibrator 1 Level × 1.0 mL × 1, Control 2 Levels × 1.0 mL × 1
22	Myoglobin (MYO) Kit (Latex Enhanced Immunoturbidimetric Method)	R1 30 mL × 3, R2 10 mL × 3, Calibrator 5 Levels × 0.6 mL × 1, Control 2 Levels × 0.6 mL × 1 R1 45 mL × 2, R2 15 mL × 2, Calibrator 5 Levels × 0.6 mL × 1, Control 2 Levels × 0.6 mL × 1
23	N-acetyl-β-D-glucosaminidase (NAG) Kit (Rate Method)	R1 30 mL × 3, R2 7.5 mL × 3, Calibrator 2 Levels × 1.0 mL × 1, Control 2 Levels × 1.0 mL × 1 R1 48 mL × 2, R2 12 mL × 2, Calibrator 2 Levels × 1.0 mL × 1, Control 2 Levels × 1.0 mL × 1
24	Prealbumin (PA) Kit (Immunoturbidimetric Method)	R1 30 mL × 3, R2 7.5 mL × 3, Calibrator 4 Levels × 0.6 mL × 1 R1 48 mL × 2, R2 12 mL × 2, Calibrator 4 Levels × 0.6 mL × 1
25	Anti-Streptolysin O (ASO) Kit (Latex Enhanced Immunoturbidimetric Method)	R1 30 mL × 3, R2 7.5 mL × 3, Calibrator 5 Levels × 1.0 mL × 1, Control 2 Levels × 1.0 mL × 1 R1 48 mL × 2, R2 12 mL × 2, Calibrator 5 Levels × 1.0 mL × 1, Control 2 Levels × 1.0 mL × 1
26	Apolipoprotein A1 (Apo A1) Kit (Immunoturbidimetric Method)	R1 30 mL × 3, R2 7.5 mL × 3, Calibrator 4 Levels × 0.5 mL × 1 R1 48 mL × 2, R2 12 mL × 2, Calibrator 4 Levels × 0.5 mL × 1

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

34	Glutathione Reductase (GR) Kit (Rate Method)	R1 30 mL × 3, R2 6 mL × 3, Calibrator 1 Level × 0.5 mL × 1, Control 2 Levels × 0.5 mL × 1 R1 50 mL × 2, R2 10 mL × 2, Calibrator 1 Level × 0.5 mL × 1, Control 2 Levels × 0.5 mL × 1
35	High Sensitive C-Reactive Protein (hs-CRP) Kit (Immunoturbidimetric Method)	R1 30 mL × 3, R2 10 mL × 3, Calibrator 6 Levels × 0.6 mL × 1 R1 45 mL × 2, R2 15 mL × 2, Calibrator 6 Levels × 0.6 mL × 1
36	Homocysteine (HCY) Kit (Enzymatic Method)	R1 30 mL × 3, R2 8 mL × 3, Calibrator 5 Levels × 0.6 mL × 1, Control 2 Levels × 0.6 mL × 1 R1 15 mL × 3, R2 4 mL × 3, Calibrator 5 Levels × 0.6 mL × 1, Control 2 Levels × 0.6 mL × 1 R1 47 mL × 2, R2 13 mL × 2, Calibrator 5 Levels × 0.6 mL × 1, Control 2 Levels × 0.6 mL × 1
37	Immunoglobulin A (IgA) Kit (Immunoturbidimetric Method)	R1 30 mL × 3, R2 6 mL × 3, Calibrator 1 Level × 1.0 mL × 1 R1 50 mL × 2, R2 10 mL × 2, Calibrator 1 Level × 1.0 mL × 1
38	Immunoglobulin G (IgG) Kit (Immunoturbidimetric Method)	R1 30 mL × 3, R2 6 mL × 3, Calibrator 1 Level × 1.0 mL × 1 R1 50 mL × 2, R2 10 mL × 2, Calibrator 1 Level × 1.0 mL × 1
39	Immunoglobulin M (IgM) Kit (Immunoturbidimetric Method)	R1 30 mL × 3, R2 6 mL × 3, Calibrator 1 Level × 1.0 mL × 1 R1 50 mL × 2, R2 10 mL × 2, Calibrator 1 Level × 1.0 mL × 1

40	Inorganic Phosphorus (P) Kit (Direct UV Method)	R 30 mL × 6 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 × 2, R2 12 mL × 2, Calibrator 1 Level × 1.0 mL × 1, Control 2 Levels × 1.0 mL × 1
42	Lipoprotein (a) (Lp(a)) Kit (Immunoturbidimetric Method)	R1 30 mL × 3, R2 10 mL × 3, Calibrator 5 Levels × 0.6 mL × 1, Control 2 Levels × 0.6 mL × 1 R1 45 mL × 2, R2 15 mL × 2, Calibrator 5 Levels × 0.6 mL × 1, Control 2 Levels × 0.6 mL × 1
43	Microalbuminuria (mALB) Kit (Immunoturbidimetric Method)	R1 30 mL × 3, R2 7.5 mL × 3, Calibrator 6 Levels × 0.6 mL × 1, Control 2 Levels × 0.6 mL × 1 R1 48 mL × 2, R2 12 mL × 2, Calibrator 6 Levels × 0.6 mL × 1, Control 2 Levels × 0.6 mL × 1
44	Serum Amyloid A (SAA) Kit (Latex Enhanced Immunoturbidimetric Method)	R1 30 mL × 3, R2 7.5 mL × 3, Calibrator 5 Levels × 0.6 mL × 1, Control 2 Levels × 0.6 mL × 1 R1 48 mL × 2, R2 12 mL × 2, Calibrator 5 Levels × 0.6 mL × 1, Control 2 Levels × 0.6 mL × 1
45	Sialic Acid (SA) Kit (Enzymatic 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 × 2, R2 15 mL × 2, Calibrator 1 Level × 1.0 mL × 1, Control 2 Levels × 1.0 mL × 1
46	Total Bile Acids (TBA) Kit (Enzymatic Cycling Method)	R1 30 mL × 3, R2 7.5 mL × 3 R1 48 mL × 2, R2 12 mL × 2
47	α-Amylase (α-AMY) Kit (E-pNP-G7 Method)	R1 30 mL × 3, R2 7.5 mL × 3 R1 48 mL × 2, R2 12 mL × 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 Immunoturbidimetric Method)	R1 30 mL × 3, R2 10 mL × 3, Calibrator 6 Levels × 0.6 mL × 1 R1 45 mL × 2, R2 15 mL × 2, Calibrator 6 Levels × 0.6 mL × 1
50	Immunoglobulin E (IgE) Kit (Latex Enhanced Immunoturbidimetric Method)	R1 16 mL × 3, R2 8 mL × 3, Calibrator 6 Levels × 0.6 mL × 1, Control 2 Levels × 0.6 mL × 1 R1 40 mL × 2, R2 20 mL × 2, Calibrator 6 Levels × 0.6 mL × 1, Control 2 Levels × 0.6 mL × 1
51	Rheumatoid Factor (RF) Kit (Latex Enhanced Immunoturbidimetric Method)	R1 30 mL × 3, R2 7.5 mL × 3, Calibrator 1 Level × 1.0 mL × 1 R1 48 mL × 2, R2 12 mL × 2,Calibrator 1 Level × 1.0 mL × 1
52	Glycated Albumin (GA) Kit (Enzymatic Method)	R1 16 mL × 1, R2 4 mL × 1, R3 20 mL × 1, Calibrator 2 Levels × 1.0 mL × 1,Control 2 Levels × 1.0 mL × 1 R1 48 mL × 1, R2 12 mL × 1, R3 60 mL × 1, Calibrator 2 Levels × 1.0 mL × 1, Control 2 Levels × 1.0 mL × 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

EU Declaration of Conformity

Manufacturer

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

Authorized Representative

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

Product Identification

Product Name:	Concentrated Detergent
REF:	042304002, 042304003
Basic UDI-DI:	69732628600070ZT
GMDN Code:	63377
GMDN Term:	Instrument/ analyser cleaning agent IVD
EMDN Code:	W01019001
Risk Class:	Class A (according to rule <5> of Annex VIII of *In vitro* Diagnostic Medical Device Regulation
Intended Purpose:	This product is used for cleaning of chemistry analyzer.

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	EN ISO 23640: 2015
EN ISO 14971: 2019	EN 62366-1: 2015	

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

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

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

Place	Chongqing, China
Signature	Rui Shao.
Name	Rui Shao
Position	PRRC on behalf of Zybio Inc.
Date of issue	2023. 9. 12.

EU Declaration of Conformity

Manufacturer

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

Authorized Representative

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

Product Identification

Product Name:	Probe Detergent
REF:	042304004, 042304005
Basic UDI-DI:	697326286000692D
GMDN Code:	63377
GMDN Term:	Instrument/ analyser cleaning agent IVD
EMDN Code:	W01019001
Risk Class:	Class A (according to rule <5> of Annex VIII of *In vitro* Diagnostic Medical Device Regulation
Intended Purpose:	This product is used for cleaning of chemistry analyzer.

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	EN ISO 23640: 2015
EN ISO 14971: 2019	EN 62366-1: 2015	

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

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

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

Place	Chongqing, China
Signature	Rui Shao.
Name	Rui Shao
Position	PRRC on behalf of Zybio Inc.
Date of issue	2023.9.12.

EU Declaration of Conformity

Manufacturer

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

Authorized Representative

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

Product Identification

Product Name:	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)
Intended Purpose:	The Chemistry Analyzer is an automated device for in vitro diagnostic use in 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:

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
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

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

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

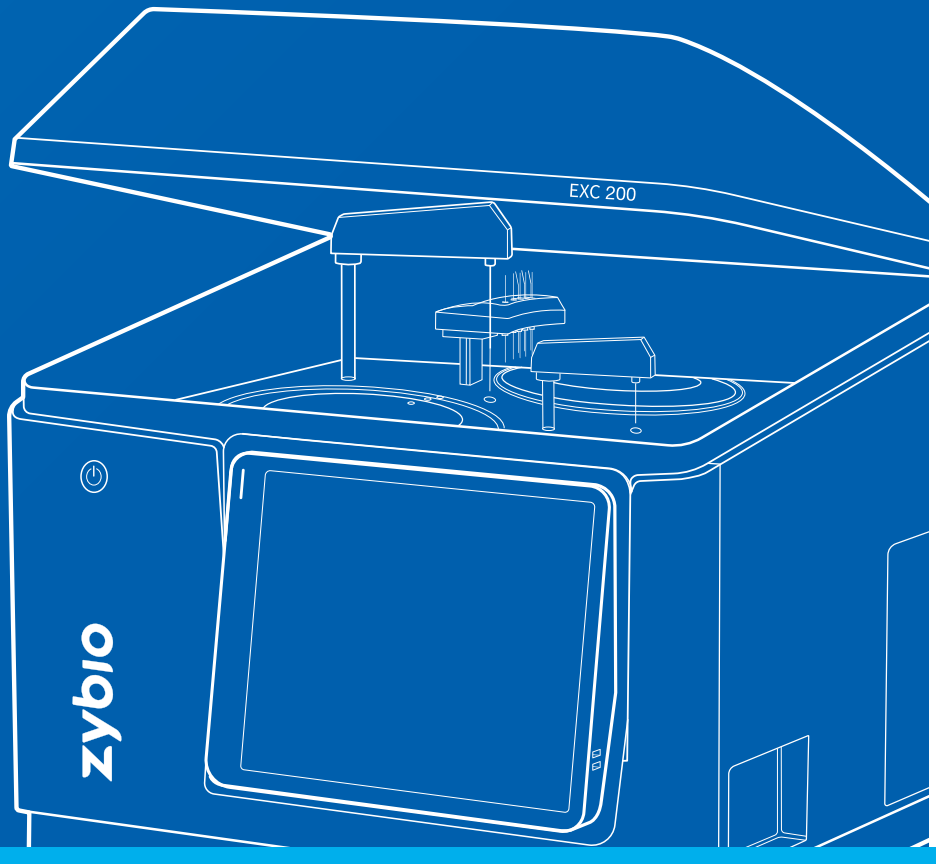
This declaration supersedes any declaration issued previously for the same product.

Place	Chongqing, China
Signature	Rui Shao
Name	Rui Shao
Position	PRRC
Date of Issue	Aug 19, 2022

zybio

EXC200/EXC220
Chemistry Analyzer

Operation Manual



Chemistry

www.zybio.com

EXC200/EXC220

Chemistry Analyzer

Operation Manual

This device bears the CE marking in accordance with the provisions of Regulation (EU) 2017/746 of the European Parliament and Directive of the Council of 5 April 2017 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 Regulation and EU Directive mentioned above.

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

The Chemistry Analyzer is for in vitro diagnostic use.

Fourth edition (March 2023)

Intellectual property rights statement

The instrument and its incorporated software described in the Operation Manual are for in vitro diagnostic use only. Zybio Inc. (hereinafter referred to as Zybio) owns the copyright over the instrument information, scheme descriptions, and relevant graphics (hereinafter referred to as Information) in this manual and the intellectual property rights over the instrument(s) herein. The Information may be used if:

- The copyright notice appears on all copies;
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All sample data in the manual (including but not limited to, the sample data in printouts, graphics, screens, etc.) are for reference only and shall not be used for clinical or maintenance evaluations. Data shown in printouts and screens do not reveal actual patient names or test results.

Labels depicted in the manual may appear different from actual labeling and are for reference only. Please take the actual labeling as the final.

Instrument users shall follow the operating instructions at any time. Zybio and its affiliates shall not be responsible for failures, errors, damages, losses, or other liabilities resulting from users’ noncompliance with the procedures and precautions given herein.

In the event that any user should make any oral, written or electronic response to Zybio (such as feedback, questions, comments, suggestions, ideas, etc.), such response and any information submitted therewith shall be considered non-confidential, and Zybio shall be free to reproduce, publish, or otherwise use such information for any purposes whatsoever including but not limited to, the research, development, manufacture, service, use, or sale of instruments incorporating such information.

Zybio is not engaged in providing medical advice or services.

Updates to the information may be provided in electronic form or paper. Always refer to the latest documents for the most current information.

Trademark statements

zybio,  and  are the registered trademark of Zybio Inc.

® and ™ are not specified in the manual.

Warranty statement

Zybio warrants the instrument against defects in materials and workmanship for a period of one year from the delivery date. If the instrument proves to be defective within the foregoing warranty period, Zybio, at its sole option, will repair, upgrade, replace the instrument or take other corrective measures.

The sales contract is your only warranty certificate and please keep it properly.

The free service is provided within the warranty period for the entire instrument, except for the consumables (Consumables refer to the disposable items that need to be replaced after each use or the fragile materials that need to be replaced regularly).

This warranty does not cover and is void with respect to the defects or malfunctions caused by:

- 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
- Force majeure, such as war, natural disaster, etc.

The limited warranty in this manual and the sales contract is the sole warranty provided by Zybio. No other warranties, express or implied, including warranties of merchantability or fitness for a particular purpose, are provided whatsoever.

In no event will Zybio be liable for any direct, indirect, consequential or incidental damages, including loss of profits and commercial opportunities, or for any claim by any third party, arising out of the use, the results of use or the inability to use this instrument.

If the warranty period and/or the warranty service described herein are conflict with the provisions of sales contract executed, the latter shall prevail.

For customer service, please contact:

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

Tel: +86 (0) 23 6895 9999

Fax: +86 (0) 23 6869 9779

Web: https: //www.zybio.com

E-mail: info@zybio.com

Revision history

Edition	Release date	Contents revised
01	August 26, 2022	First release
02	December 10, 2022	Revise details of the sample-reagent barcode scanner and related software operations.
03	December 20, 2022	Revise laser symbols and related information in the section “Safety precautions”.
04	March 6, 2023	Revise the Analyzer’s weight, EMC declaration, etc.

Contents

1 General

EXC200/EXC220 Chemistry Analyzer (hereinafter referred to as "Analyzer"), adopting spectrophotometry and used with supporting reagents, is designed for quantitative detection on human serum, plasma and urine, etc.

Note: when making a clinical determination according to test results, users should also refer to other clinical examination results or other test results.

The Manual aims to help users understand safety precautions, installation, structure, functions, analysis principles, operation procedures, maintenance and care, and alarm and troubleshooting of the Analyzer. To use the Analyzer correctly, read the Manual carefully and follow instructions in the Manual. Keep it properly for future reference after reading.

1.1 Basic information

This section introduces the basic information of the Analyzer.

Table 1-1 Basic information

Category	Content
Product name	Chemistry Analyzer
Model & REF No.	EXC200: REF 02-10-02-0002-00 EXC220: REF 02-10-02-0003-00
Structural composition	Consists of the reagent and sample handling unit, stirring unit, reaction unit, photoelectric detection unit, control and data processing unit as well as software.
Intended use	The Chemistry Analyzer is an automated device for in vitro diagnostic use in clinical laboratories. It is used for the quantitative detection of chemical components in serum, plasma, urine and other samples.
Intended user	The product should only be operated by professionals, doctors and laboratory personnel trained by Zybio or its agents.
Contraindication	None
Overvoltage category	II
Manufacturing 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
Authorised representative	Lotus NL B.V. Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Category	Content
Manufacturing date	Refer to the product nameplate.
Service life	10 years[1]

1.2 Model

The Analyzer has two models, i.e., EXC200, EXC220. The operation principles, main functions, composition, and key components of the two models are the same. The difference of the two models lies in wavelength channels, the minimum reaction volume and software model. See the table below.

Table 1-2 Difference of the two models

Analyzer models	Wavelength channels	Minimum reaction volume (μL)	Software models
EXC200	12	90	EXC200
EXC220	8	100	EXC220

1.3 About the Manual

The Manual consists of 8 chapters and 3 appendixes. The readers may refer to the relevant chapter for the information needed.

Table 1-3 About the Manual

Chapter	Content
1. General	Introduces the basic information, symbols, safety precautions, electromagnetic emission and immunity as well as residual risks of the Analyzer.
2. Installation	Introduces the installation requirements and precautions of the Analyzer.
3. Analyzer overview	Introduces the structural composition, appearance, parameters and performance, specification and configuration as well as the software interface of the Analyzer.
4. Working principle	Introduces measurement principles of the Analyzer, including analytical principles, calibration categories, measuring principles and prozone check.
5. Daily operation	Introduces basic operation methods and daily operation procedures of the Analyzer.
6. Software operation	Introduces operation procedures and precautions of the Analyzer software.

[1] This service life is determined by the lifespan test performed on the Analyzer. In the process of use, the user shall maintain and repair the Analyzer according to the requirements of the Manual. The product which retains basic safety and performance after maintenance or repair can be used normally.

Chapter	Content
7. Maintenance and care	Introduces maintenance methods of the Analyzer, including general maintenance orders and regular maintenance.
8. Alarm and error handling	Introduces information about alarm and error handling.
Appendix A Accessory list	Introduces the accessory list.
Appendix B Terms	Introduces definition of terms described in the Manual.
Appendix C Literature	Lists the literature referenced by the Manual.

1.4 Symbol

This section describes the symbols used in the Manual and on the Analyzer and its package.

Symbols used in the Manual are as follows:

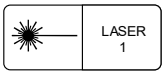
Table 1-4 Symbols used in the Manual

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

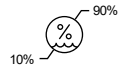
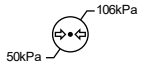
The warning labels and silk screen labels on the Analyzer are used to identify the instrument features and act as a reminder. And the labels related to instrument use are described as follows: Frequently examine the warning labels to ensure its cleaning and completeness. If the labels cannot be correctly identified and understood due to blurring or shedding, contact Zybio or its local distributor for replacement.

Table 1-5 Symbols on the Analyzer and the package

Symbol	Explanation
	Indicates the need for the user to consult the instructions for use for important cautionary information (white background).
	Indicates the need of taking care regarding the hazard specified by the supplementary sign; the user needs to consult the instructions for use (yellow background).
	Indicates the need of taking care to avoid coming into contact with electricity.

Symbol	Explanation
	Indicates that there are potential biological risks associated with the medical device, necessary to consult instructions for use for details.
	Indicates the need of taking care to avoid injury to hands when in the vicinity of equipment with closing mechanical parts.
	Outer circle: Red Indicates non-professional personnel shall not dismantle the instrument.
	Indicates the need of taking care when handling corrosive substances.
	Indicates the laser product emits laser beams of CLASS 2. Be cautious of laser radiation.
	Indicates the presence of the CLASS 2 laser radiation when open. Avoid exposure to the beam.
	Indicates that there is a Class 1 laser product, and laser radiation should be avoided.
	Indicates that the device is suitable for alternating current only.
IVD	Indicates the instrument that is intended to be used as an in vitro diagnostic medical device.
UDI	Indicates a carrier that contains unique device identifier information.
CE	Indicates CE marking of conformity.
RS232	Indicates the external communication port.
	Indicates the connecting terminals of the computer network.
ASW	Analysis section switch.
SN	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Indicates the date when the medical device was manufactured.
	Indicates the medical device manufacturer.

Symbol	Explanation
	Indicates the need for the user to consult the instructions for use.
	Indicates the authorized representative in the European Community.
	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Indicates connection to the mains.
	Indicates disconnection from the mains.
DW1	Purified water inlet
DW2	Purified water outlet
HW	High-concentration liquid waste outlet
LW	Low-concentration liquid waste outlet
CW	Concentrated wash buffer inlet
CL	Condensate water outlet
DW-D	Float senor for purified water
CW-D	Float senor for concentrated wash buffer
W-D	Float sensor for waste liquid
	Indicates the correct upright position of the distribution package for transport and/or storage.
	Indicates that distribution packages shall not be rolled or turned over.
	Indicates the maximum number of identical transport packages or items which may be stacked on the bottom package.
	Indicates that distribution packages shall be kept away from rain and be kept in dry conditions.
	Indicates that contents of the distribution package are fragile therefore it shall be handled with care.
	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.

Symbol	Explanation
	Indicates that distribution packages shall be stored, transported, and handled within temperature limits.
	Indicates that distribution packages shall be stored, transported, and handled within humidity limits.
	Indicates that distribution packages shall be stored, transported, and handled within atmospheric pressure limitation.

1.5 Safety precautions

To use the Analyzer safely and effectively, the user must observe the following warnings and precautions, otherwise there may be incorrect test results, analyzer damage, or personal injury, etc. caused.

Biological hazards

- The liquid wastes and the waste containers are very dangerous. The parts of the Analyzer, reagent-sample tray, reagents and reagent vials, and the surface of the Analyzer may be polluted by pathogens. Please wear a pair of latex gloves before touching them to prevent cross infection.
- If you accidently touch the polluted parts or surface of the Analyzer, immediately rinse the affected part with plenty of clean water and disinfect yourself according to the requirements of your lab or hospital.
- Wear a pair of latex gloves and other necessary protective equipment before handling the samples to prevent cross infection. If the sample comes into your eyes or wounds, immediately rinse the affected part with plenty of clean water and consult a physician.
- Dispose of the reagents, liquid waste, waste samples, consumables, exhaust of hazardous substances, etc. according to the local regulations.
- The controls and calibrators, etc. may be potentially infective. Wear a pair of latex gloves and other necessary protective equipment before handling them to prevent cross infection. If the control or calibrator, etc. comes into your eyes or wounds, immediately rinse the affected part with plenty of clean water and consult a physician.
- Exercise great care when handling the liquid waste. If it spills onto your body or clothes, please disinfect yourself and the clothes strictly.
- Dispose of the used consumables properly to prevent micro-organism breeding and cross infection.
- Do not use broken containers to prevent cross infection.
- Disinfect yourself according to the requirements of your lab or hospital after using the Analyzer to prevent cross infection.

General safety information

Warning

- The Analyzer can only be used by medical laboratory professionals, doctors, and laboratory technicians trained by Zybio or its authorized local distributor.
- Install the Analyzer in the environment specified in the Manual, otherwise unreliable result or damage to the Analyzer may occur.
- Operate the Analyzer pursuant to the Instructions in the Manual. Improper use may result in incorrect test results, and even system damage or personal injury.
- Before using the Analyzer for the first time, users are suggested to perform calibration and quality control to confirm the Analyzer can work normally.
- For daily use of the Analyzer, users are suggested to perform quality control to ensure the reliability of test results.
- Before starting a sample test, get the reaction tray cover and the sample-reagent tray cover well closed.
- Do not open the reaction tray cover during test.
- During a sample test, make sure there are not any obstacles in the movement path of the probes and stirring rod.
- Do not touch the reaction tray and the sample-reagent tray when they are moving.
- Do not install any software and hardware not specified by Zybio, otherwise normal operation of the Analyzer may be affected. Do not run other software while the Analyzer is working.
- In case of any serious incidents related to the Analyzer when it is running, users should report them to the manufacturer and the competent authority of the Member State which the users and/or patients are from.
- Do not use the Analyzer for other purposes. Improper use may pose a risk of virus attack. The computer virus may be transmitted through USB, programs, or Internet, etc.
- Users are recommended to stop using the Analyzer when it is at the end of its service life.
- Some substances of the discarded analyzer are subject to the pollution control regulations. Follow the local regulations to handle the discarded analyzer.

Caution

- Before a test, carefully check the joints of each pipe for any liquid leakage, which will lead to inaccurate suction and discharge capacity.
- Do not place any reagent or sample on the platform of the Analyzer to avoid spilling or leakage of liquid.
- Carefully check reagents and samples. There should be no insoluble float, e.g. cellulose, fibrin, etc. which may cause blockage of the reagent-sample probes.
- The Analyzer uses the UV-vis plastic cup (hereinafter referred to as cuvette or plastic cup). Use the cuvette specified by Zybio, otherwise undesirable results may occur.
- The water quality shall meet the Type II grade defined by ISO 3696, otherwise the valves and pumps may be damaged or cannot be cleaned completely.

Note

- The Analyzer automatically backs up data to the hard disk drive. The data will be lost if data in the drive is deleted or the drive is damaged. Users are recommended to periodically back up the analysis data and analysis parameters to other mobile storage devices.
- Incorrect analysis parameters will lead to wrong test results. In this case, contact Zybio or its local distributor.
- Zybio will send its designated after-sales service personnel or its local distributor to provide field training for users to ensure correct use performance of the Analyzer.

Analyzer maintenance

Warning

- Perform system maintenance as instructed in the Manual. Improper maintenance may result in incorrect analysis results, and even system damage or personal injury.
- After major components such as the light source lamp, reagent probe, or syringe piston are replaced, perform calibration analysis.
- When the Analyzer does not work due to faults or other causes and needs to be repaired, contact Zybio or its local distributor. And:
    - Take other measures such as using another instrument or method to complete the test in order not to delay the test results.
    - Take out the reagent from the Analyzer and store it according to the instructions for use of the reagent. For example, store it in the refrigerator to prevent it from deteriorating.

Sample

Warning

- Use the serum sample separated completely and the urine sample without floats. Fibrin in the serum sample or floats in the urine sample may get the reagent-sample probe blocked, which may affect analysis results.
- The drugs, anticoagulants, and preservatives in the sample may affect some analysis results.
- Lipid blood, jaundice and hemolysis in the sample may affect the analysis results, so blank sample analysis is recommended.
- Store the sample correctly. Improper sample storage may change the constituents of sample, which may cause an inaccurate analysis result.
- Do not leave the sample open for a long time to prevent sample volatilization, otherwise the accuracy of the analysis results may be affected.
- A certain amount of sample is required when the Analyzer performs analysis; When sampling, please take appropriate amount of sample according to the instructions for use of the reagents and this Manual.
- Before analysis, ensure that the sample is placed correctly; otherwise, the test results

may be incorrect.

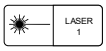
Reagent, calibrator and control

Warning

- When operating the Analyzer for analysis, use matched reagents, calibrators and controls (Note: Users can select reagents, calibrators and controls of Zybio or from other manufacturers. And for ordering them, users can contact Zybio or its local distributor).
- Use the reagent that can be applicable to the Analyzer. If you cannot determine whether the reagent is usable, consult the manufacturer or its distributor of reagents and Zybio or its distributor.
- For use and storage of reagents, calibrators, and controls, refer to the instruction for use provided by the reagent manufacturer or distributor.
- Improper storage of reagents, calibrators and controls (even if they are within shelf life) may result in inaccurate test results.
- After reagent replacement, please do calibration and QC analysis. If calibration and quality control analysis are not performed, the accurate analysis result may be unavailable.
- During analysis, cross contamination of the reagents may impact the analysis results. For the information about cross contamination of reagents, contact the reagent manufacturer or distributor.
- Before analysis, ensure that the sample is placed correctly; otherwise, the test result may be incorrect.

Laser safety

Warning

- According to IEC 60825-1:2014, the Analyzer is a Class 1 laser product, and the optional built-in barcode scanner in the Analyzer is a Class 2 laser product used to scan sample and reagent barcodes. Only professionals from Zybio or its local distributor can assemble or dismantle the Analyzer, otherwise there is a risk of uncontrolled laser radiation leakage.
-  is pasted near the built-in scanner,  is on the Analyzer platform near the scanner, and 

is on the back of the Analyzer.
- When installing, debugging and maintaining the Analyzer, carefully read the warning information on the Analyzer to prevent potential harmful laser radiation.
- It is important to prevent laser rays or reflected laser rays! Long-term direct exposure to laser radiation can cause retinal injury.

1.6 EMC declaration

The Analyzer complies with the emission and immunity requirements described in IEC 613262-6:2020 Electrical equipment for measurement, control and laboratory use - EMC

requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment and IEC 61326-1:2020 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements.

The Analyzer has been designed and tested to CISPR 11 Class A. The calculation formula to determine the separation distance between the Analyzer and a mobile phone is given by $d=6/E\sqrt{p}$, where d is the minimum separation distance in metres, P is the maximum power in watts, and E is the immunity test level in V/m.

Warning

- This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.
- This equipment is designed for use in a PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT. It is likely to perform incorrectly if used in a HOME HEALTHCARE ENVIRONMENT. If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the equipment and the source of the interference.
- It is the user' s responsibility to ensure that a compatible electromagnetic environment for the Analyzer can be maintained in order that the device will perform as intended. The electromagnetic environment should be evaluated prior to operation of the Analyzer.
- Do not use the Analyzer near sources of strong electromagnetic radiation, as these may interfere with the proper operation.

1.7 Residual risk

The Analyzer is a dedicated medical device, and its functionality requires correct operation of hardware and software components, as well as appropriate operating conditions.

A safe and effective operation of the Analyzer requires that the users have undergone necessary training, especially on the intended purpose of the Analyzer and the safety precautions on the usage.

According to the criteria for risk acceptability of overall residual risk, the overall residual risk is acceptable.

- The benefit related to the intended use outweighs overall residual risks;
- The clinical performance of the device reaches the average performance of similar devices on the market;
- The experts with clinical and application experience take part in the evaluation on benefit and overall residual risks;
- The results of further investigation into the cause of the risk or the interdependence of applied risk control measures are acceptable.

2 Installation

This chapter introduces the installation requirements and precautions of the Analyzer. Follow the instructions below to install the Analyzer.

2.1 Transportation and storage requirements

The packaged Analyzer shall be transported according to the requirements stipulated in the contract and shall be protected from severe shock, vibration, and rain and snow spray and splashes as well as sun exposure during transportation.

The packaged Analyzer shall be stored in a clean and well-ventilated room that meets the following ambient temperature and humidity requirements and is free from corrosive gases.

Table 2-1 Transportation and storage environment

Ambient temperature	Relative humidity	Atmospheric pressure
– 20℃ - 55℃	10% - 90%	50 kPa - 106 kPa

2.2 Handling requirements

When the Analyzer can run correctly after installation, do not move the Analyzer to avoid vibration-causing damage to the precision components and vulnerable parts which may influence the correct running of the Analyzer. Only Zybio or its local distributor can pack and unpack, and relocate the Analyzer. If relocation of the Analyzer is required, contact Zybio or its local distributor.

Warning

- If the Analyzer is unpacked or installed by the personnel not authorized or trained by Zybio, personnel injury or damage to the Analyzer damage may be caused. Do not unpack or install the Analyzer in absence of authorized personnel of Zybio or its local distributor.
- Always disconnect the power supply at first before removal of the Analyzer, and contact Zybio or its local distributor for service.

2.3 Package check

The Analyzer has been carefully tested and well packed before delivery. Check the package upon your acceptance of the Analyzer. And check if the Analyzer is subject to the following:

- Inversion or deformation of the outer package;
- Obvious water stains on the outer package;
- Obvious signs of bumping on the outer package;

- Signs of unpacking on the outer package.

Once the above-mentioned damage is found, inform Zybio or its local distributor immediately. If the outer packaging is intact, unpack and examine the package contents in the presence of the personnel from Zybio or its local distributor.

- Check if all parts are delivered according to the packing list in the package box;
- Carefully check if there are cracks, crashes or deformation on analyzer appearance.

In event of transportation damage or incomplete configuration, inform Zybio or its local distributor immediately.

2.4 Installer

The Analyzer shall be installed by Zybio or its local distributor only. Users shall provide the appropriate environment and space for installation. Zybio shall not be liable for instrument failure or personal injury caused by unauthorized installation of the Analyzer.

Upon receiving the Analyzer, contact Zybio or its local distributor.

2.5 Installation requirements

This section introduces requirements for space, power supply, environment, and water supply and discharge.

2.5.1 Space requirements

To provide a space for repair and maintenance, the followings shall be satisfied for installing the Analyzer:

- The table surface shall be flat (gradient less than 1/200);
- The surface is capable of supporting at least 320kg;
- Place the Analyzer with the left, right, back and front not closer than 50 cm to the wall;
- The distance from the Analyzer to the sewage outlet shall not be shorter than 200 cm.

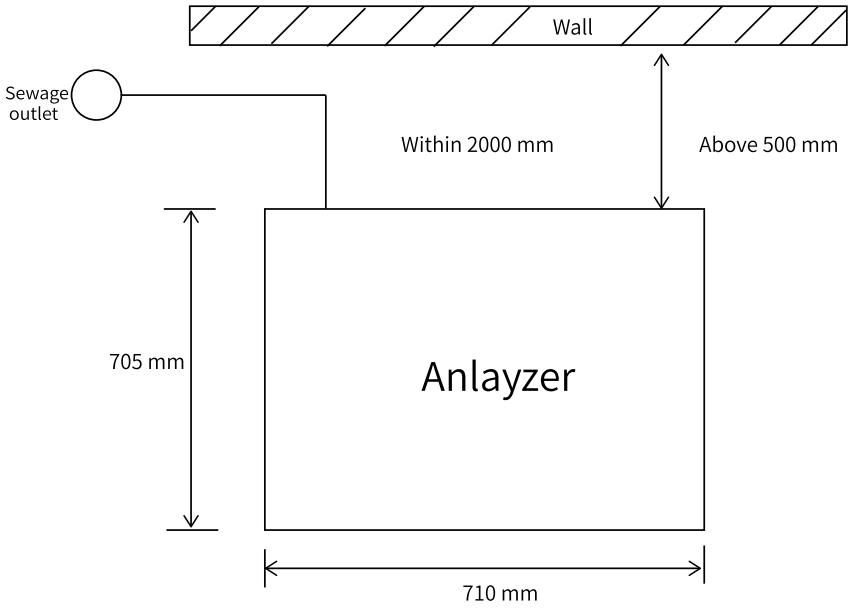


Figure 2-1 Space requirements

2.5.2 Power requirements

The power supply connected to the Analyzer shall meet the requirements below:

- Power Voltage: 100-240V~;
- Power Frequency: 50/60Hz;
- Input power: ⩽500VA.

Warning

- Make sure the power supply socket is correctly grounded. Incorrect grounding may cause electric shock and damage to the Analyzer. Ensure the output voltage of power socket meets the requirements;
- The power supply shall be correctly grounded, otherwise electric shock may occur;
- The impedance between the protective earthing and each accessible part of the instrument shall be lower than 0.1Ω; otherwise, unstable analysis result, electric leakage of the housing, and electric shock may occur due to poor grounding.

2.5.3 Environment requirements

The environment for the Analyzer installation shall meet the requirements below.

Table 2-2 Working environment

Ambient temperature	Relative humidity	Atmospheric pressure	Altitude
10℃-30℃	30% - 85%, no condensation	70.0kPa~106.0kPa	Below 3000 m

- Rated pollution degree: 2;
- For indoor installation use only;
- The table surface is not subject to vibration;
- The environment is in good ventilation and free from dust;
- Avoid direct sunlight and placing the Analyzer near the heat or wind source;
- The site shall be free from corrosive or flammable gases;
- No significant noise source and power interference;
- Do not place the Analyzer near the brush-type engine and the electrical contacts that are frequently switched on and off;
- Do not place the Analyzer near devices that generate electromagnetic waves, for example, mobile phones, radio transceivers, etc.

Caution

Operate the Analyzer in a specified condition and humidity, otherwise the test results may be unreliable. If the ambient temperature and humidity exceed the specified range, use air-conditioning equipment.

2.5.4 Water supply and drainage requirements

The following the requirements for water supply and drainage shall be met.

- Water quality must meet requirements specified in ISO3696 Class II Standard;
- Water supply volume: at least 50 L/h;
- The distance between the water supply apparatus and the Analyzer inlet shall be no more than 10 meters;
- Connection to liquid waste container: The container is placed at the same level of or below the Analyzer, and the container mouth is lower than the liquid waste outlet at the rear panel of the Analyzer;
- Connection to sewer: The distance of waste liquid outlet from the ground cannot be over 12 cm;
- The length of the waste liquid tube shall not be more than 2 meters.

Caution

Water quality must meet water supply requirements. If not, water purity may influence test results.

Wear gloves, masks and protective clothes during operation to prevent infection. Besides, wear safety goggles, if needed.

After installation of the Analyzer, correctly connect the fluid tubes according to the figure below:

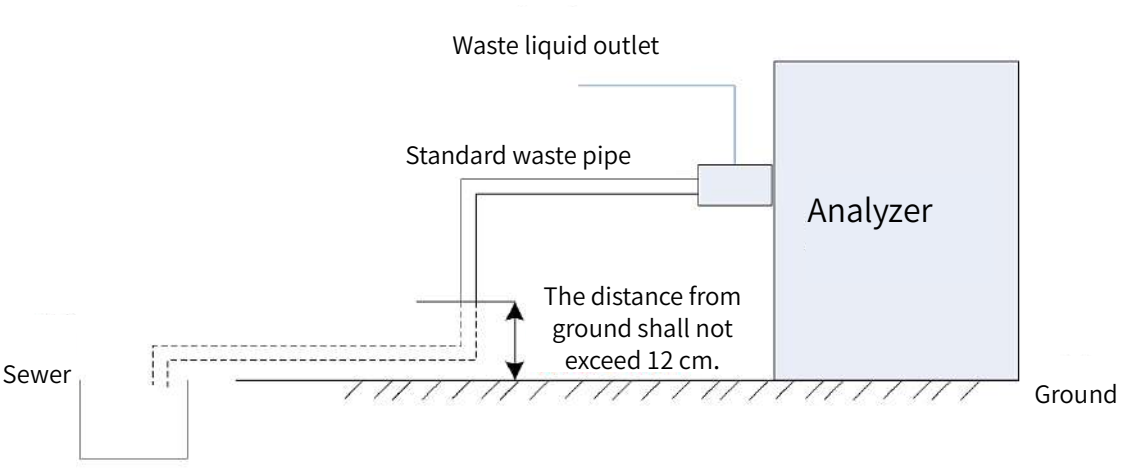


Figure 2-2 Fluid tube connection requirements

Dispose of the liquid waste according to the local regulations.

Note

When connecting drainage tubes, be careful not to fold or flatten the tube.

The waste liquid, mainly containing blood, shall be treated and discharged according to the discharge standard for biological risks.

3 Analyzer overview

This chapter introduces the structural composition, appearance, parameters and performance, specification and configuration as well as the software interface of the Analyzer. The illustrations below may be inconsistent with the real Analyzer due to the differences in product types, software versions, etc.

3.1 Analyzer appearance

This section, with the EXC200 as the example, demonstrates the appearance of the Analyzer.

3.1.1 Front view

This section introduces structures and important parts of the front of the Analyzer. See the figure below for the front view:

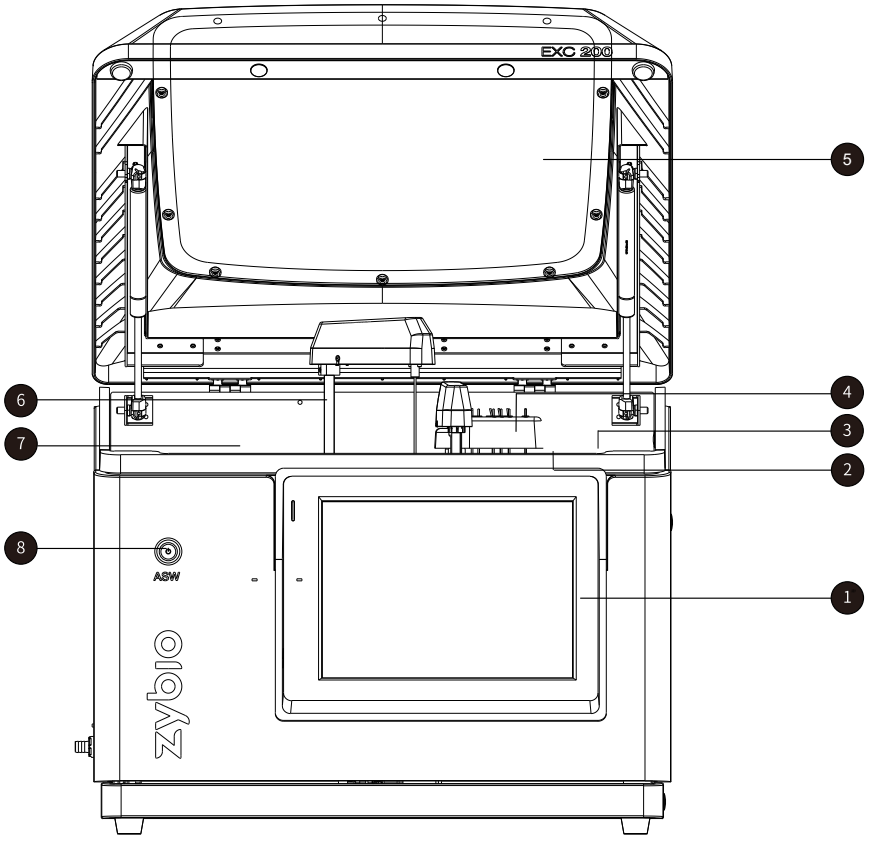


Figure 3-1 front view

No.	Name	Description
①	Touch screen	Control operation of the Analyzer.
②	Stirring rod	Stir the mixed reaction liquid in the cuvette.

No.	Name	Description
③	Reaction tray	Place the cuvette and make colorimetric measurement.
④	Automatic cleaning structure	Clean the cuvette.
⑤	Top cover	/
⑥	Reagent-sample probe	Aspirate samples from the sample tube, or aspirate R1/R2 reagents and discharge them to the cuvette.
⑦	Reagent-sample tray	Rotate sample tubes and reagent vials to the corresponding sample and reagent aspiration positions.
⑧	Analysis section switch	Indicates the analysis section switch of the Analyzer.

3.1.2 Back view

This section introduces structures and important parts at the back of the Analyzer. See the figure below for the back view:

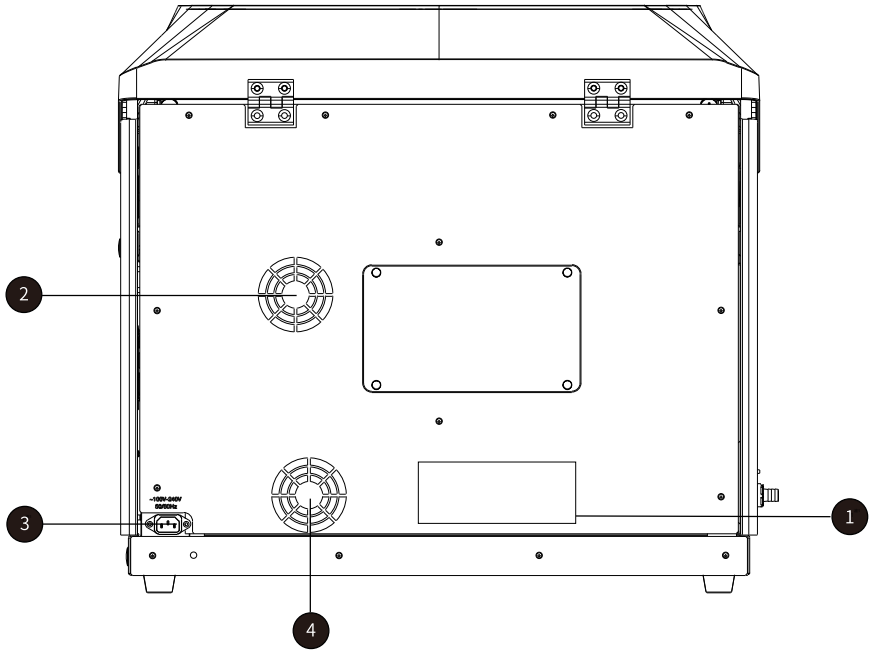


Figure 3-2 Back view

No.	Name	Description
①	Air inlet	For air exchange of the Analyzer.
②	Fan	For heat dissipation of the Analyzer.
③	Power supply socket	For connecting the power supply cable.
④	Fan	For heat dissipation of the Analyzer.

3.1.3 Left view

This section introduces structures and important parts on the left side of the Analyzer. See the figure below for the left view:

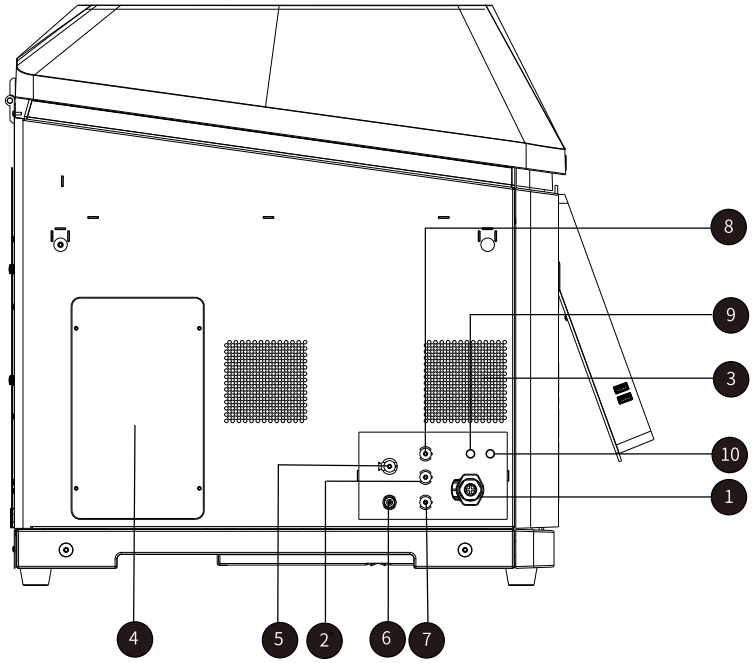


Figure 3-3 Left view

No.	Name	Description
①	Liquid waste tube port 2	For connecting to a liquid waste tube
②	Purified water port 2	For connecting to a purified water pipe.
③	Air inlet	For air exchange of the Analyzer.
④	Maintenance window	For maintenance of the Analyzer.
⑤	Purified water port 1	For connecting to a purified water pipe.
⑥	Acid-base wash buffer port	For connecting to an acid-base wash buffer pipe.
⑦	Liquid waste tube port 1	For connecting to a liquid waste tube
⑧	Purified water outlet	For discharging purified water
⑨	Float senor for purified water	Connect to the float sensor which is connected to the purified water pipe
⑩	Float senor for concentrated wash buffer	Connect to the float sensor which is connected to the concentrated wash buffer pipe

3.1.4 Right view

This section introduces structure and important parts on the right side of the Analyzer. See the figure below for the right view:

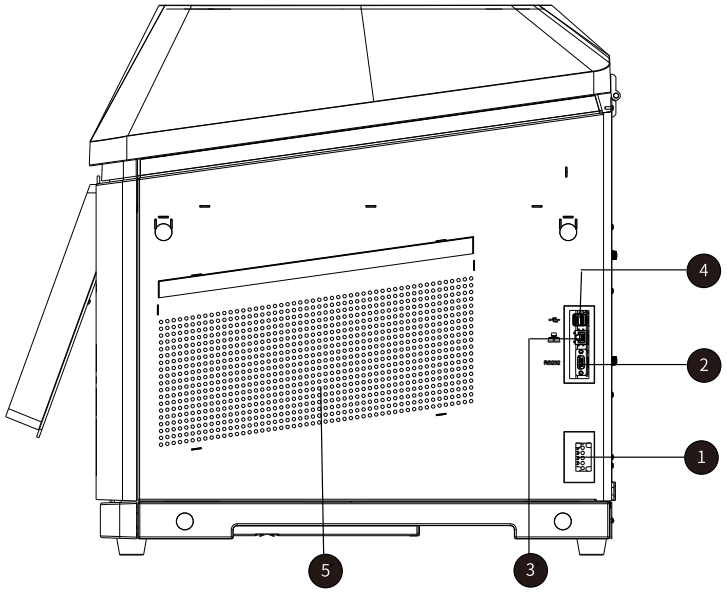


Figure 3-4 Right view

No.	Name	Description
1	Main power switch	Indicate the main power switch for the Analyzer.
2	Serial port interface	Connect with a printer or communicate with the serial port.
3	Network interface	Transmit LIS data by using the network cable to connect with router.
4	USB interface	Connect with a USB printer or USB to copy data (Before using USB, please disinfect the virus for it).
5	Air inlet	For air exchange of the Analyzer.

3.2 Product components

The Analyzer consists of the reagent-sample handling unit, stirring unit, reaction unit, photoelectric detection unit, control and data processing unit as well as software.

3.2.1 Reagent and sample processing unit

The reagent and sample processing unit is designed to load reagents and samples, including adding the first reagent, adding samples, adding the second reagent, etc. And the unit offers optional barcode scanning. It sends the reagents and samples to the corresponding aspiration positions, and then inject them into the cuvettes. The photoelectric detection unit then measures the absorbance of the reaction liquid.

The reagent and sample processing unit consists of reagent-sample tray components, barcode scanning components, reagent-sample probe components, reagent refrigeration system, sample tubes and reagent vials.

3.2.1.1 Reagent-sample tray components

Reagent-sample tray components consist of reagent-sample trays (The tray caps are also included) and reagent refrigeration system.

- Reagent-sample tray

The tray is designed as a round one and located on the left side of the front of the Analyzer. It transfers sample tubes and reagent vials to the corresponding aspiration positions for the reagent-sample probe. The tray, divided into the inner, middle and outer circles, includes 80 reagent/sample positions in total. Where:

- The inner circle includes 19 R1/R2 reagent positions and 1 wash buffer position;
- The middle circle includes 19 R1/R2 reagent positions and 1 diluent position;
- The outer circle includes 40 samples positions.

- Reagent refrigeration system

  As it can offer 24h continual refrigeration, it is used to guarantee reagents in the reagent vial are stored in low temperature, so as to keep reagents stable and reduce volatilization.

Reagent-sample tray installation

(1) Hold the handle in the middle of the sample tray, align the positioning hole beneath the handle with the pin on the base, and then place the tray vertically down onto the base;

(2) Press the two panel fasteners on the tray.

Reagent-sample tray disassembly

(1) Pull out the two panel fasteners on the tray;

(2) Hold the handle of the tray and pull the tray up to take it out.

Warning

Before you put in or take out the tray, confirm that all moving parts, such as the reagent-sample probe, the stirring rod, the cleaning structure, the reaction tray, and the reagent-sample tray, of the Analyzer stop running.

Wear gloves, masks and protective clothes during operation to prevent infection. Besides, wear safety goggles, if needed.

3.2.1.2 Bar-code scanning components (optional)

The optional barcode scanning components are composed of a barcode scanner and decoding software.

The main working principle: The scanner emits laser which forms the scanning line through scanning system and then the line irradiates the barcode. After reflection of “piece” and “blank”, the barcode will be received by the optical receiver system, followed by photoelectric conversion, and signal amplification and reshaping. Finally, the barcode will be decoded by decoding software, after which reagent or sample information of the barcode will be identified.

Barcode types supported by the Analyzer include Codebar, Code39, Code93, Code128, Interleaved 2 of 5 and UPC/EAN.

3.2.1.3 Reagent-sample probe components

The sample-reagent probe components are composed of the reagent-sample probe, rocker arm, driving shaft, syringe and wash well of the probe as well as related fluid paths. It is designed to absorb specified amount of sample or reagent from the sample tube or reagent vial, then inject them into the cuvette for reaction.

Reagent-sample probe

The reagent-sample probe consists of the sample probe, the first and second reagent probes. The volume of samples or reagents to be aspirated is based on item types.

- Function

  Aspirate the specified volume of samples from the sample tube, or aspirate R1/R2 reagents and discharge them to the cuvette.

- Specification

  Sample: 2～50 μL, increasing at a rate of 0.5 μL; Reagents: 10～400 μL, increasing at a rate of 0.5 μL.

- Action

  Move up and down at the following positions.

  The following figure shows the sample aspiration process:

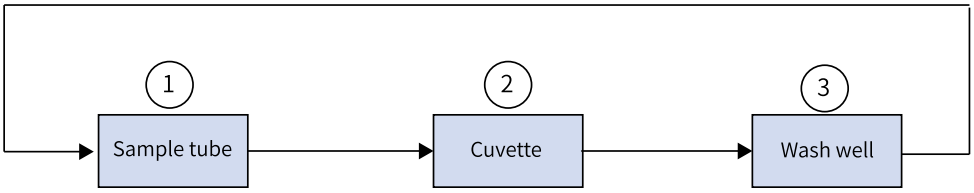


Figure 3-5 Sample aspiration positions

The following figure shows the reagent aspiration process:

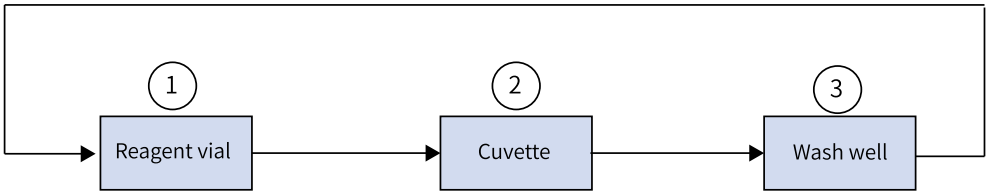


Figure 3-6 Reagent aspiration positions

The fluid path diagram is shown as below:

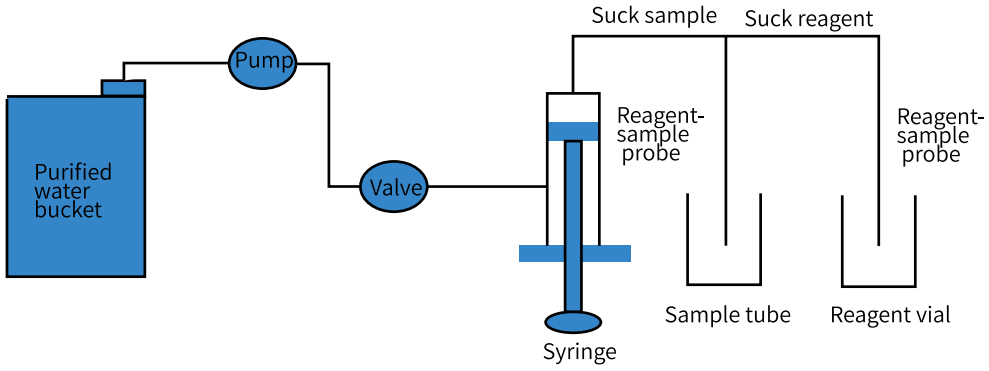


Figure 3-7 Fluid path

Beside the sample and reagent aspiration, the reagent-sample probe offers the following:

- Three-dimensional collision avoidance: the probe can detect obstacles in the vertical direction and starts the automatic protection system in case of collision, so as to protect the probe from damage.
- Fluid level detection and volume tracing: the probe automatically detects the fluid level in the sample tube and determines, based on the required sample volume, the depth into which the probe dips below the fluid level.

Warning

When the Analyzer runs, do not put your hands or other body parts or put obstacles in the movement path of the rocker arm of the reagent-sample probe. Otherwise, personal injury or instrument damage may be caused.

Reagent-sample probe cleaning

The reagent-sample probe gets its inside and outside cleaned in the wash well. Open the maintenance window on the left rear of the Analyzer, and you can see the probe syringe.

3.2.1.4 Reagent refrigeration system

Install the cooler at the bottom of the reagent-sample cabin to absorb heat in the cabin and dissipate the heat to the outside through air components. The cooler includes a temperature sensor which monitors temperature of the cooler. When temperature decreases to 2±0.1°C, the control system will reduce the current passing the cooler based on the control algorithm to decrease power of the cooler. When temperature rises, the system will increase the current to increase power to keep the cooler at 2±0.1°C.

And thermal insulation foam is attached around and at the bottom of the cabin for heat preservation. This can keep the temperature around the sample-reagent tray at 2-8°C, so as to ensure reagents are stored in low temperature. preventing the ambient temperature from affecting reagent performance during long testing time.

3.2.1.5 Sample tubes

Sample tubes are used to hold samples. The following sample tube types are applicable to the sample tray.

- Micro cuvettes: ϕ14*25mm，ϕ12*37mm;
- Original blood collection tubes/Plastic tubes: ϕ12*68.5mm, ϕ12*99mm, ϕ12.7*75mm, ϕ12.7*100mm, ϕ13*75mm, ϕ13*95mm, ϕ13*100mm.

The minimum sample volume required varies with the tube specification. The volume in each sample tube must meet the requirements for minimum sample volume. Otherwise, sample aspiration errors may be caused. If the sample volume is less than the dead volume, transfer the sample to a smaller sample tube before a test. The minimum sample volume in a tube is the sum of the minimum sample volume required in a test plus the dead volume of the tube.

3.2.1.6 Reagent vials

Reagent vials are used to hold reagents and classified into 35mL and 20mL.

3.2.2 Stirring unit

Stirring unit mainly mixes samples and reagents.

The unit consists of the stirring rod and wash well of the stirring rod. Driven by the motor, the stirring rod stirs the mixed reaction liquid in the cuvette to make reaction better.

- Function:

  Mix reagents and samples in the cuvette.

- Action

  Move up and down and revolve at the following positions:

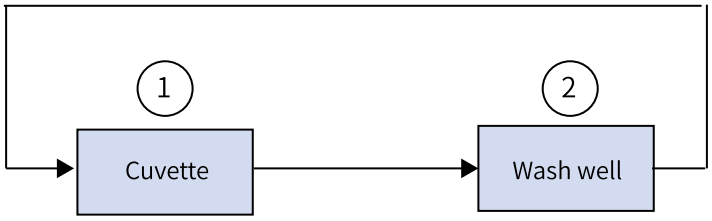


Figure 3-8 Stirring positions

3.2.3 Reaction unit

The reaction unit completes incubation and reaction of reagents and samples as well as automatic cleaning of the cuvette. The unit consists of reaction system and automatic cleaning system.

- Reaction system

  Includes the reaction tray, cuvette and temperature control chamber. The reaction tray is used to place the cuvette, and the cuvette is a plastic cup used for reaction and colorimetric measurement. The temperature control chamber offers a constant-temperature environment. The drive parts transfer the cuvette to the corresponding reagent loading, sample loading, stirring and cleaning positions for the reaction.

  - Reaction tray

    During analysis, the reaction tray conveys the specified cuvette to the reagent loading, sample loading, stirring or cleaning position. The reaction tray is a single circle and can hold 63 cuvettes.

    Function: load cuvettes to allow samples and reagents to react in a 37°C constant-temperature oven, and directly perform the colorimetric measurement through cuvettes.

    Specification: number of cuvettes: 63.

    Actions: rotate anticlockwise.

    The temperature control chamber controls the reaction temperature at 37°C±0.2°C with a fluctuation less than 0.1°C.

  - Cuvette

    Cuvettes are plastic, with an optical path of 5±0.03 mm.

    After a test is completed, the system automatically cleans and dries the cuvettes through 6-step cleaning, so that cuvettes can be used in the next test.

  - Temperature control chamber

In the temperature control chamber, there is a heater that will heat the chamber before a test, and also a temperature sensor that allows the heater to stop heating when the temperature is too high or to continue heating when the temperature is too low. This can ensure that the chamber and biochemical reaction is kept at a constant temperature of 37°C, stimulating human temperature, so as to guarantee accuracy of test results.

- Automatic cleaning system

  The system supports 6-step automatic cleaning. After a test is completed, cuvettes are automatically cleaned by using the 6-step cleaning probes. The automatic cleaning system consists of cleaning probes, a lifting motor, and relevant fluid paths. The lifting motor controls cleaning probes to move up or down at each cleaning step to clean the cuvettes.

  Function: clean the cuvette after a test, suck out the reaction liquid, inject purified water and concentrated wash buffer into the cuvette, and dry the cuvette.

  Specification: six cleaning heads, where:

  - 1st cleaning heads: suck out the reaction liquid and inject purified water mixed with concentrated wash buffer.
  - 2nd to 4th cleaning heads: suck out the purified water injected in the previous step, and re inject purified water.
  - 5th and 6th cleaning heads: suck out the residual waterdrop in the cuvette completely.

  Actions: move up and down in the cuvette to suck out the reaction liquid and add purified water and concentrated wash buffer.

3.2.4 Photoelectric detection unit

The photoelectric detection unit measures the absorbance of reaction liquid in cuvettes and collects photoelectric signal. It consists of an optical system and a signal detection system. It is mainly used to detect the light intensity variations of light-transmitting reactants. It converts optical variation signals resulted from the chemical reaction into electrical signals by using a photoelectric conversion method, and determines the light intensity variations by detecting the variations of the electrical signals.

The optical system consists of a light source, an optical path colorimetry system, and a light splitting assembly. It provides monochromatic light with sufficient intensity and a stable and reliable colorimetric optical path structure.

The signal detection system includes a photoelectric conversion component and an AD collection and processing component. It converts a light intensity signal of monochromatic light into an electrical signal (The monochromatic light is aggregated to the photoelectric conversion component after being absorbed by the reactant.). After the electrical signal is amplified and A/D collection is done, photoelectric data that reflects the light intensity is output and transferred to the corresponding control unit which will calculate the absorbance.

- Function

  Measure the absorbance of reaction liquid in the cuvettes in the rotation process of the reaction tray.

- Specifications

  - Wavelength: 340nm - 800nm (EXC220) or 340nm - 700nm (EXC220). The wavelength is optional.

- Number of wavelengths simultaneously measured: 1 or multiple wavelengths can be measured at the same time;
- Accuracy of wavelength: ±2 nm;
- Half wave width: 8±2 nm;
- Detector: Photodiode;
- Light source: Tungsten-halogen lamp, 12 V, 20 W.
- Diagram is shown below:

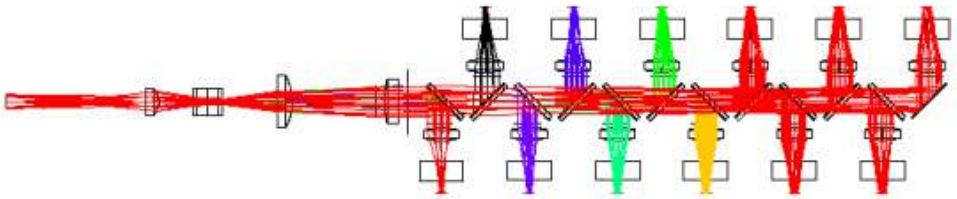


Figure 3-9 Optical path

3.2.5 Control and data processing unit

The control and data processing unit controls the touch screen, built-in main control board and hard disk drive. You can operate on the touch screen to control operation of the Analyzer. The main control board and hard disk board can handle the photoelectric signal value and convert it to varied results required by detection.

3.3 Specifications and configuration

This section introduces specifications and configuration of the Analyzer. Refer to the following table for details:

Table 3-1 Specifications and configuration of the Analyzer

Items	Description
Size (length width height)	710mm × 705mm × 635mm
Weight	● Gross weight: 150Kg ● Net weight: 90kg
Host interface	● Four USB interfaces: Type A, female, USB 2.0; working output voltage: DC 5V. Used for connecting a printer, or an external mouse, keyboard and USB in case of debugging, maintenance and upgrading of system. ● Network interface: RJ45 port, used for connecting the Analyzer to the Laboratory Information System (LIS) or a printer for bi-directional data transmission; and the transmission protocol is TCP/IP; ● RS232 communication interface: Used for debugging by an engineer. Note: ● External devices such as printer shall pass the certification for IT equipment. Use of unqualified external devices may cause abnormal operation of

Items	Description
	Analyzer or personal injury. ● Supports HP and EPSON printers.
Power supply	Power Voltage: 100-240V~; 50/60Hz
Input power	⩽ 500VA
Minimum hardware configuration	● CPU: Intel (R) Celeron™ J1900; ● Memory: 4GB ● Hard disk: 128GB ● Display: Resolution of screen 1024×768; ● Graphics card: DirectX 9.0 supported
Software running environment	● Operating system software: Windows 10 IoT Enterprise 2016 LTSB English X64 from Microsoft Co.; ● Support software: Microsoft visual C++ 2015 Redistributable (x64) - 14.0.24212 from Microsoft Co. ● Application software: Mysql-5.7.18 from Oracle.
Network requirements	The network type is LAN. Network connection or bandwidth is not required. No network communication is required during a test, but LAN shall be connected when connecting to LIS or printing a report via a network printer.
Software name	Chemistry Analyzer Software
Software release version	V5

3.4 Parameters and performance

This section introduces parameters and performance of the Analyzer. Refer to the following table for details:

Table 3-2 Basic parameters and performance

Parameter name	Content	
Light source	Tungsten-halogen lamp, 12 V, 20 W;	
Reaction tray	63 cuvettes, optical path: 5 mm±0.03mm	
Reagent positions	40	
Sample positions	40	
Sample volume	(2-50) μL, increasing at a rate of 0.5 μL	
Reagent volume	(10-400) μL, increasing at a rate of 0.5 μL	
Wavelength	340-800 nm (EXC200)	340-700 nm (EXC220)
Light splitting method	Rear-spectroscopy: 12 wavelength channels (EXC200)	Rear-spectroscopy: 8 wavelength channels (EXC220)
Minimum reaction volume (μL)	90 (EXC200)	100 (EXC220)

Parameter name	Content
Water consumption amount	⩽5 L/H
Test speed	Constant rate 160T/H
Reagent-sample probe	It has the functions of liquid level detection, volume tracking and three-dimensional collision avoidance.

Table 3-3 Other parameters and performance

Parameter name	Content			
Stray light	Absorbance is not less than 4.5A			
Temperature precision and fluctuation	Temperature value is within the specified ±0.2℃ and fluctuation is less than ±0.1℃.			
Carryover rate	⩽0.005%			
Absorbance linear range	The maximum absorbance is no less than 4.0 within the ±5% relative deviation.			
Absorbance accuracy	Absorbance value A		Acceptable error △A	
	0.5		±0.02	
	1.0		±0.04	
Sample accuracy and repeatability	Category	Addition volume (μl)	Accuracy error	Coefficient of variation (CV)
	Sample	2	± 4%	⩽2%
		5	± 4%	⩽2%
		50	± 4%	⩽1%
	Reagents	10	± 3%	⩽2%
		400	± 3%	⩽1%
Precision in clinical batch	Item	Concentration range		Coefficient of variation (CV)
	ALT (Alanine aminotransferase)	30 U/L-50U/L		⩽4%
	UREA	7.0mmol/L~11.0mmol/L		⩽2.5%
	TP (Total protein)	50.0 g/L-70.0g/L		⩽2%

3.5 Cybersecurity instructions

The following cybersecurity measures (not limited to those listed here) are taken for the Analyzer.

User access control: the software has a user access control mechanism, including user identification method (user name and password), user type and authorization (Administrator user, general user and service personnel of Zybio. Administrator user has the permissions for general user; service personnel of Zybio has the permissions for administrator user and general user).

Configure network features: the IP address, default gateway and subnet mask can be modified according to users' requirements with the permission of the authorized personnel.

Security software: Windows Defender available on Window system. Full version: 4.12.1625.15. Supplier: Microsoft Co..

Requirements for updating software: updating of software shall be done by authorized personnel of Zybio or its local distributor.

Restriction on use:

- The Analyzer is not allowed to be connected to Internet during operation, otherwise the cybersecurity cannot be guaranteed;
- Only authorized users can access the Analyzer;
- For the USB flash drive plugged into the Analyzer, it shall be scanned for disinfecting virus regularly;
- The Analyzer shall be operated in a protected wired LAN environment.

3.6 Software interface

The software is named as Chemistry Analyzer Software. It has such functions as sample, result, reagent, status, calibration, quality control, settings and maintenance. You can run it to apply sample tests, search results, manage reagents, check testing status, apply calibration and quality control, set up the Analyzer, and make varied maintenance.

As shown in the figure below, the operation interface mainly comprises the toolbar, the status bar and the functional area.

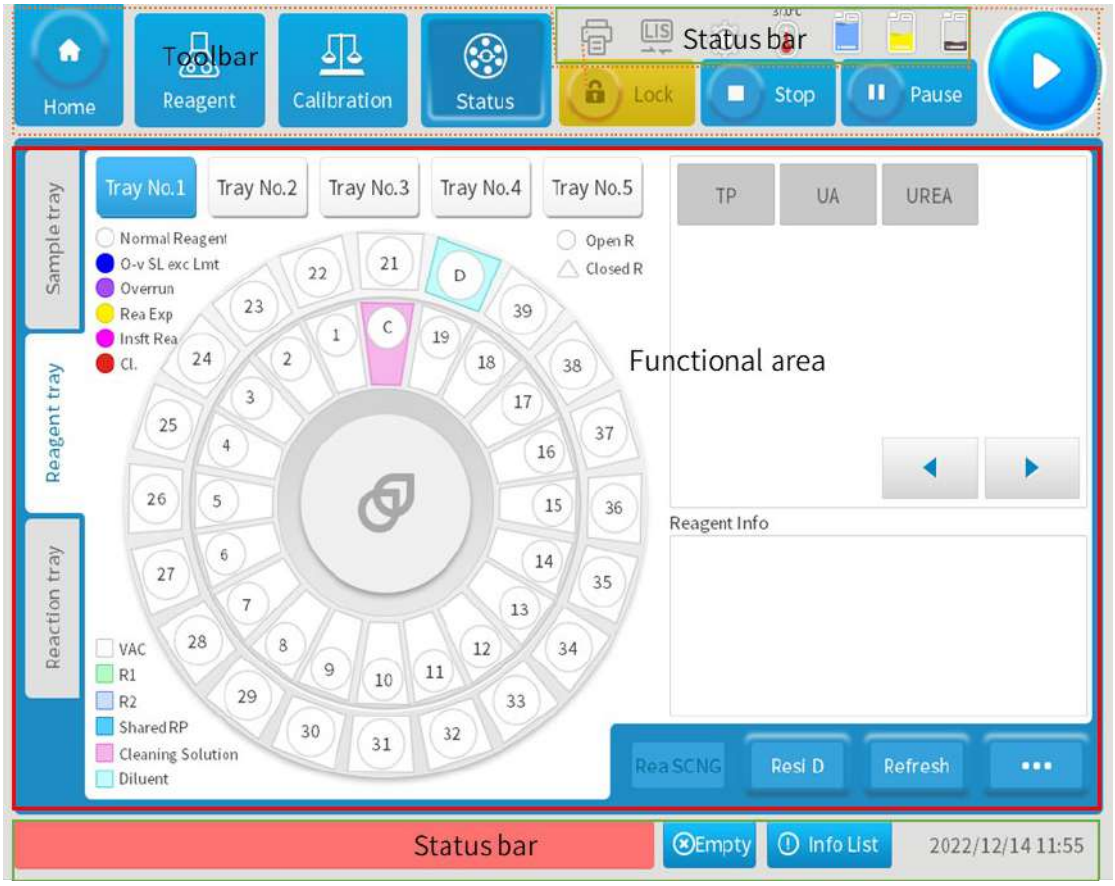


Figure 3-10 Main interface of the software

No.	Name	Description
1	Status bar	Includes status area and alarm information area.
2	Toolbar	Includes multiple functional buttons and shortcut button.
3	Functional area	It means the functional page that is displayed after click a functional button.

3.6.1 Status bar

This section introduces the status bar of the software, including status area and alarm information area.

- Status area

Table 3-4 Status area

Status area	Name	Description
	System operation status	When the Analyzer is performing a test, the gear icon in the upper side of the interface revolves. The number above the gear icon represents the total number of operation cycles of the reaction tray in the latest or ongoing test.

Status area	Name	Description
	Reaction tray temperature	Indicates the actual temperature of the reaction tray.
	Printer connection	The highlighted icon indicates a printer is connected with the Analyzer, while gray indicates the printer is disconnected.
	LIS connection	The highlighted icon indicates the Analyzer is connected to LIS, while gray icon indicates the Analyzer is not connected to LIS.
	Wash buffer tank, purified water tank, liquid waste tank icons	Display the status of the tanks.
	System date and time	Displayed in the lower right corner.
	Empty	Clear the current alarm information.
	Info List	Check alarm information and troubleshooting.

- Alarm information area

  Displays the error or alarm information when an error occurs. You can click Empty in the status bar area to clear the current error or alarm and click Info List to enter the alarm details page.

3.6.2 Toolbar

This section introduces the toolbar of the software, including functional and shortcut buttons. Functional buttons are mainly used to open various functional pages of the software.

- Functional buttons:

Table 3-5 Functional buttons

Functional buttons	Name	Description
	Sample	Has such functions as sample testing (including batch application), patient information inputting, sample position setting, etc.
	Calibration	You can set the information and position of the calibrator, apply for calibration tests and reagent blank tests, and view the calibration and blank test results.

Functional buttons	Name	Description
	QC	You can set control information, apply for a QC test and view QC results.
	Status	● Displays information about the sample tray, reagent tray and reaction tray. For the sample tray, you can view the sample information, refresh sample positions, view the reaction curves and detect reagent residual. For the reaction tray, you can view status of the reaction tray, test information of cuvettes, reaction curves, etc. ● (Note: The sample tray and reagent tray are combined as the reagent-sample tray, but they are divided on the software for easy operation. On the software interface, the sample tray indicates 40 sample positions in the outer circle on the reagent-sample tray of the Analyzer, while the reagent tray indicates 40 reagent positions in the middle and inner circles.)
	Reagents	You can view reagent information, residue detection, reagent loading and unloading.
	Result	You can view sample results of patients, reaction curves, view and edit patient information, etc.
	Setup	Includes settings for testing, system, user and item.
	Maintenance	Includes daily maintenance and engineer maintenance. Daily maintenance includes periodical maintenance, troubleshooting, data backup, temperature curve, consumables maintenance and unit status, while engineer maintenance includes maintenance and debugging.

- Shortcut button

Table 3-6 Shortcut buttons

Shortcut buttons	Name	Description
	Start	Start testing all samples applied for testing.

Shortcut buttons	Name	Description
	Pause	Stop adding samples.
	Stop	Stop adding reagents.
	Lock	Lock the interface so that other function buttons become unavailable.
	Home page	Return to the home page with a click.

4 Working principles

This chapter introduces measurement principles of the Analyzer, including analytical principles, calibration categories, measuring principles and prozone check.

4.1 Analysis method

The Analyzer monitors the absorbance in each photometric spot during the reaction, according to the light absorption rule in solution. Based on the absorbance change before and after the reaction, or the change rate during the reaction and on corresponding calibration parameters or calculation factors, the concentration or activity of the measured substance can be calculated.

4.2 Analysis procedure

The analysis procedure includes the acting process, acting position, measuring process, and photometric spot.

4.2.1 Acting process

The Analyzer completes all tests through cyclic performance of the following actions.

(1) The cuvette turns to the first cleaning head for automatic cleaning;

(2) The first cleaned cuvette turning to the 1st reagent (R1) means the 1st cycle and the 1st photometric spot. Sample (S) will be added in the 10th cycle and the 2nd reagent 2 in the 36th cycle. Absorbance will be measured in each cycle. In the 52th cycle, also the 52th photometric spot, tests will be completed and then automatic cleaning will be initiated;

(3) After cleaning, the cuvette turns to the first cleaning head again and prepares for the next loop.

4.2.2 Measuring process

The measuring process of the Analyzer is fixed and includes 52 cycles during each reaction.

4.2.3 Photometric spot

For the same reaction, absorbance will be measured in each cycle. There are 52 photometric spots with a time interval of 15 and 22.5 seconds between every two spots in the high-speed and general mode respectively.

Note: the above time interval is for reference only. The actual time interval shall be subject to software settings.

4.3 Analysis methods and reactivity calculation

The absorbance calculation formula of the Analyzer is as follows:

Absorbance of solution=Lg (AD water-AD darkness) / (AD dissolved-AD dark)

Where:

- “Lg” is the logarithm to the base 10.
- “AD” is the light intensity value after photoelectric and digital-to-analog conversions.
- “AD Darkness” is the AD when the lamp is turned off; “AD Water” is the AD of pure water in the cuvette; “AD Dissolved” is the AD of the to-be-tested solution in the cuvette.
- The absorbance value in the reaction curve is magnified by 20000 times.

Note:

Based on the reaction speed, three analysis methods can be applied to all reactions: endpoint method, two-point method, and kinetics method.

- Reaction time N P: The time duration of a reaction from its beginning to the end of reaction monitoring. For a single-reagent project, reaction time starts from the time when the sample S is added. For a dual-reagent project, it starts from the time when the reagent R2 is added. There are two inputs for entering the start time and end time of reaction monitoring, which are represented by N and P, respectively.
- Blank time L M: The time duration before the reaction of a test starts. For a single-reagent project, blank time lasts from the time when the reagent R1 is added to the time when the sample S is added. For a dual-reagent project, it lasts from the time when the sample S is added to the time when the reagent R2 is added. There are also two inputs for entering the start time and end time of blank monitoring, which are represented by L and M, respectively.
- For a dual-wavelength project, absorbance A is the absorbance difference value of dominant wavelength and sub wavelength. For a single-wavelength project, it is the absorbance of the dominant wavelength.

4.3.1 End-point method

The reaction reaches a balanced status after a certain time. At this time point, absorbance no longer changes. The increase or decrease of absorbance resulted from the reaction is proportional to the concentration of the measured subject. This method is also called the “balance” method.

4.3.1.1 Single-reagent endpoint method

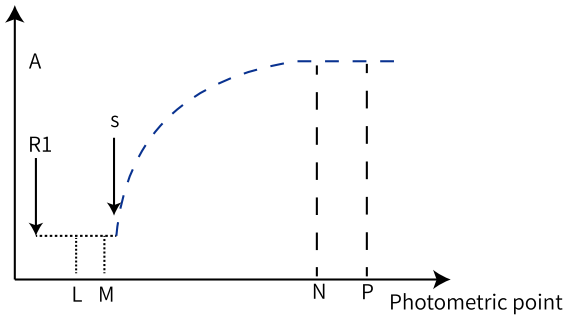


Figure 4-1 Single-reagent endpoint method

Reaction time N P, 11 ⩽ N ⩽ P ⩽ 52, while N + 4 ⩾P;

Blank time L M, 1⩽L⩽M⩽9, while L+4⩾M.

- The calculation of absorbance A_i used for reactivity calculation during the reaction time

is as follows:

- If N = P, enter [P] [P] and use one photometric spot. Then $A_i=A_N$.
- If P = N +1, enter [N] [N+1] and use two photometric spots. Then $A_i=\frac{A_N+A_{N+1}}{2}$.
- If P = N +2, enter [N] [N+2] and use three photometric spots. Then A_i is the absorbance values left after extremums are removed.
- If P = N + 3, enter [N] [N+3] and use four photometric spots. Then A_i is the mean of two absorbance values left after extremums are removed.
- If P = N +4, enter [N] [N+4] and use five photometric spots. Then A_i is the mean of three absorbance values left after extremums are removed.

- The calculation of absorbance A_b used for reactivity calculation during the blank time is as follows: It is the same as that of absorbance in the reaction time A_i.
- Calculation of reactivity: $R=A_i - KA_b$.
- In the formula, $K=\frac{V_{R1}}{V_{R1}+V_S}$ is the calibration factor of a single-reagent volume. V_{R1} and V_S represent volumes of the 1st reagent and sample volume. The KA_b of the above formula is the calibration value of reagent blank. Reagent blank can be deducted in real time, while the sample blank cannot. If sample blank calibration is needed, a sample blank test must be performed separately. The sample blank reactivity R_{Sb} is calculated in the same way as shown in the above R formula, which is $R_{sb}=A_i - KA_b$. Thus, reactivity after calibration of the sample blank is $R'=R - R_{Sb}$.

4.3.1.2 Dual-reagent endpoint method

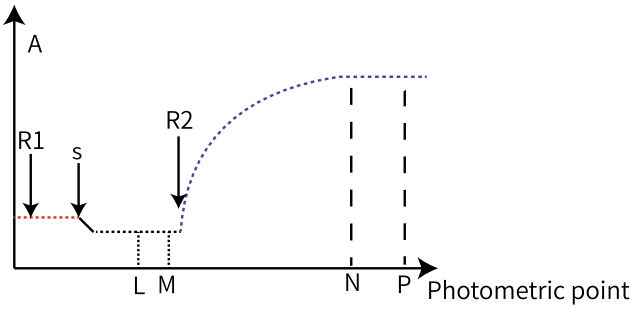


Figure 4-2 Reaction curve of dual-reagent endpoint method

Reaction time N P, $23 \leqslant N \leqslant P \leqslant 52$, while $N + 4 \geqslant P$;

Blank time L M, $11 \leqslant L \leqslant M \leqslant 22$, while $L+4 \geqslant M$.

- The calculation of absorbance A_i used for reactivity calculation during the reaction time is as follows: It is the same as that of the single-reagent endpoint method.
- The calculation of absorbance A_b used for reactivity calculation during the blank time: It is the same as that of the single-reagent endpoint method.
- Calculation of reactivity R: $R=A_i - K'A_b$.

- The $K'A_b$ in the formula is the calibration value of the mixed blank of the 1st reagent and sample. The $K'=\frac{V_{R1}+V_S}{V_{R1}+V_S+V_{R2}}$ is the calibration factor of dual-reagent volume.
- The mixed blank of the 1st reagent and sample can be deducted in real time, while the R2 2nd reagent (R2) blank cannot. If reagent R2 calibration is needed, a sample blank test must be performed separately. R2 blank reactivity R_{R2} is calculated in the same way as shown in the above formula for R, which is $R_{R2}=A_i - K'A_b$. Thus, reactivity after reagent blank calibration is $R'=R - R_{R2}$.

4.3.2 Two-point method

The two-point method is also called the first-order kinetics method, two-point rate method, or fixed time method. It means that the reaction rate is proportional to the first power of the substrate concentration in a specified duration, which can be represented as V = k[S]. As the substrate depletes, the reaction rate keeps decreasing, which means increase or decrease of absorbance and the speed keeps slower. In a specified duration, the absorbance increase or decrease (△A/min) of the reaction liquid is proportional to the concentration of the measured subject.

The two-point method can detect whether the substrate is depleted. If it is true, there will be a mark in the result.

4.3.2.1 Single-reagent two-point method

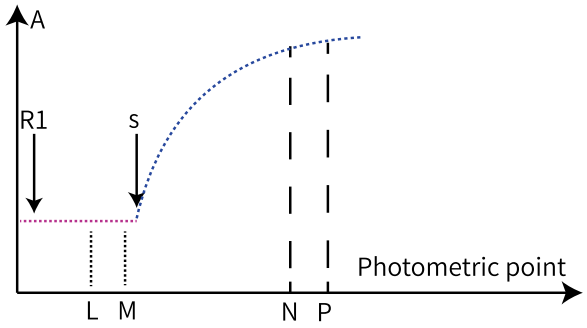


Figure 4-3 Single-reagent two-point method

Reaction time N P, 11≤N<P≤52;

Blank time L M, 1≤L≤M≤9. L and M are blank and will not be used for blank calibration by default.

- Calculation of reactivity R: $R=\frac{A_P-A_N}{t_P-t_N}$ (R should be converted to the R value per minute);
- Calculation of blank reactivity R_b: It is the same as that of reactivity R, $R_b=\frac{A_M-A_L}{t_M-t_L}$ (R_b should be converted to the R_b per minute).
- If blank time is set, blank calibration must be performed. The reactivity after blank calibration will be calculated as $R'=R - KR_b$, K is the calibration factor of the single-reagent volume, $K=\frac{V_{R1}}{V_{R1}+V_S}$.

4.3.2.2 Dual-reagent two-point method

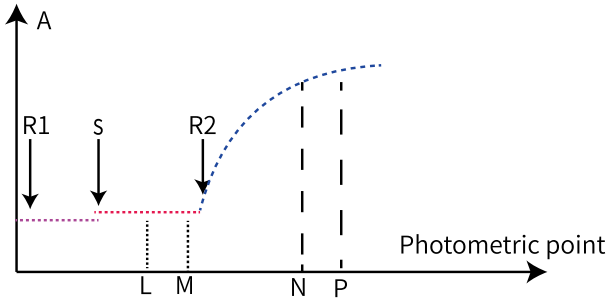


Figure 4-4 Reaction curve of the dual-reagent two-point method

Reaction time N P, 23≤N<P≤52;

Blank time L M, 11≤L≤M≤22. L and M are blank and will not be used for blank calibration by default.

- Calculation of reactivity R: It is the same as that of the single-reagent two-point method;
- Blank reactivity R_b: It is the same as that of the single-reagent two-point method;
- If blank time is set, blank calibration must be performed. The reactivity after blank calibration $R^{'}=R-K^{'}R_b$, $K^{'}$ is the calibration factor of the dual-reagent volume, $K^{'}=\frac{V_{R1}+V_S}{V_{R1}+V_S+V_{R2}}$. By setting blank time, only the mixed blank of the 1st reagent and sample can be automatically deducted, while the 2nd reagent blank cannot. If the 2nd reagent blank needs to be deducted, a reagent blank test must be performed separately. The calculation of the 2nd reagent blank reactivity R_{R2} is the same as that of reactivity R above. Reactivity after blank calibration is calculated as $R^{''}=R-R_{R2}$.

4.3.3 Kinetics method

The kinetics method is also called as the zero-order rate method, rate method, or continuous monitoring method. It means that reaction speed is proportional to the substrate concentration to the power of zero, which means that there is no relationship between reaction speed and substrate concentration. Therefore, the reaction subject can produce matters at a constant speed during the reaction. The result is that the absorbance of the measured solution under one wavelength decreases or increases uniformly. Its speed (△A / min) is proportional to the activity or concentration of the measured subject (catalyst). The kinetics method is mainly used for the measurement of enzyme activity.

In actual practices, the substrate concentration is limited, so the reaction is no longer in zero-order when a certain part of the substrate is depleted. Therefore, the zero-order rate method is for a specific time duration and the reaction time in zero-order must be selected for monitoring, so as to ensure accuracy of results.

The kinetics method can detect whether the substrate is depleted. If it is true, there will be a mark in the result. The kinetics method can detect the linearity limit and give a mark in the result if exceeding the limit.

- Calculation of reactivity:

  The least-squares method is applied into the calculation of reactivity in the zero-order kinetic reaction section. The formula of the least-squares method is:

$$R=\frac{\sum_{i=N}^{P}(t_i-\bar{t})\cdot(A_i-\bar{A})}{\sum_{i=N}^{P}(t_i-\bar{t})^2}$$

In the formula, N represents the start of the zero-order reaction section and P represents its end. A_i is the absorbance in spot i and $\bar{A}$ is the average absorbance from spot N to spot P. t_i is the time of spot i and $\bar{t}$ is the average time from spot L to spot M.

4.3.3.1 Single-reagent kinetics method

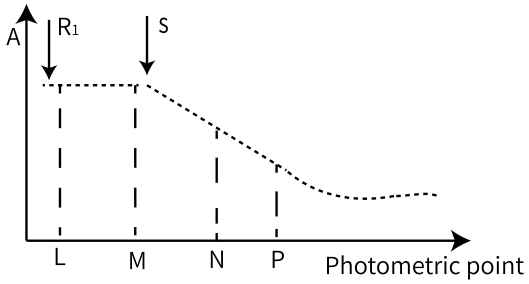


Figure 4-5 Reaction curve of the single-reagent kinetics method

Reaction time N P, 11≤N<P≤52, while N + 2 ≤ P, which means there are at least three photometric spots.

Blank time L M, 1≤L<M≤9, while L + 2 ≤ M, which means there are at least three photometric spots. In addition, L and M are blank and will not be used for blank calibration by default.

- Calculation of reactivity R: $R=\Delta A_{NP}$, Δ is absorbance change rate per minute between spot N and spot P, calculated by the least-squares method.
- Calculation of blank reactivity R_b is the same as that of reactivity, which is R, $R=\Delta A_{LM}$.
- If blank time is set, blank calibration must be performed. The reactivity after blank calibration will be calculated as $R'=R-KR_b$. K is the calibration factor of the single-reagent volume and is calculated as $K=\frac{V_{R1}}{V_{R1}+V_S}$.

4.3.3.2 Dual-reagent kinetics method

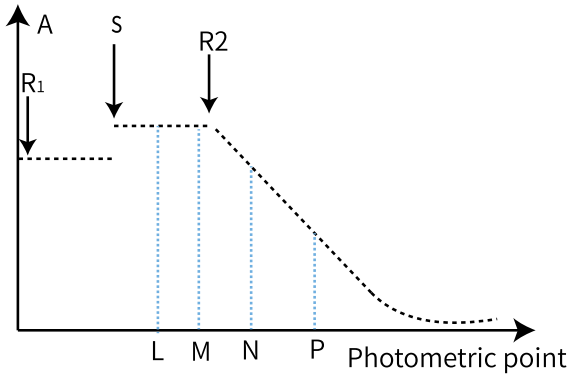


Figure 4-6 Reaction curve of the dual-reagent kinetics method

Reaction time N P, 23≤N≤P≤52, while N + 2 ≤ P, which means there are at least three photometric spots.

Blank time L M, 11≤L<M≤22, while L+2 ≤ M, which means there are at least three

photometric spots. In addition, L = 0 and M = 0, and will not be used for blank calibration by default.

- Calculation of reactivity R: $R=\Delta A_{NP}$, Δ is absorbance change rate per minute between spot N and spot P, calculated by the least-squares method.
- Blank reactivity R_b: It is the same as that of the single-reagent rate method.
- If blank time is set, blank calibration must be performed. The reactivity after blank calibration $R^{'}=R-K^{'}\times R_b$, $K^{'}$ is the calibration factor of the dual-reagent volume, $K^{'}=\frac{V_{R1}+V_S}{V_{R1}+V_S+V_{R2}}$. By setting blank time, only the mixed blank of the 1st reagent and sample can be automatically deducted, while the 2nd reagent blank cannot. If the 2nd reagent blank needs to be deducted, a reagent blank test must be performed separately. The calculation of the 2nd reagent blank reactivity R_{R2} is the same as that of reactivity R above. Reactivity after 2nd reagent blank calibration is calculated as $R^{''}=R-R_{R2}$.

4.4 Calibration

4.4.1 Calibration type

The Analyzer provides linear and non-linear calibrations. Linear calibration includes single-point (K factor method), two-point, and multi-point calibrations, mainly used in projects where reaction liquid is a solution. Non-linear calibration includes Logistic-Log4P, Logistic-Log5P, Exponential5P, Polynomial 5P, and Spline, mainly applied to projects with turbid liquid as the reaction liquid, for example, turbidimetric inhibition immunoassay.

4.4.2 Calibration parameters

For different calibration types, the number and calculation of calibration parameters are also different. See below for details.

- Single-point linear calibration

  Formula $C=KR$ contains one calibration parameter, which is K.

  $$K=\frac{C_{Standard}}{R_{Standard}}$$

  In the formula: C is the concentration of the standard. R is the reactivity of the standard.

- Two-point linear calibration

  Formula $C=K(R-R_0)$ contains two calibration parameters, which is K and R_0.

  $$K=\frac{C_2-C_1}{R_2-R_1}$$

  $$R_0=R_1-\frac{C_1(R_2-R_1)}{C_2-C_1}$$

  In the formula: C_1 and C_2 are the concentration of the standard 1 and 2. R_1 and R_2 are the reactivity range of the standard 1 and 2.

- Multi-point linear calibration

  Formula $C=K(R-R_0)$ contains two calibration parameters, which is K and R_0.

Calibration parameters are calculated based on the least square method.

- Logit-4P

  Calibration formula $R=R_0+K/[1+e^{-(a+b\ln C)}]$ contains four parameters, which are R_0, K, a and b. At least four standards are required. Parameters are calculated by the iteration method.

- Logit -5P

  Formula $R=R_0+K/[1+e^{-(a+b\ln C+c*C)}]$ contains five calibration parameters, which is R_0, K, a, b and c. At least five standards are required. Parameters are calculated by the iteration method.

- Exponential-5P

  Calibration formula $R=R_0+Ke^{[a\ln C+b(\ln C)^2+c(\ln C)^3]}$ contains five parameters, which is R_0, K, a, b and c. At least five standards are required. Parameters are calculated by the iteration method.

- Polynomial-5P

  Calibration formula $\ln C=a+b(R-R_0)+c(R-R_0)^2+d(R-R_0)^3$ contains five parameters, which is R_0, K, a, b and c. At least five standards are required. The concentration (active) of the first one is zero, so its R is R_0. Other parameters are calculated by the iteration method.

- Spline

  Calibration formula $C-C_i=R_{0i}+a_i(C-C_i)+b_i(C-C_l)^2+c_i(C-C_i)^3-R$ contains four parameters, which is R_{0i}, a_i, b_i and c_i. At least two standards are required. Parameters of each section are calculated by the iteration method.

4.5 Concentration calculation

- If the K-factor method is adopted as the calibration method, calibration is not needed and the theoretical calculation factor K can be entered directly. The calculation formula of concentration is as follows:

  $$C=KR/10000$$

  Where: K is the calculation factor entered and R is the reactivity of the to-be-measured sample.

- If calibration categories are linear calibration, Logit-4P, or Polynomial-5P, concentration can be calculated directly by calibration parameters and reactivity R.

- If calibration categories are Logit-5P, Exponential-5P, or Spline, concentration can be calculated based on calibration parameters and reactivity R and through the bisection method for finding real root.

4.6 QC

4.6.1 QC rule

The default rule of the Analyzer is the Westguard multiple rules. Based on actual requirements, you can judge the QC status of different items by one or more rules.

Westguard multi-rule QC rule includes six sub rules. The meaning of each sub rule is as

follows:

Symbol	Definition	QC status judgment
1_{2s}	One point is more than + 2 SD or - 2 SD of the mean value, but within +3SD or 3SD	Warning
1_{3s}	One point is more than the +3SD or -3SD of the mean value	Out of control (random error)
2_{2s}	Two points are more than the +2SD or -2SD of the mean value in succession.	Out of control (system error)
R_{4s}	Difference value of two values in the same batch is more than 4SD	Out of control (random error)
4_{1s}	Four points are more than the 1SD or -1SD of the mean value in succession	Out of control (system error)
10_X	Ten points are in the same side of the mean value.	Out of control (system error)

The flow chart of judging the sub rules mentioned above by the Analyzer is as follows:

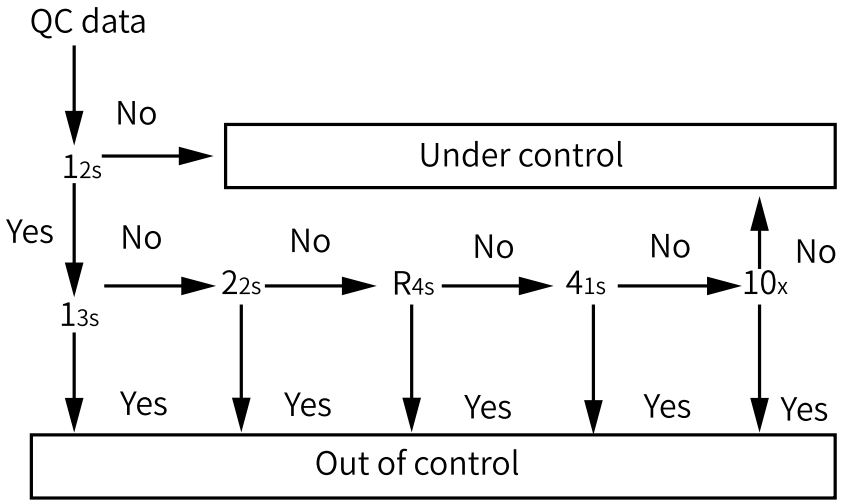


Figure 4-7 QC rule judgment flow chart

4.6.2 QC category

The Analyzer provides two QC categories, which are real time QC and interday QC. QC status judgment can be made according to the set QC rule.

- Real-time QC: perform QC status judgement for 10 consecutive QC data within one day.
- Interday QC: perform QC status judgement for all QC data among different days.

4.6.3 QC chart

The Analyzer provides three types of QC charts, namely, L-J and Twin Plot.

- L-J QC chart

  Take the measured QC data as the ordinate, draw a horizontal line from the QC target value, draw 6 lines parallel to the mean line above + 1SD (standard difference, hereinafter called SD), + 2SD, + 3 SD and below -1SD, -2SD, -3SD, and mark them with ± 1SD, ± 2SD and ± 3 SD. The values of the quality control material measured each

time are drawn on the QC chart, and the adjacent points are connected by fine lines.

- Twin Plot QC chart

  For projects measuring concentrations of two controls at the same time, a Twin Plot chart can be shown. According to target values and SD (entered by users in the QC Setting) take the measured value of a control, usually the one with a lower concentration, as abscissa, and the other, usually the one with a higher concentration, as ordinate. Then, draw central lines from their means and other lines with ±1SD, ±2SD, and ±3SD. SD. Last, regard measured values of two controls as a point and record the point in the chart. See the figure below:

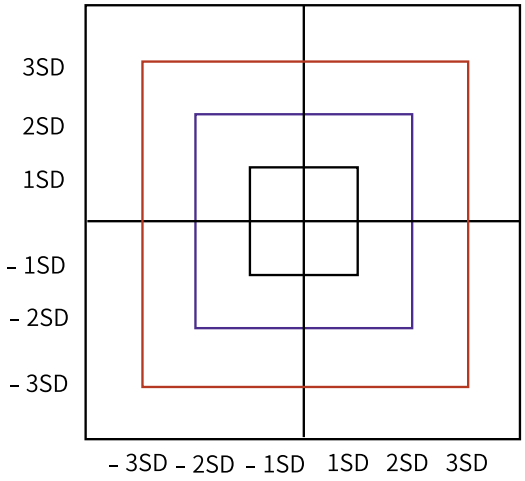


Figure 4-8 Twin plot control chart

This chart shows the system and random errors clearly. If a point locates within blue lines (±2SD), it means QC status is in control. If it locates in the first or third quadrant of areas between red and blue lines, it means there is a system error. If it locates in the second or fourth quadrant of areas between red and blue lines, or outside red lines, it means there is a random error.

4.7 Other calculations

4.7.1 Calibration curve calculations

- Calibration sensitivity

  Refers to the reactivity difference value of calibrator with maximum and minimum concentrations. If the difference value is lower than the set value, the sensitivity is then unqualified.

- Reactivity of blank calibrator

  Refers to the reactivity of calibrator with zero concentration. If the reactivity is higher than the set value, it is then unqualified.

- Calibration repeatability

  Refers to the difference value between the maximum and minimum reactivity after multiple measurement of each calibrator. If the difference value is higher than the set value, the calibration repeatability is then unqualified.

- Calibration curve SD

  It is only used for multi-point linear and non-linear calibration curves First, calculate the difference between the reactivity (R) of each calibrator and the reactivity (R) calculated based on calibration curves. Then, calculate the quadratic sum of the

difference value and divide the value of freedom degree. Last, extract the square root of the value obtained in the former step. The formula is as follows:

- Multi-point linear calibration

$$SD=\sqrt{\frac{\sum_{i=1}^{N}\sum_{j=1}^{n}\left(Rij-Ri^{'}\right)^{2}}{Nn-2}}$$

Where: Rij is the reactivity of the calibrator i in one valid measurement. $Ri^{'}$ is the reactivity of the calibrator i calculated based on the calibration curve. N is the number of calibrator and n is the number of valid repeated measurements.

- Logit -4P

$$SD=\sqrt{\frac{\sum_{i=1}^{N}\sum_{j=1}^{n}\left(Rij-Ri^{'}\right)^{2}}{Nn-4}}$$

Where: Rij is the reactivity of the calibrator i in one valid measurement. $Ri^{'}$ is the reactivity of the calibrator i calculated based on the calibration curve. N is the number of calibrator and n is the number of valid repeated measurements.

- Logit -5P

$$SD=\sqrt{\frac{\sum_{i=1}^{N}\sum_{j=1}^{n}\left(Rij-Ri^{'}\right)^{2}}{Nn-5}}$$

Where: Rij is the reactivity of the calibrator i in one valid measurement. $Ri^{'}$ is the reactivity of the calibrator i calculated based on the calibration curve. N is the number of calibrator and n is the number of valid repeated measurements.

- Exponential-5P and polynomial-5P

$$SD=\sqrt{\frac{\sum_{i=1}^{N}\sum_{j=1}^{n}\left(Rij-Ri^{'}\right)^{2}}{Nn-5}}$$

Where: Rij is the reactivity of the calibrator i in one valid measurement. $Ri^{'}$ is the reactivity of the calibrator i calculated based on the calibration curve. N is the number of calibrator and n is the number of valid repeated measurements.

- Spline

$$SD=\sqrt{\frac{\sum_{i=1}^{N}\sum_{j=1}^{n}\left(Rij-Ri^{'}\right)^{2}}{Nn-4}}$$

Where: Rij is the reactivity of the calibrator i in one valid measurement. $Ri^{'}$ is the reactivity of the calibrator i calculated based on the calibration curve. N is the number of calibrator and n is the number of valid repeated measurements.

- Calibration curve-related factors

It is only used for multi-point linear and non-linear calibration curves. The formula is as follows:

$$R^{2}=\frac{\sum_{i=1}^{N}\sum_{j=1}^{n}\left(Cij-\overline{C}\right)^{2}\left(Rij-\overline{R}\right)^{2}}{\sum_{i=1}^{N}\sum_{j=1}^{n}\left(Cij-\overline{C}\right)^{2}\sum_{i=1}^{N}\left(Rij-\overline{R}\right)^{2}}$$

Where: C is the concentration of a calibrator. R is the reactivity. N is the number of the calibrator and n is the number of valid repeated measurements.

4.7.2 Substrate depletion judgment

Substrate depletion judgment is only applied in the kinetics and two-point methods. As some high-concentration (active) samples deplete substrate very quickly, reaction speed will not be in expectation (zero or first order reaction). Therefore, to accurately present measurement results, substrate depletion judgment is needed. The specific judgment is as follows:

- Reaction increase

  During the start and end time duration, once the absorbance value in one or multiple photometric spot is more than the set value, it means that the substrate has been depleted.

- Reaction decrease

  During the start and end time duration, once the absorbance value in one or multiple photometric spot is less than the set value, it means that the substrate has been depleted.

4.7.3 Linearity check

Linearity check is only applied in the kinetics method. During the start and end time duration of reaction, check if the linearity of the reaction curve accords with the set value based on data of all photometric spots. The calculation method is as follows:

- If there are over 9 photometric spots from the start to end of reaction;

  Linearity limit = (absorbance change rate of the first 6 points minus that of the last 6 points)/absorbance change rate of all points.

- If the number of photometric spots is no less than 4 and no greater than 8 from the start to end time of reaction;

  Linearity limit = (absorbance change rate of the first 3 points minus that of the last 3 points)/absorbance change rate of all points.

- In the following cases, linearity will not be checked:

  - The number of photometric spots is no greater than 3.
  - The absorbance change rate or the difference value of the rate is less than 0.006 per minute.
  - Reagent blank test, sample blank test, and test of zero concentration calibrator.

4.7.4 Prozone check

In antigen-antibody reactions, the insoluble antigen-antibody complex produced is closely related to proportions of antigens and antibodies. With proper proportions, the volume of the complex and the absorbance value peak, while light transmitted is minimum. However, the complex and absorbance will decrease and light increase once the proportions change. See following figure for this: without prozone check, complex volumes of two samples with very significantly different concentrations may be the same, and the measured results will also be the same.

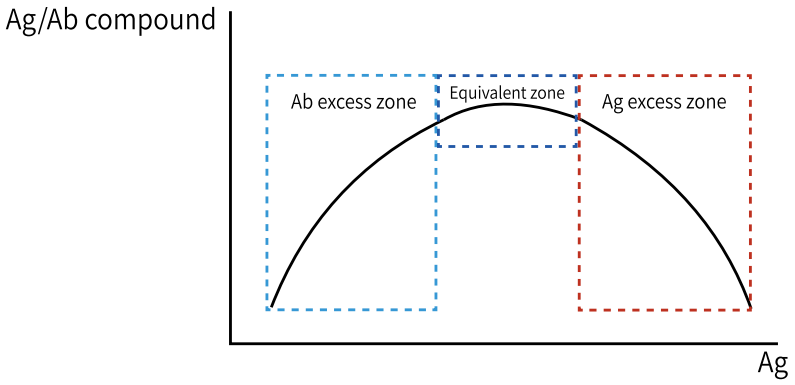


Figure 4-9 Prozone check

Follow procedures below to make prozone check in the Analyzer.

- Dual-reagent endpoint method

  As shown below, L represents the start of reaction, and M represents the start of the reaction time. N and P are prozone check points. Their relationships are 23≤L＜N＜P＜M≤ the end of the reaction time.

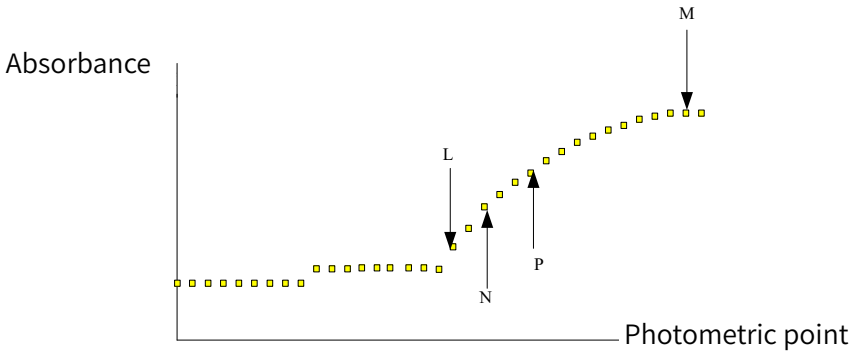


Figure 4-10 Prozone check of dual-reagent endpoint method

Prozone check value is:

$$PC=\frac{\frac{A_M-A_P}{M-P}}{\frac{A_P-A_N}{P-N}}\times 100\%$$

If the value is greater than the set prozone check limit, it means there appears a prozone phenomenon.

- Single-reagent endpoint method

  As shown below, L represents the start of reaction, and M represents the start of the reaction time. N and P are prozone check points. Their relationships are 11≤L＜N＜P＜M≤ the end of the reaction time.

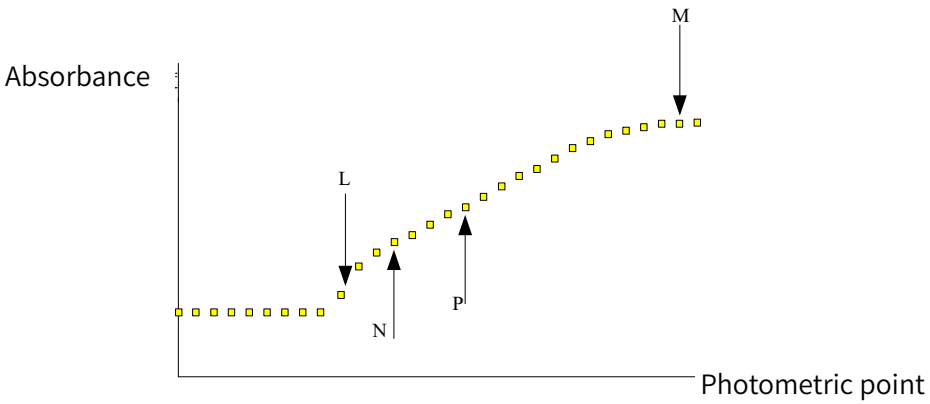


Figure 4-11 Prozone check of single-reagent endpoint method

Prozone check value is:

$$PC=\frac{\frac{A_M-A_P}{M-P}}{\frac{A_P-A_N}{P-N}}\times 100\%$$

If the value is greater than the set prozone check limit, it means there appears a prozone phenomenon.

4.7.5 Reaction balance judgment

Reaction balance judgment is used only for the endpoint method. The reaction is judged whether it reaches a balanced status in the endpoint, based on the absorbance of each photometric spot. The calculation is as follows:

- Calculate the absorbance differences between the end point and the subsequent 3 consecutive spots.
- If all differences are less than 0.01, the reaction then reaches a balanced status. If not, the reaction is not balanced.
- If the end point of reaction is greater than 49, reaction balance will not be judged.

4.7.6 Lamp status judgment

When the photoelectric data of a cuvette is higher than 32000, a warning of “Cuvette blank is beyond the limit” or “High brightness” will appear. With warning of “Cuvette blank is beyond the limit” five times in a row, tests will not be performed. After users change the bulb and the light source AD is automatically configured as required, tests can be performed again if brightness is qualified.

When the photoelectric data of a cuvette is lower than 8000, a warning of “Dirty cuvettes” will appear. If the warning pops up five times, users will be told about “Low brightness” and forbidden tests. In this case, users need to check if there are water leaks of the Analyzer. If there are no errors, users should change the bulb and the light source AD should be automatically configured as required. After this, tests can be performed again if brightness is qualified.

5 Daily operation

This chapter introduces the basic operation method and daily operations about the Analyzer. The following table will list the main operation steps.

Table 5-1 Operation steps

Operation steps	Description
1.Check before startup	Check water and power supply, liquid waste connection, the reagent-sample probe/stirring rod and residue of concentrated wash buffer.
2. Startup	Turn on the power switch of the Analyzer, and start the operating software.
3. Analyzer status check	Check the system status, alarm status, reagent/calibration status, and maintenance status.
4. Reagent preparation	Prepare biochemical reagents, wash buffer and sample diluent.
5. Calibration	Apply for calibration items, prepare calibrators, and start calibration tests.
6. QC	Apply for QC items, prepare controls, and start QC tests.
7. General test	Apply for general sample tests, prepare samples and start sample tests.
8. Start	Start the applied item tests.
9. Stop	Stop the applied item tests.
10. Sample test status and results query	Search sample test status and results.
11. Daily maintenance	Clean the reagent-sample tray chamber and Analyzer panel.
12. Shutdown	Carry out shutdown.
13. Operations after shutdown	Turn off the power supply, store samples and reagents, clean the Analyzer, empty the liquid waste, etc., for safety.

5.1 Check before startup

Before startup, users shall check the followings.

5.1.1 Check the water supply

(1) Check if the external water container holds sufficient deionized water and if water can be supplied continuously. If not, add the waster first;

(2) Check that the water pipe between the water source, the water input module, and the Analyzer is firmly connected;

(3) Check that the liquid pipes are smooth without bends or twists, or leaks.

5.1.2 Check the power supply

(1) Check the power supply to ensure that it is turned on and can provide the correct voltage;

(2) Check the power cord of the Analyzer and make sure it is firmly and tightly connected.

5.1.3 Check the probes and stirring rod

(1) Check whether the sample probe is polluted or bent.

- If polluted, clean the probe;
- If bent, replace it.

(2) Check whether the stirring rob is polluted or bent.

- If polluted, clean it;
- If bent, replace it.

5.1.4 Check wash buffer residue

(1) Check the wash buffer residue at the acid base cleaning position. If the wash buffer is insufficient, add or replace it in time;

(2) Check whether there is sufficient concentrated wash buffer in the external 5L bucket. If not, add or replace it in time.

5.1.5 Check liquid waste connection

(1) Check whether the waste liquid bucker is thoroughly drained. If not, empty the bucket;

(2) Ensure that the liquid waste tube is not bent and the waste liquid outlet cannot be over 12 cm above the ground.

Dispose of the liquid waste according to the local regulations.

5.1.6 Check moving parts

Check that the moving parts such as the reagent-sample probes, stirring rod, cleaning structure, the reaction tray, reagent-sample tray, and syringe can move smoothly without interference and can accurately pinpoint positions.

5.2 Startup

5.2.1 Turn on power of the Analyzer

(1) Prior to power cable plugging, check whether the main power switch of the Analyzer is in OFF. If not, turn the switch to OFF, and then plug in the power cable;

(2) After correctly plugging in the power cable, turn the power switch of the Analyzer to ON, and then press the Analyzer switch. The indicator will light, and the Analyzer will start. Then the initialization and self-test will be executed. After the system startup is finished, the login interface will appear, as shown in the following.

5.2.2 Login

(1) Enter the user name and password in the Login dialog box, and click "Login";

Caution

- For the first-time use, Zybio or its local distributor provides the user with an initial account and password. It is suggested to change the password when logging in the Analyzer for the first time and use the password that contains capitalized and lower-case English letters and numeric numbers to ensure the account safety;
- If you forget the password, contact Zybio or its local distributor.

(2) After login and normal startup of the Analyzer, the home page of the software will be shown, which mean the start-up process finishes.

Caution

To ensure accurate test results, wait for 30 minutes after turning on the Analyzer, and then start a test to ensure stable control of light source and temperature.

5.3 Analyzer status check

After startup, check the Analyzer statuses when necessary. For example, reagent status and maintenance and alarm status. When the Analyzer status is in problem, refer to the chapters of Maintenance and care as well as Alarm and troubleshooting.

5.3.1 Check reagent status

(1) On the main interface, choose "Status" > "Reagent tray". Open covers of all reagents, and then click "Resi D" on the interface, to select corresponding reagent positions to detect the residue;

(2) If the reagent is insufficient or used up, the corresponding position is pink indicating insufficient reagents.

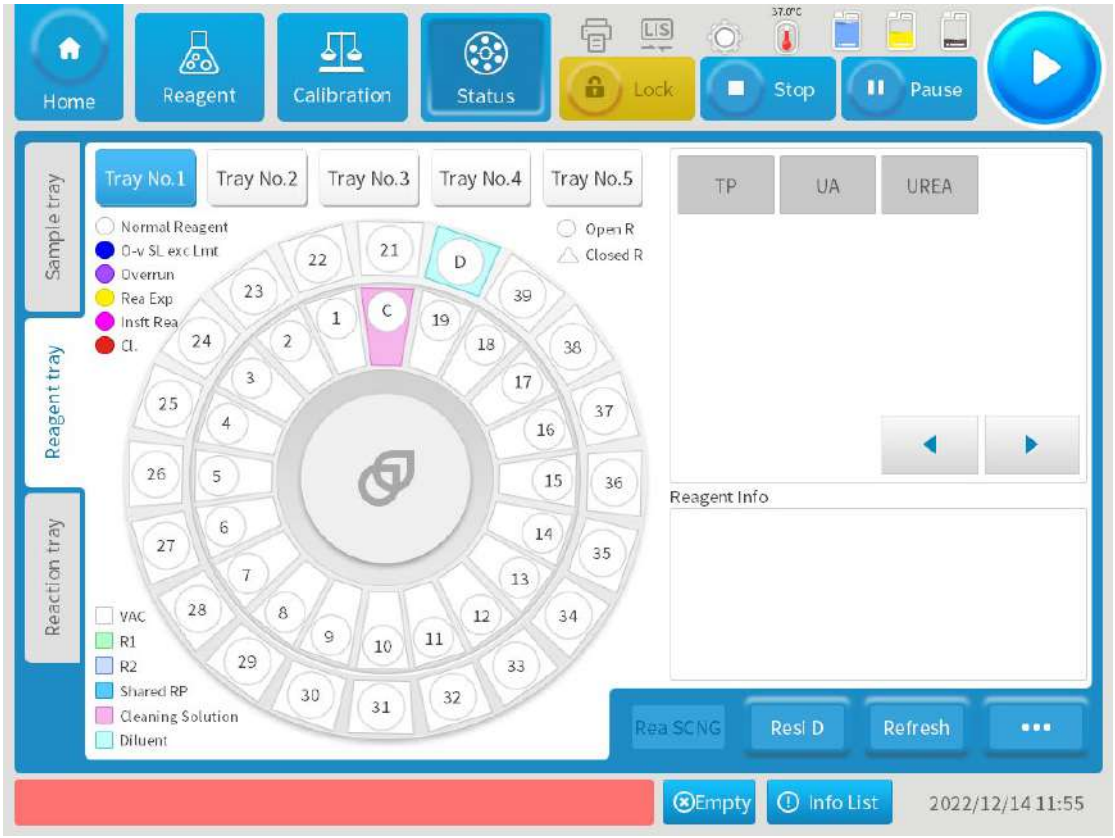


Figure 5-1 Reagent tray status

(3) Replace or add reagents based on the reagent status, and then refresh the status.

5.3.2 Check maintenance and alarm status

Check the maintenance status of the Analyzer after startup every day to confirm whether there are expired items. If yes, perform maintenance immediately to ensure normal operation of the Analyzer.

Click “Maintenance” > “Daily Maint.” > “Perd.Maint” to check if there are expired items.

5.4 Prepare reagents

After completing the pre-test check of the Analyzer, prepare the reagent for the day. Users cannot apply for test items not loaded with reagents.

There are no special requirements for reagents and all reagents in the market are suitable. Users can set or import items as measurable items of the Analyzer are unrestricted.

There are two manners to load reagents for the Analyzer: manual loading (applicable to open reagents, namely those not produced by Zybio) or loading though barcode scanning (applicable to closed reagents, namely those produced by Zybio). If the built-in barcode scanner is configured, you can choose the latter. Otherwise, you need to input reagent information manually.

- Manual reagent loading

  (1) Ensure that the Analyzer is in standby. If the Analyzer is testing, you need to click “Stop” and wait the reagent tray for stopping working. Then, click “Reagent” > “Rea Load” (or “Status” > “Reagent tray” > “...” > “Rea LD”);

(2) In the pop-up interface, you can select items, reagent types and reagent positions, and input shelf life, open-vial date, batch No. and more of reagents;

(3) Click “Save”;

(4) Then, open the reagent tray cover, place the reagents into the set position correctly and close the tray cover.

- Reagent loading though barcode scanning

(1) Ensure that the Analyzer is in standby. If the Analyzer is testing, you need to click “Stop” and wait the reagent tray for stopping working. Then, place the reagents on the reagent tray;

(2) Click “Reagent” (or “Status” > “Reagent tray”) > “Rea SCNG” to enter the “Reagent barcode scanning” interface;.

(3) Select “Tray No.”, and then you can choose to scan all reagent positions by ticking “Select All”, or input position Nos. in the “Selection range” you want to scan;

(4) Click “Start”, and the Analyzer starts scanning the selected reagent positions and acquire reagent information. When loading the reagent firstly, you can only modify “O-vial D”.

Wear gloves, masks and protective clothes during operation to prevent infection. Besides, wear safety goggles, if needed. Do not touch the reagent. Otherwise, skin damage or inflammation may be caused.

Note

If the built-in barcode scanner is configured and the closed reagent position is set, the barcode will be scanned whenever the Anlalyzer powers on.

5.5 Prepare concentrated wash buffer

The concentrated wash buffer is a basic one that requires PH value is greater than 8.5. It is used to clean cuvettes and can only be added manually. When adding the wash buffer, remove the cover, take out the float sensor, and install the sensor and cover to a new bucket of concentrated wash buffer.

Note

- When taking out and installing liquid level sensor components, please note that the tube and sensor cannot touch wash buffer bottles and other parts, and do not pull the sensor cable and tube forcibly.
- Do not put the sensor taken out on the Analyzer rack or other parts, but in a new bottle to avoid pollution of wash buffer.
- After changing the wash buffer, clear up the dripped liquid.
- Before loading the intensified wash buffer, make sure that there is no bubble in the reagent bottle to ensure the cleaning effect.

5.6 Prepare intensified wash buffer

Intensified wash buffer is used to clean reagent-sample probes. It can only be loaded manually. When the wash buffer is expired or insufficient, please replace it or add more.

5.7 Prepare sample diluent

For diluent items, sample diluent is needed and can only be loaded manually. The diluent mainly refers to physiological saline. When testing diluent items, users can set dilution ratio based on dilution multiple.

5.8 Calibration

Calibration tests are intended to calculate calibration parameters, so as to further calculate sample results. Users are recommended to carry out a calibration test in any of the following cases:

- An alarm is generated during the QC test while the reagent, calibrator, and control are not expired.
- Change the reagent batch No. or vial No.
- The calibration validity of an item is expired.
- Change the calibration rules, including the calibration method, the number of repetitions, the calibrator concentration and the calibrator used.
- Replace the light source lamp, syringe, reagent-sample probe, etc.

Users need to perform calibration If any of the following parameters is modified:

- Dominant wavelength.
- Sub wavelength.
- Blank time.
- Reaction time.
- Reagent volume.
- Sample volume.
- Analysis method.
- Reaction direction.
- Unit of the sample blank and result.

Warning

When performing calibration tests repeatedly, do not damage the Analyzer and reduce protection against risks.

5.8.1 Prepare calibrators

When making a calibration test, users need to prepare the calibrator in advance and manually add the calibrator. There are no special requirements for calibrators and users can order those produced by Zybio or other manufacturers. Note that calibrators must be within the shelf life.

5.8.2 Calibration tests

In any of the foregoing cases, take the following steps to apply for calibration. Before performing calibration of a chemical item, make sure that the calibrator is correctly configured.

5.8.2.1 Calibrator setup

Click "Calibration" > "Cal Setting" to enter the following page where users can set the position, batch No., shelf life and concentration of calibrators.

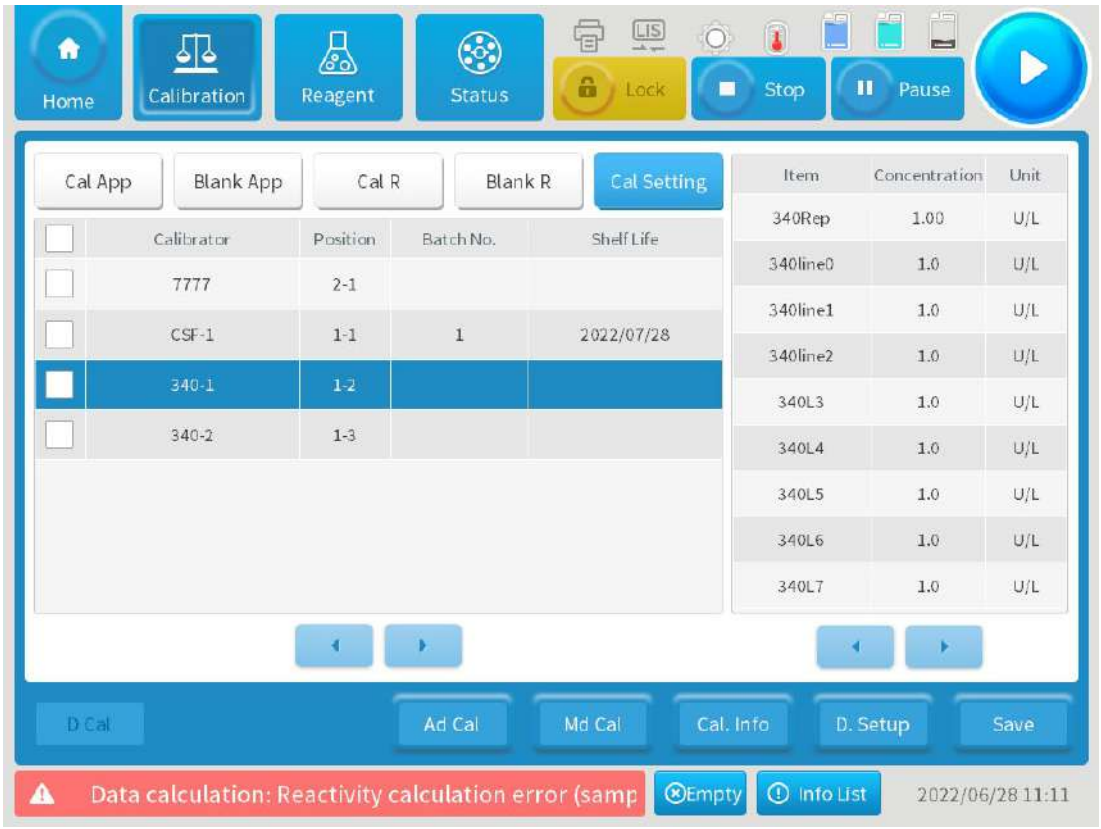


Figure 5-2 Calibration settings

Parameters	Definition	Operation
Cal App	Apply for calibration	Click it to enter the interface of calibration application
Blank App	Apply for reagent blank	Click it to enter the interface of blank application
Cal R	Search calibration results	Click it to enter the interface of calibration result search
Blank R	Search blank test results	Click it to enter the interface of blank result search
Cal Setting	Set calibrator parameters	Click it to enter the interface of calibration settings
Select	Tick calibrators	Tick calibrators with a click and cancel ticking with another click

Parameters	Definition	Operation
Calibrator	Name of calibrators	No operation required
Position	The tray No. and cuvette positions for calibrators	No operation required
Batch No.	Batch No. of calibrators	No operation required
Shelf life	Shelf life of calibrators	No operation required
Item	Item name	No operation required
Concentration	Set the calibrator concentration of the current items	Input the concentration
Unit	Concentration units	No operation required
Ad Cal	Add other calibrators	Click it to enter the interface of calibration addition
Md Cal	Modify calibrator settings	Click it to enter the interface of modifying calibrators
D Cal	Delete calibrators from the list.	Click it
Cal. Info	Set calibration information of items	Click it to enter the interface of calibration information
D. Setup	Set calibration dilution parameters	Click it to enter the interface of dilution settings

- Add calibration

  (1) Click “Ad Cal”, and the “Add Calibrator” window will pop up;

  (2) Input name and batch No. of calibrators;

  (3) Drop down to select shelf life of the calibrator;

  (4) Click “SEL. Pos.”, select tray No. and cuvette No.in the dialog box popped up and then click “OK”;

  (5) Click “SEL. Item”, select related items in the dialog box popped up and then click “OK”;

  (6) To save the added calibrator, click “Save”. Otherwise, click “Cancel”.

- Set calibrator concentration

  (1) Select (Click to select, not ticking) the to-be-set calibrator in the left list;

  (2) Then, in the right concentration list, users can see the corresponding item and input the concentration in the corresponding box next to the item name;

  (3) To save the input concentration, click “Save”.

- Modify calibrator

  (1) Select the to-be-modified calibrator in the left list, but users cannot modify calibrator information during a test;

  (2) Click “Md Cal”, and input correct information in the box popped up. The operation is the same as that of “Add calibrator”;

(3) To save the modified information, click “Save”. Otherwise, click “Cancel”.

- Delete calibrator

(1) Select the to-be-deleted calibrator in the left list;

(2) Click “D Cal”;

(3) Click “OK” to confirm the deletion, or click “Cancel”.

- Calibration information

(1) Click “Cal.Info”, and the “Calibration information” window will pop up;

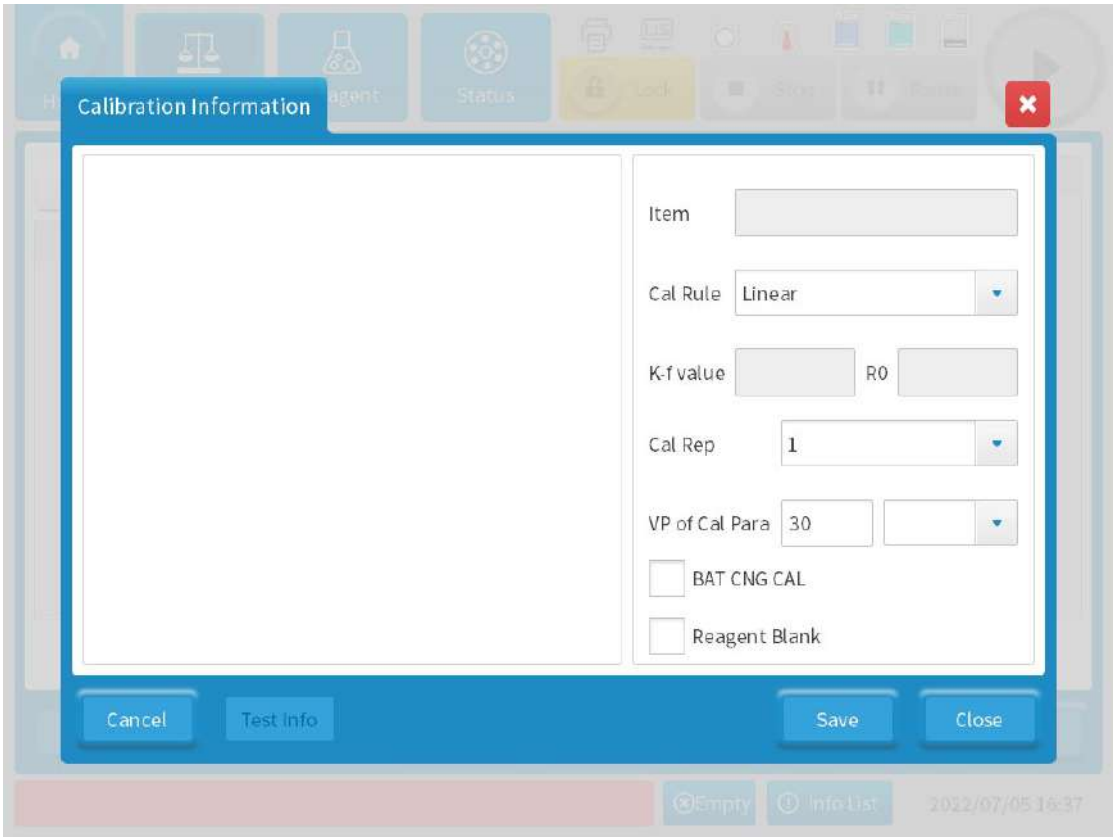


Figure 5-3 Calibration information

(2) In the left item list, select to-be-set item;

(3) In the calibration rule on the left, click the drop-down icon to select a proper calibration rule. And if necessary, select “BAT CNG CAL”, “V CNG Cal/sb” or “Reagent Blank”;

(4) Click “Test Info” to set the calibration test information;

(5) After confirmation, click “Save”. Otherwise click “Cancel”.

5.8.2.2 Calibration application

Click “Cal App” to enter the following interface to apply for calibration test and reagent blank.

Figure 5-4 Calibration application

Parameters	Definition	Operation
Sam T	Select the tray No. for calibrators.	Drop down to select
Rea T	Select the tray No. for reagents.	Drop down to select
Item	The name of the item selected in the item list.	No operation required
Rea B	Tick it to make reagent blank	Tick it or cancel ticking
Dil Cal	Perform dilution calibration or not	No operation required
Sel Cal	Select the calibrator foe an item	Click it to enter the interface of selecting calibrators.
App List	View lists of items that has been applied for calibration	Click it to enter the interface of calibration application list.

- Calibration application

  (1) Click “Calibration” > “Cal App”;

  (2) Drop down to select the tray No. of calibrators and reagents;

  (3) Select the to-be-calibrated item in the left side; To perform reagent blank tests simultaneously, tick “Rea B” in the right side of Item Selected. After ticking, ☑ will be shown;

(4) In the right side of "Item Selected", select one item. Then, click "Sel Cal" to pop up the "Select Calibrator" interface where users can select the required calibrator for the item. Last, click "Save" > "Close" to return to the "Cal App" interface;

(5) To save the applied calibration test, click "Apply". If not, click "Cancel".

- Delete calibration application

(1) Click "App List" to pop up the "Calibration application list" interface;

(2) Tick to-be-deleted calibration items and then click "Delete". Otherwise, click "Close".

5.8.2.3 Calibration results search

Click "Cal R" to enter the calibration result interface where users can view calibration results, curve, etc.

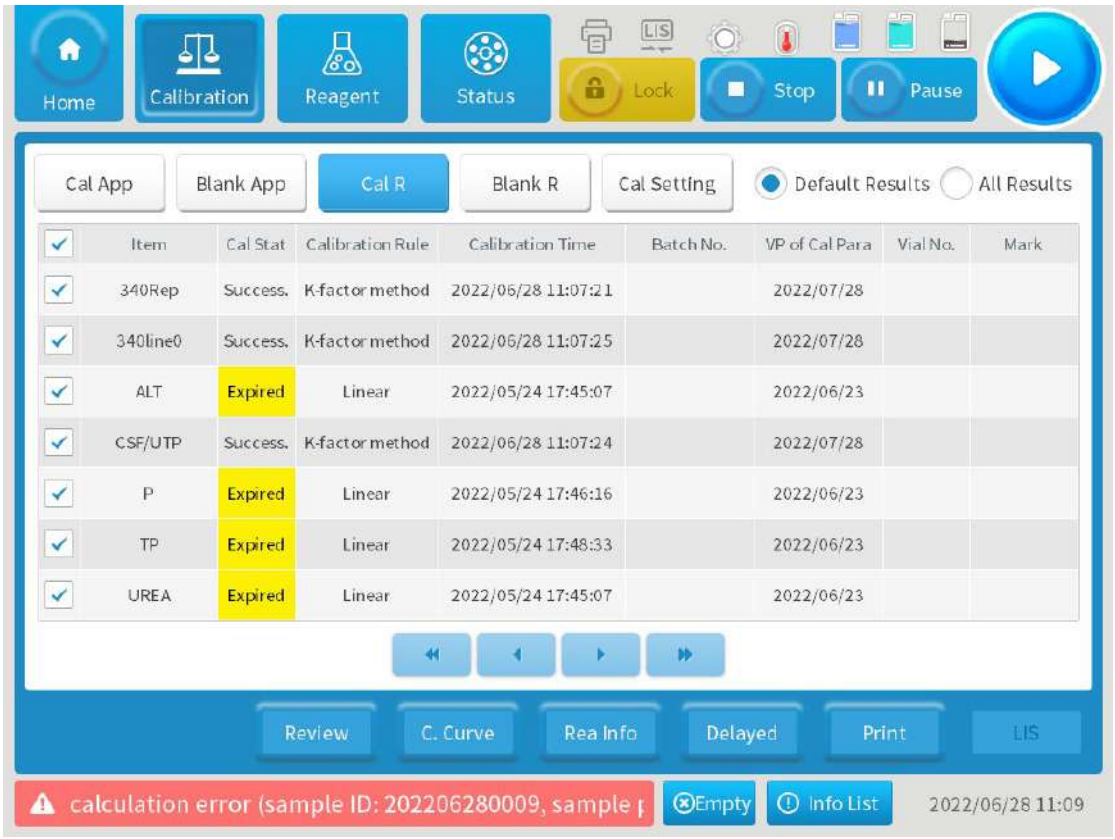


Figure 5-5 Calibration results

Parameters	Definition	Operation
Item	Name of calibration items	No operation required
Cal Stat	The status of reagent calibration, including successful, failed, expired and delayed	No operation required
Calibration Rule	Include linearity calibration, Logit-4P, Logit-5P, Exponential-5P, Polynomial-5P, Spline and K factor method	No operation required

Parameters	Definition	Operation
Calibration Time	Calibration start time	No operation required
VP of Cal Para	Valid period of calibration parameters	No operation required
Default	The calibration result is default or not	No operation required
Mark	Mark for calibration items, including using expired calibrators (ECF), using expired reagents (ER) and recalculating calibration results (#).	No operation required

- Search calibration results

  (1) Click "Review" in the "Cal R" interface to open the calibration result review interface;

  (2) Select the item for which you need to search results and drop down to select calibration date;

  (3) Then, click "OK".

- View calibration curve

  (1) Select the item for which you need to view the calibration curve in the "Cal R" interface. Then, click "C. Curve" to enter the calibration curve interface. See the following figure:

  (2) Click "Cal P" to view the calibration parameter in the pop-up window;

  (3) Select the calibrator in the right side of "Calibrator Data" and then click "RT Curve" to view the reaction curve for the calibrator;

  (4) After clicking "Blank C", drop down to select the test date in the pop-up window. Then, click "Review" and select reagent blank for the item. Clicking Calibration indicates finishing calibration. Otherwise, click "Close";

  (5) Drop down to change the calibration rule, or click "Recal" after changing the selected calibrator. Then refresh the calibration curve and re-calculate calibration parameters;

  (6) To view calibration test information, click "T info";

  (7) Click "Save" to save the change;

  (8) Click "Print" to print the calibration curve;

  (9) Click "Close" to close the calibration curve interface.

- View reagent information

  (1) Select an item in the "Calibration result list";

  (2) Click "Rea Info" to view the reagent category, batch No., vial No., and more for the item.

- Delay

  (1) Select an or multiple items in the calibration result list;

  (2) Click "Delayed" to enter the delayed calibration parameters interface;

(3) Drop down to set the delayed date. The delayed date and previously set calibration parameter valid period mean the latest valid period.

- Set as D

(4) Select an item in the "Calibration result" interface;

(5) Click "Set as D" to set the calibration result as the default one.

- Print

(1) Select an item in the "calibration result list";

(2) Click "Print" to print the selected or all results in the pop-up dialog box.

- LIS

(1) Select an item in the "calibration result list";

(2) Click "LIS" to send the selected or all results in the pop-up dialog box.

5.8.2.4 Reagent blank

- Apply for reagent blank

(1) Click "Calibration" > "Blank App" to enter the "blank application" interface;

(2) Select the item to be tested for reagent blank in the lower side;

(3) To save the applied reagent blank test, click "Apply". If not, click "Cancel".

- Delete reagent blank

(1) Click "Blank App" > "App List" and the list for reagent blank application will pop up;

(2) Select the reagent blank item to be deleted;

(3) To deleted the selected item, click "Delete". If not, click "Close".

5.8.2.5 Reagent blank result

Click "Blank R" to enter the blank result interface where users can view blank results, reaction curve, etc.

- Search blank results

(1) Drop down to select test date;

(2) Select a to-be-searched item in the left item list;

(3) Click "Query", and then the test date and reagent blank reactivity will be displayed on the right side.

- Reagent information

(1) Select a result in the right list;

(2) Click "Rea Info" to view the reagent category, batch No., vial No., and more for the item in the pop-up interface;

(3) Click "Back" or "Next" to present different reagent information.

- View blank reaction curve

(1) Select a to-be-viewed result in the right item list;

(2) Click “RT Curve” to enter the blank reaction curve.

- Delete reagent blank result

  (1) Select a to-be-deleted result in the right item list;

  (2) Click “Delete”.

- Print reagent blank result

  (1) Select a to-be- printed result in the right item list;

  (2) Click “Print”.

5.9 QC

The QC test guarantee the accuracy of sample test results. Users are recommended to carry out QC tests every day.

5.9.1 Prepare controls

When performing a QC test, users need to prepare the control in advance and manually add it. There are no special requirements for controls and users can order those produced by Zybio or other manufacturers. Note that controls must be within the shelf life.

5.9.2 QC tests

Users can apply for a QC test based on the control or on the combination of control and item. You need to select at least one item. Otherwise, the application cannot be submitted. Make sure that you have configured the mean and the standard deviation for the item Otherwise, the application cannot be submitted.

5.9.2.1 Control settings

Click “QC” > “QC Setting” to enter the following interface:

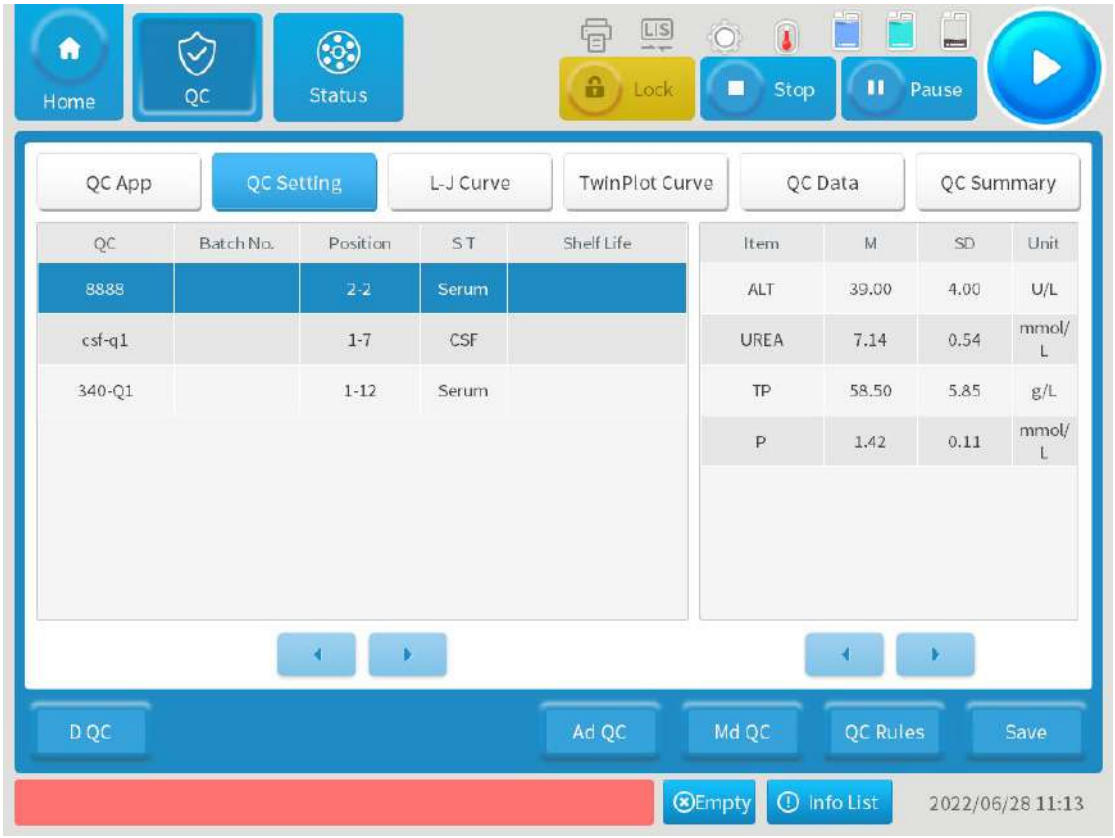


Figure 5-6 QC settings

Parameters	Definition	Operation
QC	Name of controls	No operation required
Batch No.	Batch No. of controls	No operation required
Position	Tray and cuvette No. of controls	No operation required
S T	Sample type	No operation required
Shelf life	Shelf life of controls	No operation required
Item	Item names	No operation required
M	The mean of controls for each item	Input in the box.
SD	The standard deviation of controls for each item	Input in the box.
Save	Save the input control information.	Click it.
Ad QC	Add new controls	Click it to enter the interface of control addition.
Md QC	Modify control settings	Click it to enter the interface of modifying control
D QC	Delete controls from the list	Click it.
QC Rules	Set QC rules for items	Click it to enter the interface of QC rules

- Add controls

  (1) Click “Ad QC” to enter the control addition interface;

  (2) Input QC name and batch No.;

  (3) Drop down to select sample type and shelf life of the control;

  (4) Click “SEL Pos.”, select tray No. and cuvette No.in the pop-up dialog box and then click “OK”;

  (5) Click “SEL Item”, select related items in the pop-up dialog box and then click OK;

  (6) To save the added control, click “Save”. Otherwise click “Cancel”.

- Set the mean and standard deviation of the control

  (1) Select an item in the left control list;

  (2) Then, in the right list, users can see the corresponding item name and input the mean and standard deviation in the corresponding box next to the name;

  (3) To save the input information, click “Save”.

- Modify QC

  (1) Select the to-be-modified control in the left list, but users cannot modify control information during a test;

  (2) Click “Md QC”, and input correct information in the pop-up box. The operation is the same as that of “Add control”;

  (3) To save the modified information click “Save”.

- Delete controls

  (1) Select the to-be-deleted control in the left list;

  (2) Click “D QC”. To delete, click “OK”. Otherwise, click “Cancel”.

- Set QC rules

  (1) Click “QC Rules” to enter the QC rule settings interface;

  (2) Select an item on the left side and tick “QC rules” on the right side of “Multi-rule QC”;

  (3) To make joint QC, users need to select QC (X) and QC (Y);

  (4) If you do not want to make joint QC, users do not need to select QC (X) and QC (Y); but just click “Save”;

  (5) And click “Close” to exit the interface.

5.9.2.2 QC application

Click “QC App” to enter the following interface:

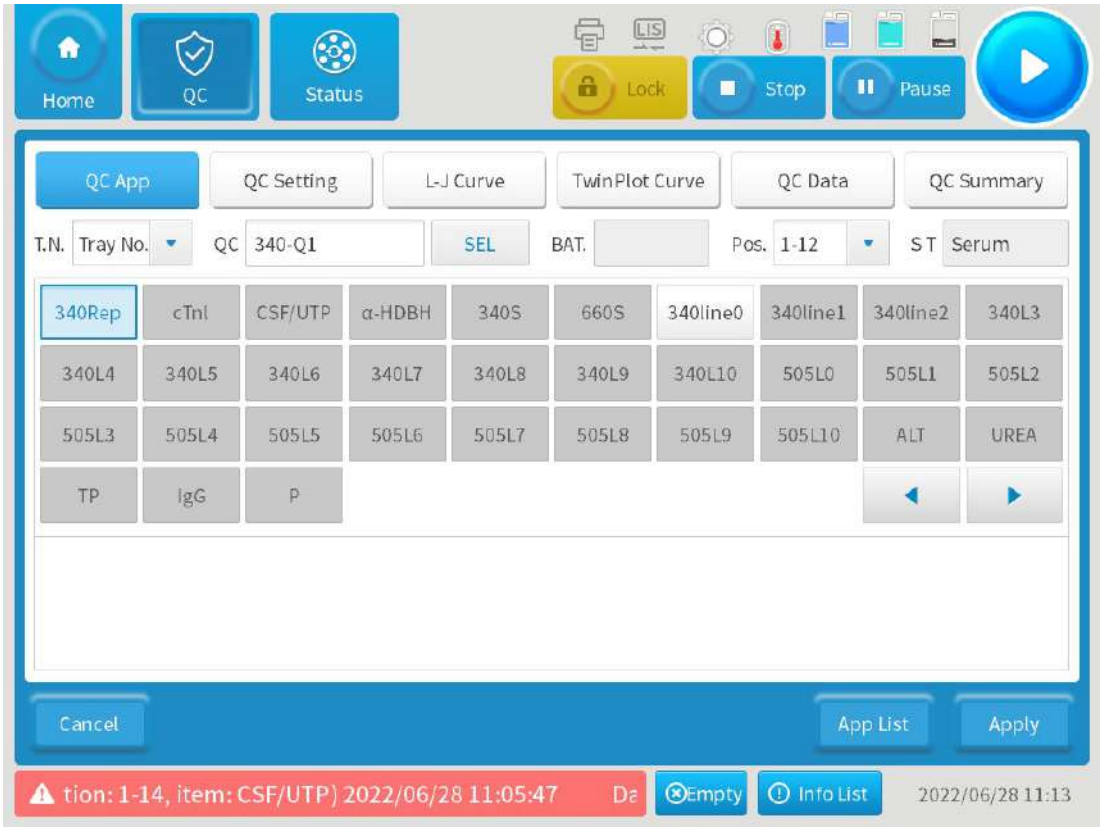


Figure 5-7 QC application

Parameters	Definition	Operation
T.N.	The selected tray No. of controls	Select in the drop-down list.
QC	The set name of controls	Click SEL to enter the interface of selecting controls.
BAT.	The selected batch No. of controls	No operation required
Pos.	Tray and cuvette No. of controls	Select in the drop-down list.
S.T	The sample type of the selected controls	No operation required
App List	The list of samples applied for QC	Click App List to view the application list
Cancel	Cancel this QC application	Click it to return to the previous menu
Apply	After selecting an item, click Apply	Click it.

- Apply for QC

  (1) Click “QC App” to enter the QC application interface;

  (2) Click “QC” > “SEL” (and “S T”) to confirm the control batch No. and sample type;

  (3) If not selecting the control position, drop down in the “Pos.” menu to select the

tray and cuvette No.;

(4) Select the QC item from “Regular items” or “Joint items”;

(5) Click “Apply”.

- Delete QC application

(1) Click “App List” to enter the application list interface;

(2) Select the to-be-deleted QC application;

(3) Click “Delete” to confirm deletion. Otherwise, click “Close”.

5.9.2.3 QC data

Click “QC Data” to enter the QC test data interface as shown below:

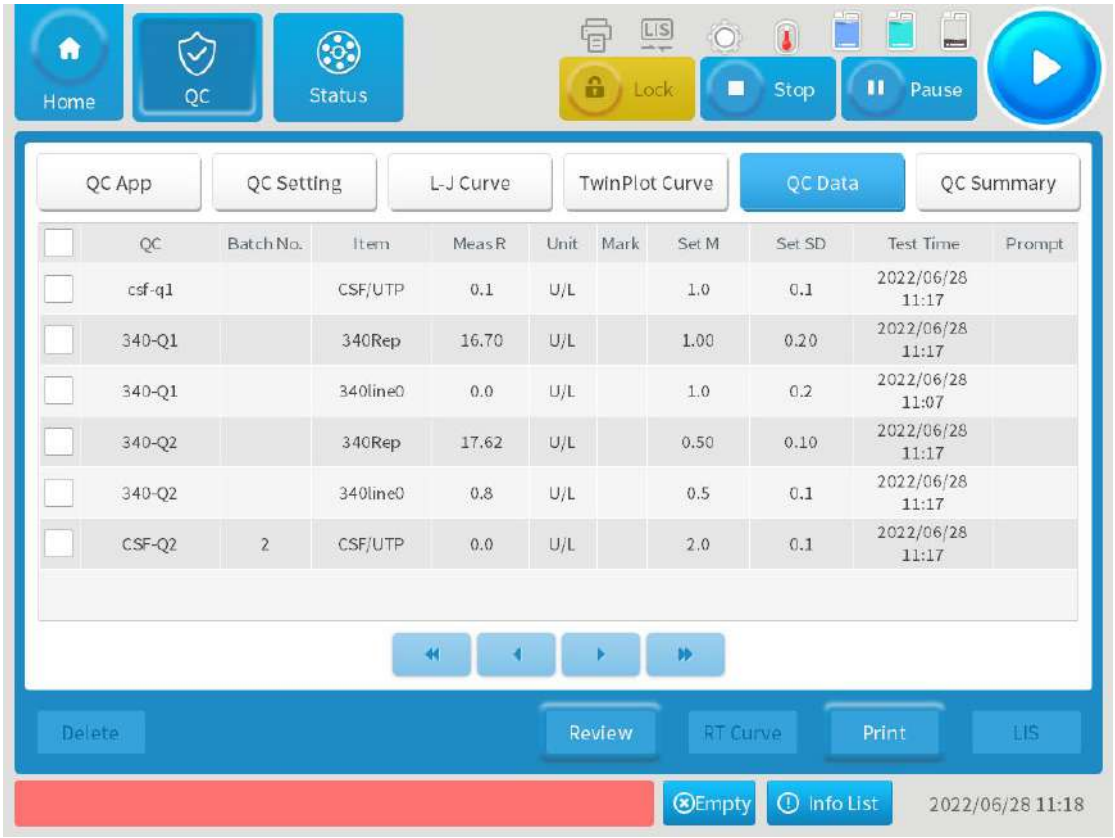


Figure 5-8 QC data

Parameters	Definition	Operation
QC	Name of applied controls	No operation required
Batch No.	Batch No. of applied controls	No operation required
Item	Items for controls	No operation required
Meas R	QC results	No operation required
Unit	A unit of QC results	No operation required
Set M	The set mean in QC settings	No operation required

Parameters	Definition	Operation
Set SD	The set standard deviation in QC settings	No operation required
Mark	Mark symbols include using expired controls “+”, using expired reagents “&”, out of control of QC “1_{2S}, 1_{3S}, 2_{2S}, R_{4S}, 4_{1S}, 10_{X}”, etc.	No operation required
Prompt	Marking symbols, including: use of expired QC “EQC”, use of expired reagent “ER”	No operation required
Test time	Start time of QC tests	No operation required

(1) Click “Review”, click item and QC in the pop-up window and drop down to select QC date. Then, click “OK” to search QC results;

(2) Tick one QC result and click “RT Curve” to view the curve for the results;

(3) Tick one QC result and click “Delete” to delete the results;

(4) Tick one QC result and click “Print” to print the ticked or all QC results in the pop-up box;

(5) Tick one QC result and click “LIS” to send the ticked or all QC results in the pop-up box.

5.9.2.4 QC summary

Click “QC summary” to enter the QC summary interface as shown below:

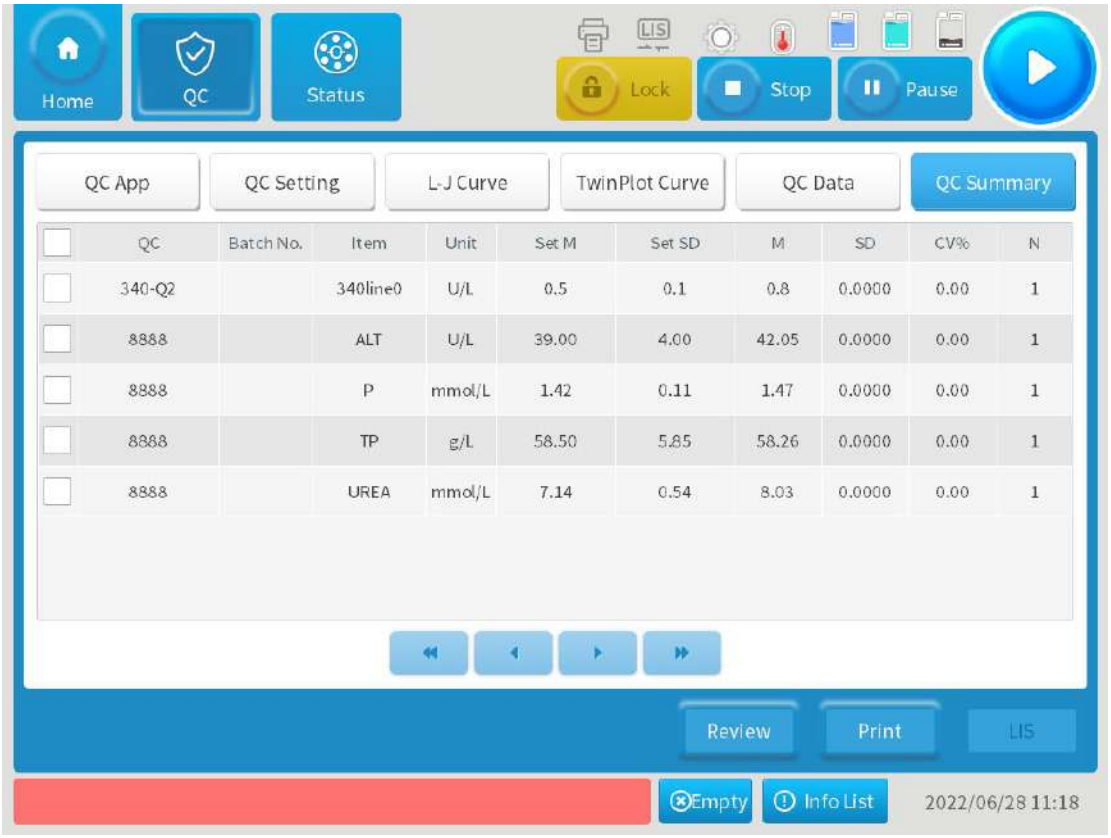


Figure 5-9 QC summary

Parameters	Definition	Operation
M	The mean of all QC results for the same control and item	No operation required
SD	The standard deviation of all QC results for the same control and item	No operation required
CV%	The repeatability CV% of all QC results for the same control and item	No operation required
N	The total test numbers of all QC results for the same control and item	No operation required

(1) Click “Review”, click item and QC in the pop-up window and drop down to select QC date. Then, click “OK” to search QC results;

(2) Tick one QC result and click “Print” to print the ticked or all QC results in the pop-up box;

(3) Tick one QC result and click “LIS” to send the ticked or all QC results in the pop-up box.

5.9.2.5 L-J Curve

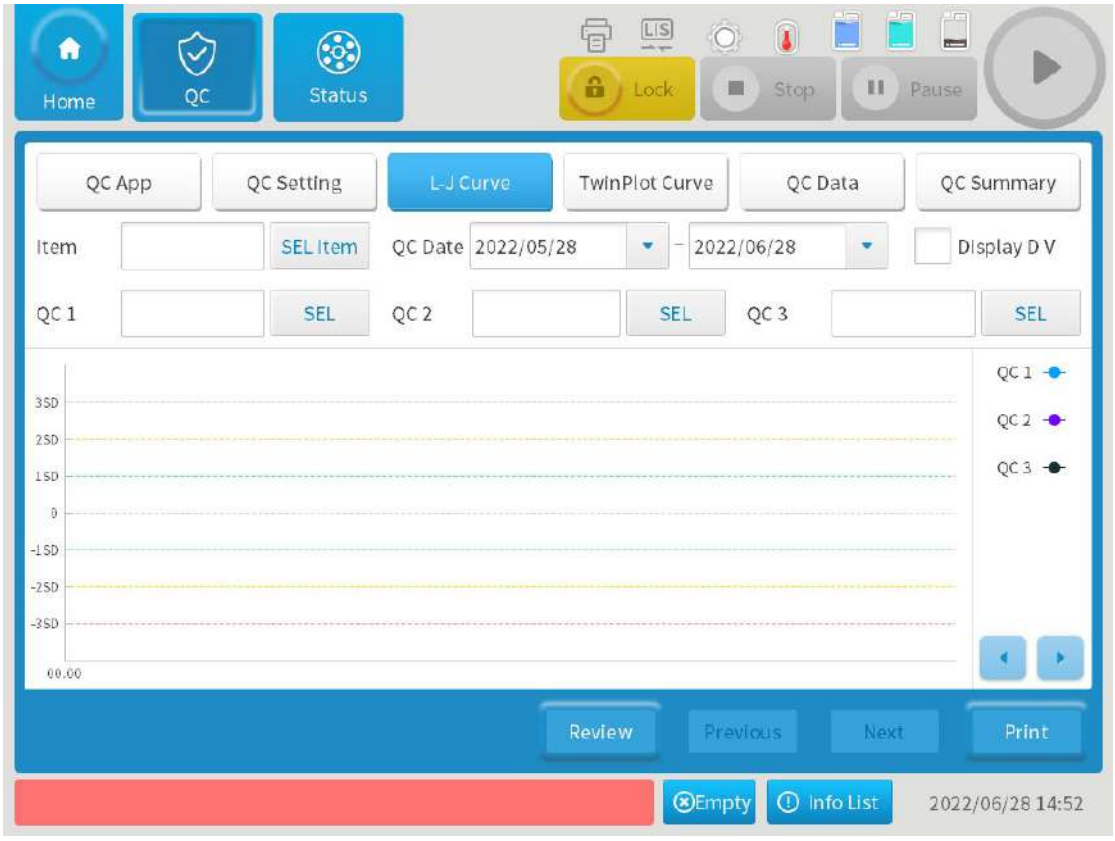


Figure 5-10 L-J Curve

(1) Click “SEL Item” and drop down to select QC Date. Then click “Review” to view QC results L-J curve;

(2) To view results of other controls, click “QC 2” and “QC 3”;

(3) To present the QC results deleted in QC Data, tick “Display D V”;

(4) Click “Previous” or “Next” to view the previous or next QC results in the item list;

(5) Click “Print” to print QC results;

(6) Click “LIS” to send QC results.

5.9.2.6 TwinPlot Curve

Figure 5-11 TwinPlot Curve

(1) Click “SEL Item” and drop down to select QC Date. Then click “Review” to view QC results. And the name, mean and standard deviation of control X and Y will be displayed in the lower left corner;

(2) Other operations are the same as those of L-J Curve.

5.10 General test

This section will introduce how to apply for general sample tests.

In the sample application menu, users can apply for sample tests and batch sample as well as repeatable tests when needed, and also view the application list, input patient information and more.

Click “Sample” icon on the main interface to enter the sample application interface as shown below.

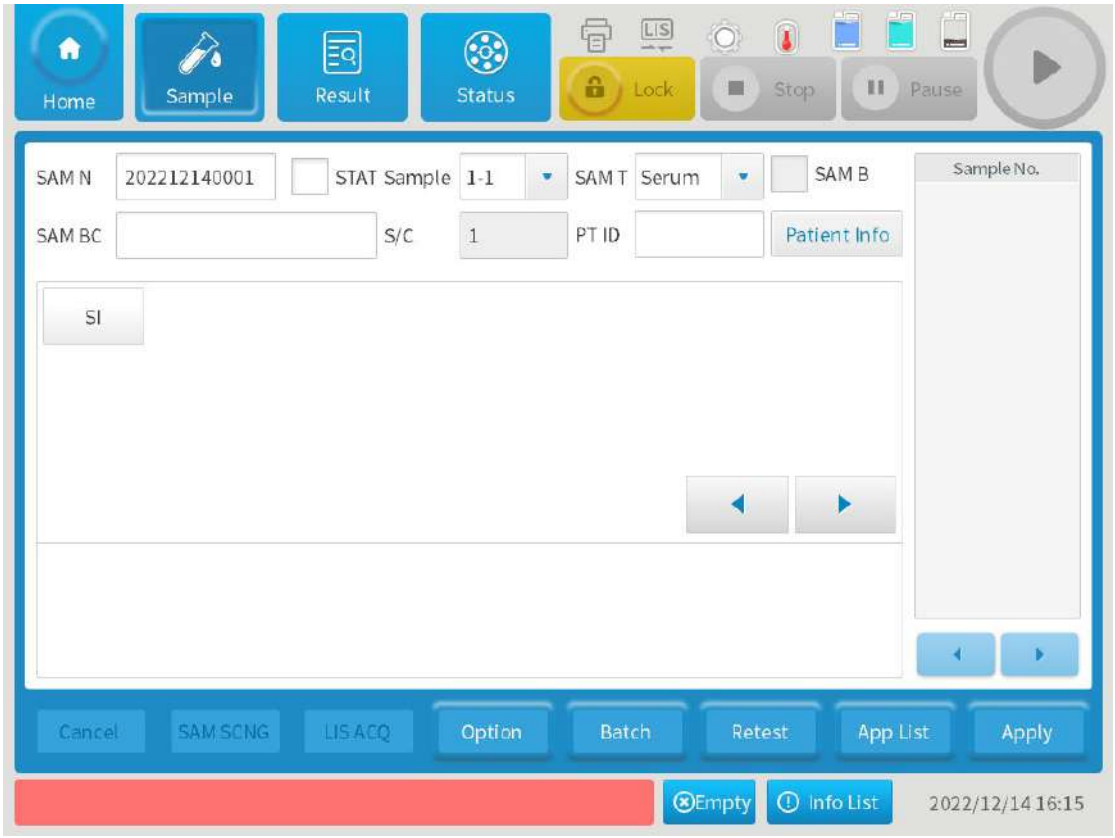


Figure 5-12 Sample application

Parameters	Definition	Operation
SAM N	Testing sample No.	Input in the box
STAT	Set this sample as emergency	Ticking the box indicates selecting emergency
Sample	Select sample positions	Select the tray and cuvette No. in the drop-down box
SAM T	Select sample types	Select them in the drop-down list
SAM BC	Testing sample barcode	Input in the box
PT ID	Input the patient information	Click it to enter the patient information interface
S/C	Sample serial code	Input in the box
SAM B	Perform sample blank tests	Tick the box with a click and cancel ticking with another click
SAM SCNG	Scan sample barcode	Click it to view the sample scanning dialog box
LIS ACQ	Select information acquired by LIS	Click it to enter the setting interface
Option	Select a test method	Click it to enter the option interface
Batch	Apply for batch sample testing	Click it to enter the batch application interface
Retest	Retest items	Click it to enter the retest interface

Parameters	Definition	Operation
App List	View lists of applied sample and items	Click it to enter the applied sample review interface
Cancel	Cancel this sample application	Click it
Apply	Apply tests	Click it

Note:

- Sample positions include the tray No. and cuvette No. General samples support virtual tray settings. At most 5 trays can be set. By default, the positions are assigned starting from cuvette No. 1 on tray No. 1 each day. Occupied positions cannot be selected unit until they are released.
- A sample No. consists of digits prefixed with the date. The samples are numbered starting from 0001. Users can directly enter digits ranging from 1 to 9999, and the system converts the digits into the default format. If you enter digits exceeding the range, an error is reported, prompting you to re enter digits in the correct format. Users cannot set the previous No. after releasing the sample position unit the sample is deleted.

Basic operation

- Apply for a sample

  If the built-in scanner is configured, the Analyzer can acquire sample barcodes automatically. And you can also choose to input sample information manually.

  (1) Acquire sample barcodes by one of the two ways below;

  - Directly input the barcode in the box of “SAM BC”.
  - Click “SAM SCNG”. Select “Tray No.”, and then you can choose to scan all sample positions by ticking “Select All”, or input position Nos. in the “Selection range” you want to scan. Next, click “Start”.

  (2) Enter sample No. and serial code;

  (3) Select the sample tray position in the drop-down box of “Sample” and sample types in “SAM T”;

  (4) Click to select the test item, click once to select, and click again to cancel;

  (5) Click “Apply” after confirmation.

- Apply for batch samples

  (1) Select the sample tray position in the drop-down box of “Sample”;

  (2) Select sample types in the drop-down box of “SAM T” and input “S/C”;

  (3) Click to select the test item, click once to select, and click again to cancel;

  (4) Click “Batch” and input the start and end numbers or input batch numbers in the pop-up box. Then click “OK”;

  (5) Click “Apply”.

Note

- When applying for batch sample, the batch sample No. and the sample positions on the sample tray increase from the No. and position of the starting sample;
- The starting sample of batch application must be one not applied. And if the sample position increasing in order includes those samples with status as Applied, Testing, Unfinished or Completed, then the sample position will be ignored and set from the next sample.

- Delete sample application

  (1) Click "App List" to enter the application list interface;

  (2) Select the sample to be deleted in the "Sample List". The interface also offers the "Query" option through which you can search the sample based on sample status, sample No., sample barcode and serial code;

  (3) Click "Delete" to enter the pop-up window where users can select the selected sample, deleted samples in the designated tray or delete all samples. Then, click "OK";

  (4) For deleting items, select one on the left side of the "Sample List", tick the to-be-deleted item on the right side and then click "Delete". Or click "Item List", select one and then click "Delete".

- Apply for adding or reducing sample tests

  (1) Select an item No. and then click "Option";

  (2) In the pop-up window, choose the test mode;

  (3) After this, click "Save".

- Retest

  (1) Click "Retest" to enter the retest window;

  (2) In the window, select the date, position and item of the to-be-retested sample;

  (3) Click "OK" and then the Analyzer will retest.

- Patient information

Parameters	Definition	Operation
SAM N	Sample No.	No operation required
SAM BC	Sample barcode	No operation required
S/C	Sample serial code	No operation required
PT ID	Patient No.	Input the No.
PT NM	Current patient name	Input in the box
Gender	Current patient gender	Select one in the drop-down list
Age	Current patient age	Input the patient age in the first box, then select one in the drop-down list of the second box.
BLD T	Current patient blood type	Select in the drop-down list
Ad No.	Patient admission No.	Input in the box
Bed No.	Patient bed No.	Input in the box

Parameters	Definition	Operation
SAM D	Sampling date	Drop down to select
SAM T	Sampling time	Input or drop-down options
Sub D	Sample submission date	Drop down to select
Dep.	Where the patient stays	Input or click the options
Submitter	The doctor who writes out the inspection application form for the current patient	Directly input or click the options
INSP D	Sample inspection date	Drop down to select
DIAG R	Diagnosis result of the current patient	Input or click the options
Exa Phys	The doctor who inspects the patient sample	Input or click the options
Reviewer	The person who reviews the inspection report	Input or click the options
Note	Note the special conditions or other related contents about current patient	Input or click the options
Query	Search the sample No. and barcode	Click Query
Previous	View information of the previous patient	Click it
Next	View information of the next patient	Click it
Cancel	Do not save this input information	Click it
Save	Save this input information	Click it
Close	Close the patient information window	Click it

Input the patient information

(1) Click “Patient Info” and input related information in the pop-up window;

(2) Then, click “Save” to save information.

5.11 Emergency test

This section will introduce how to apply for emergent sample tests.

Apply for a sample

(1) Refer to steps for general tests, input or scan the sample barcode, serial code and sample No., and select the sample position and type;

(2) Then, select the “STAT” box;

(3) Click to select the test item, click once to select, and click again to cancel;

(4) Click “Apply”.

Apply for batch sample

(1) Select the sample tray position in the drop-down box of “Sample”;

(2) Select sample types in the drop-down box of “SAM T” and input “S/C”;

(3) Select the “STAT” box;

(4) Click to select the test item, click once to select, and click again to cancel;

(5) Click “Batch” and input the start and end numbers or input batch numbers in the pop-up box. Then click “OK”;

(6) Click “Apply”.

5.12 Start

Start testing the completed sample/item application. See below for the basic operation:

(1) Click “Start” to enter the “Start A Test” interface. You can choose to select sample or reagent tray No. and tick the “SAM SCNG” box. You can also input S/C or sample position, or click “SEL” to select positions or tick “All”;

(2) Then, click “OK”, and the Analyzer will start a test.

5.13 Pause

Pause means ending after adding samples. The “pause” option is only applied in the case that users need to stop the current operation.

Click “Pause” > “OK”. All tests will stop immediately except that the single-reagent items added with R1 will continue to execute adding samples and dual-reagent items added with S will execute adding R2. After this, the sample tray and sample probe will stop rotating, and in this case, other samples can be added.

5.14 Stop

- Function description
  - Stop all the ongoing tests in which reagent R1 is not added. Tests with reagent R1 added proceed to subsequent steps, for example, adding samples and reagent R2.
  - During the stop for reagent addition, the reaction tray continues to operate. After all the sample and reagent R2 (if the dual-reagent item) addition is completed for the items in ongoing testing, the reagent-sample tray and reagent-sample probe stop moving. Then, users can add samples and reagents.
- Steps

  (1) Click “Stop” in the upper right corner of the interface. The Analyzer will stop adding the reagent;

  (2) After stop ends, click “Start” on the right side to re-start the test.

5.15 Sample test status and results query

- View sample test status

  (1) Click “Status” > “Sample tray”. Select the position for the to-be-viewed sample and then users can see the test status of all designated sample items in the test list;

  (2) Click “Status” > “Reaction tray” and then you can see the current status of all cuvettes; Click “RT Curve” in the reaction try interface to view the curve of the valid test (Sample, calibration, QC, sample blank and reagent blank).

- View sample test results

  Click “Result” on the main interface > “Historical Results” / “Historical Results” to view the current and historical test results.

5.16 Daily maintenance

Before a test each day, perform maintenance for the Analyzer according to the maintenance items in the maintenance list and the maintenance items displayed in yellow. Daily maintenance items include the following:

- Check the external water pipe connection;
- Check concentrated wash buffer residue;
- Check if there is leakage and bubble for the syringe;
- Check intensified wash buffer residue;
- Check whether the water outlet of the reagent-sample probe is normal (verify whether the probe inner wall is blocked);
- Check whether the water outlet of the wash well is normal (verify whether the probe outer wall cleaning is normal).

5.17 Shutdown

(1) Make sure that the Analyzer is not running sample test;

(2) Click “Shutdown” > “OK” in the upper left corner of the main interface and wait for the shutdown process to finish;

(3) When the software shuts down, power off the Analyzer.

5.18 Emergency shutdown

The emergency shutdown is applicable in the case that the Analyzer is in trouble when running and cannot turn off normally. For emergency shutdown, the Analyzer does not execute any shut down process and directly turns off.

Click “Emergency Shutdown” > “OK” to close the Analyzer immediately. Otherwise, click “Cancel”.

5.19 Operations after shutdown

(1) Open the reagent-sample tray cap and take out calibrators, controls, etc.;

(2) Examine if there are any stains on the analyzer platform. If there are, wipe the platform with a clean cloth;

(3) Examine the high-concentration liquid waste container. If there is liquid waste, empty it;

(4) Close the tray cap and upper cap.

6 Software operation

This chapter introduces operation procedures and precautions of the Analyzer software.

6.1 Home page

After turning on the software, users can enter the home page. See the picture below:

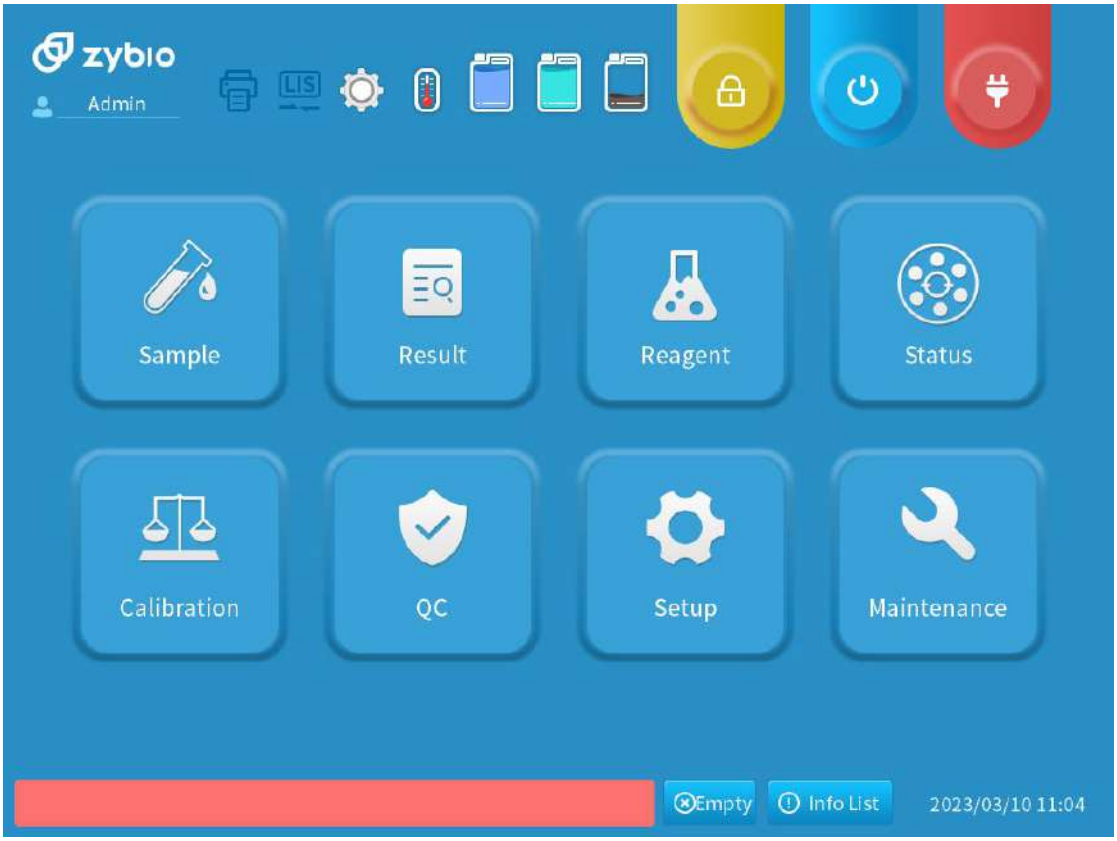


Figure 6-1 Home page

6.2 Status

The status page includes the on-line status of the sample tray, reagent tray and reaction tray. See the following description.

6.2.1 Sample tray

View the test status of applied samples on the sample tray.

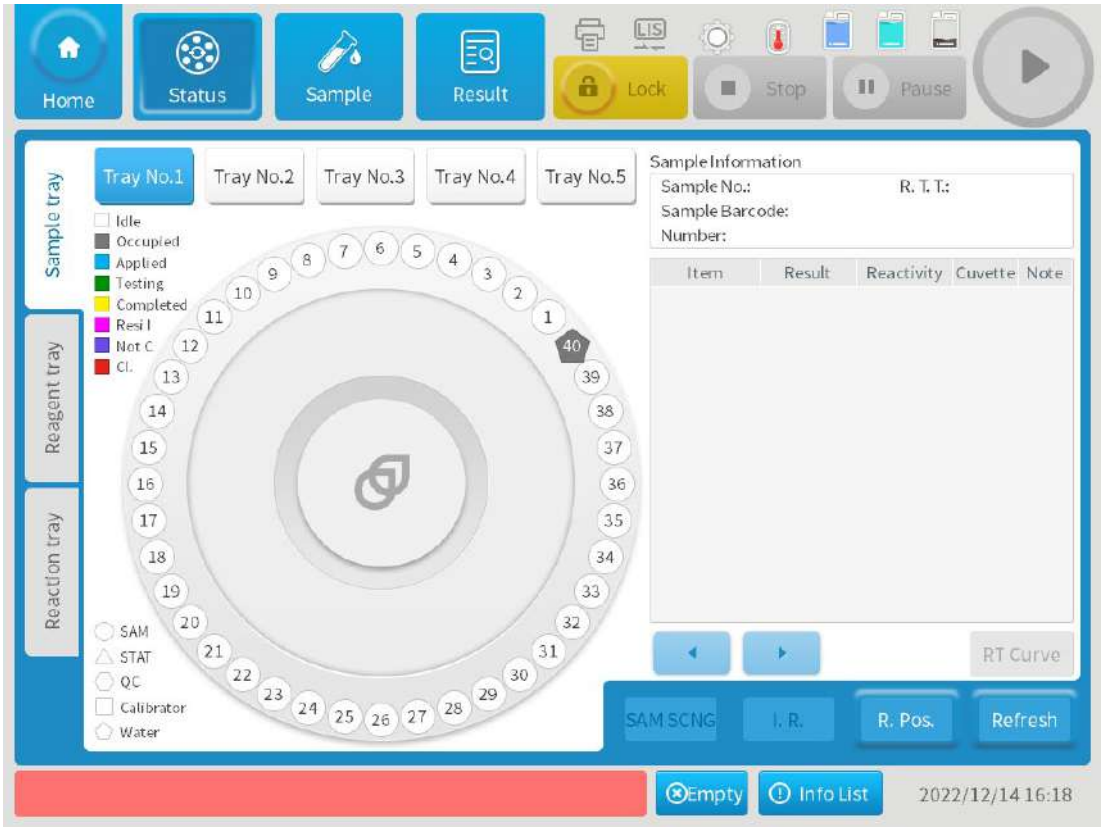


Figure 6-2 Sample tray status

The explanations of sample colors shown in the sample tray status interface are as follows:

Status	Color/shape	Explanation
Idle	Blank	Clean cuvettes with which users can test
Occupied	Grey	The cuvette is occupied
Applied	Blue	The sample is applied for test, while the start does not start
Testing	Green	The sample is being tested
Completed	Yellow	All testing for the sample is completed
Resi I	Pink	The sample residue is insufficient
Not C	Purple	The test for the sample is not completed due to abnormality and errors
Cl.	Red	Sample probe collision occurred during the sample test

The explanations of shapes shown in the sample tray status interface are as follows:

Sample position shapes	Explanation
Round	The sample is a general one
Triangle	The sample is an emergent one
Square	The sample is a calibrator

Sample position shapes	Explanation
Hexagon	The sample is a control
Pentagon	The sample is water

- View sample tray status

  (1) Click “Tray No.1” to “Tray No. 5” to view the test status of samples on the corresponding trays;

  (2) In the left side of the sample tray interface, sample types and test status are displayed via different shapes and colors;

  (3) Select a sample on the sample tray. Then sample information (control or calibrator information) will be shown in the left side (sample information area) of the interface and the test list for the sample position will be shown in lower right area.

Note

When samples are in shortage, users must click “Refresh” to start the test for the sample after adding the sample.

- Sample scanning

  You can click “SAM SCNG” to scan sample barcodes.

- Immediately release

  Select a sample on the tray and then click “I.R.” To release the current sample position immediately.

- Release position

  Click “R. Pos.” to release the position for a sample. And in the pop-up window, designated position and status and full tray are available for users to select.

- Refresh

  Click “Refresh” to refresh the test status of sample trays. And in the pop-up window, designated position and all positions are available for users to select.

- Reaction curve

  Click “RT Curve” to view the reaction curve of the selected sample that is completely tested.

6.2.2 Reagent tray

The on-line status interface of reagent trays is shown as below:

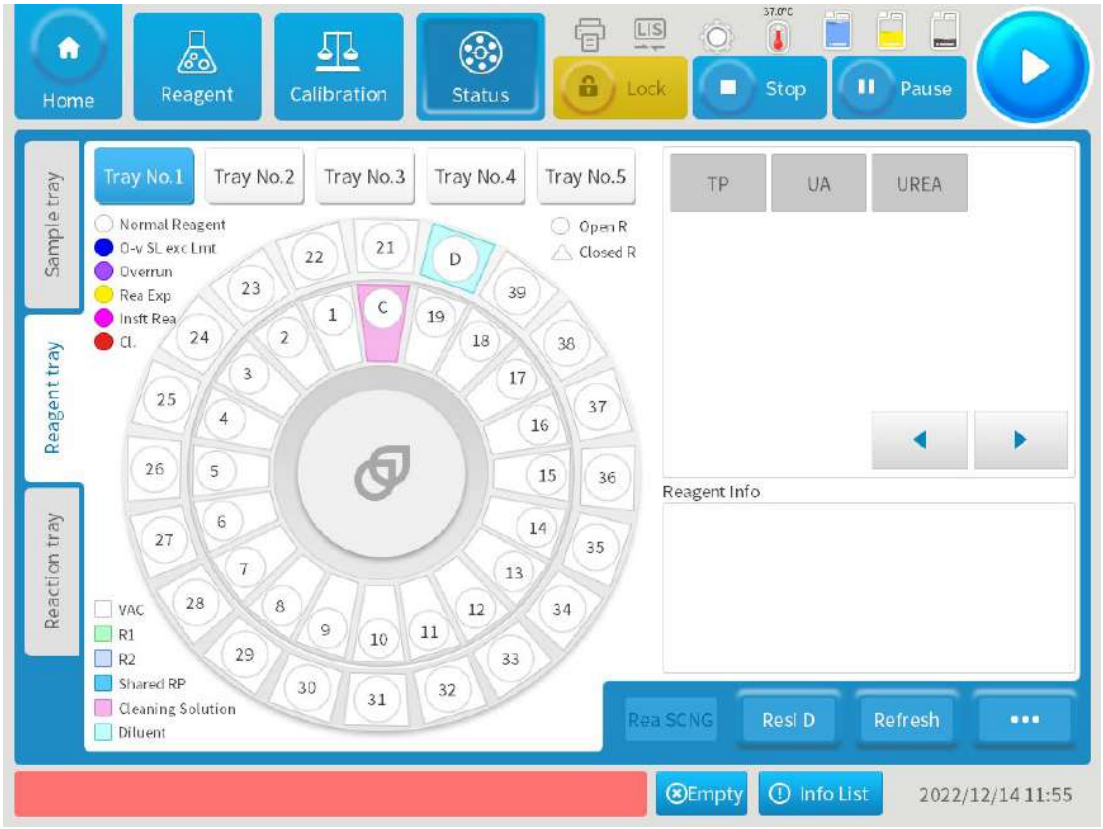


Figure 6-3 Reagent tray status

- View reagent tray status
  - Users can select the tray No.1 to No.5 and then the cuvette No. in trays to view reagent information of different trays and the corresponding of the current reagent position.
  - The status of reagent positions on the reagent tray includes vacant, diluent, R1, R2, Shared reagent positions and wash buffer. They are displayed with different colors. And the diluent (water) is in the fixed D position and wash buffer in the C position.
  - There is a circle in every reagent position, and different colors represent varied status of reagents, including normal reagents, expired reagents, testable barcodes exceeding the limit, exceeding the shelf life for opening the vial, insufficient reagents and probe collision.
  - The shapes of the reagent position icon represent different meaning: circle indicates open reagents, and triangle indicates closed reagents.
  - In the item list shown in the upper right side. The grey means that the reagent is identified, and the blue means that the reagent is identified. Click an item, and a black box will appear in the position of the reagent tray.
  - Click a position on the tray and the reagent information will be shown in the lower right area.
- Reagent scanning

  You can click “Rea SCNG” to scan reagent barcodes, and see the section 5.4 for steps of scanning reagents.
- Residue detection

  (1) Click “Resi D” and a pop-up window will occur for residue detection;

(2) Set the designated position, designated item or all position of cuvettes for residue detection;

(3) Click “OK” to start detecting residue. Otherwise, click “Cancel”.

Note

- R1 and R2 of dual-reagent items must be in the same reagent tray;
- The Analyzer can detect reagent residue only on standby.

- Status refresh

  (1) Click “Refresh” to enter the status refresh interface;

  (2) Select designated positions or all positions to refresh status.

Note

When reagents of an item are in shortage, users must click “Refresh” to start the test for the item after adding reagents and after restoring from probe collision.

- Shared reagent positions

  (1) Click three points (...) > “Shared PR” to enter the shared reagent position interface;

  (2) Click the cuvette No. to view reagent information for the current cuvette that has been occupied;

  (3) Click “Valid R” to change the preferential reagent of the current cuvette.

- Reagent loading

  Click “Rea LD” to enter the reagent loading interface, and you can refer to the section 5.4 for steps of reagent loading.

Table 6-1 Parameters explanation of the reagent laoding page

Parameters	Definition	Operation
REA BC	Reagent barcodes	Input them
B. Analy	Analyze the reagent information of the barcode	Click it
Item	Display the item name for the reagent	No operation required
Rea T	The reagent type	Select in the drop-down list
Tray No.	Select the tray No. for the reagent	Select in the drop-down list
Rea P	Set the cuvette No. for the reagent	Select in the drop-down list
SL of Rea	Valid days after the reagent is manufactured	Select in the drop-down list
Rea Sp	Reagent bottle specifications Inner circle: Fixed 35 ml and no optional specifications	No operation required

Parameters	Definition	Operation
	Middle circle: Fixed 20ml and no optional specifications	
O-vial D	The date of opening the vial, which is calculated after the reagent position is set.	Select in the drop-down list
Batch No.	Batch No. of the reagent box	Input it
O-vial SL	The valid days after opening the vial, which are calculated after the reagent position is set.	No operation required
Vial No.	Reagent bottle number information	Input the start number in the edit box.

- Reagent unloading

  (1) Select a reagent in the reagent tray and then click “Rea UNLD” > “OK”;

  (2) Or click “Rea UNLD” > “Designated Position” > “SEL Pos.” > “OK”;

  (3) And users can also click “Designated Item” > “SEL Item” to unload reagents for the selected item, and click “Full Tray Unloaded” to unload all reagents in the tray.

- Change reagent vials

  (1) Select a reagent in the reagent tray, and click “Rep. Rea.”.

  (2) For open reagents, you can input the shelf life, open-vial date, batch No. and vial No. to replace the reagent vial. And closed reagents can be replaced by inputting the barcode and then clicking “B. Analy”.

  (3) After this, click “Save”.

6.2.3 Reaction tray

The on-line status interface of reaction trays is shown as below:

Figure 6-4 Reaction tray status

Definitions of all parameters and the operation for the reaction tray status interface are shown in the table below:

Parameters	Definition	Operation
Cuv. Pos.	Cuvette No.	Click "Sel. Cuv." and then "Query" to view test information of the selected cuvette
Sample No.	Sample No.	Automatically display the sample No. of the selected cuvette
Type	Test type	Automatically display the test type of the selected cuvette
Item	Test item	Automatically display the test item of the selected cuvette
Result	Result of the tested sample	Automatically display the test result of the selected cuvette
RT Curve	View the real-time absorbance curve for the tested item	Click "RT Curve" after selecting an item

- View reagent tray status

  (1) Click "Sel Cuv." to select the cuvette.No. that you want to search and then click "OK" to return to the reaction tray interface. And then click "Query" to view the reagent information from the cuvette;

  (2) The cuvette status on the tray is shown via 8 colors, including idle, clean, dirty, R1,

S, R2, END1 and END2. Of these, R1, S and R2 means R1, S and 2 are added separately, END1 means the test is over, but result is not calculated, andEND2 means the test is over and the result is generated.

- Day Item

  (1) Click “Sel Cuv.” to select the cuvette.No. and then click “OK” to return to the reaction tray interface;

  (2) Click “Day Item” to view all status of the cuvette in this day;

  (3) Click “Previous” or “Next” to present different status information.

- View reaction curve

  (1) Select a testing cuvette on the tray;

  (2) Click “RT Curve” to enter the reaction curve interface where the reaction curve for the cuvette is displayed.

6.3 Result

Click “Result” on the home page to enter the result interface as shown below:

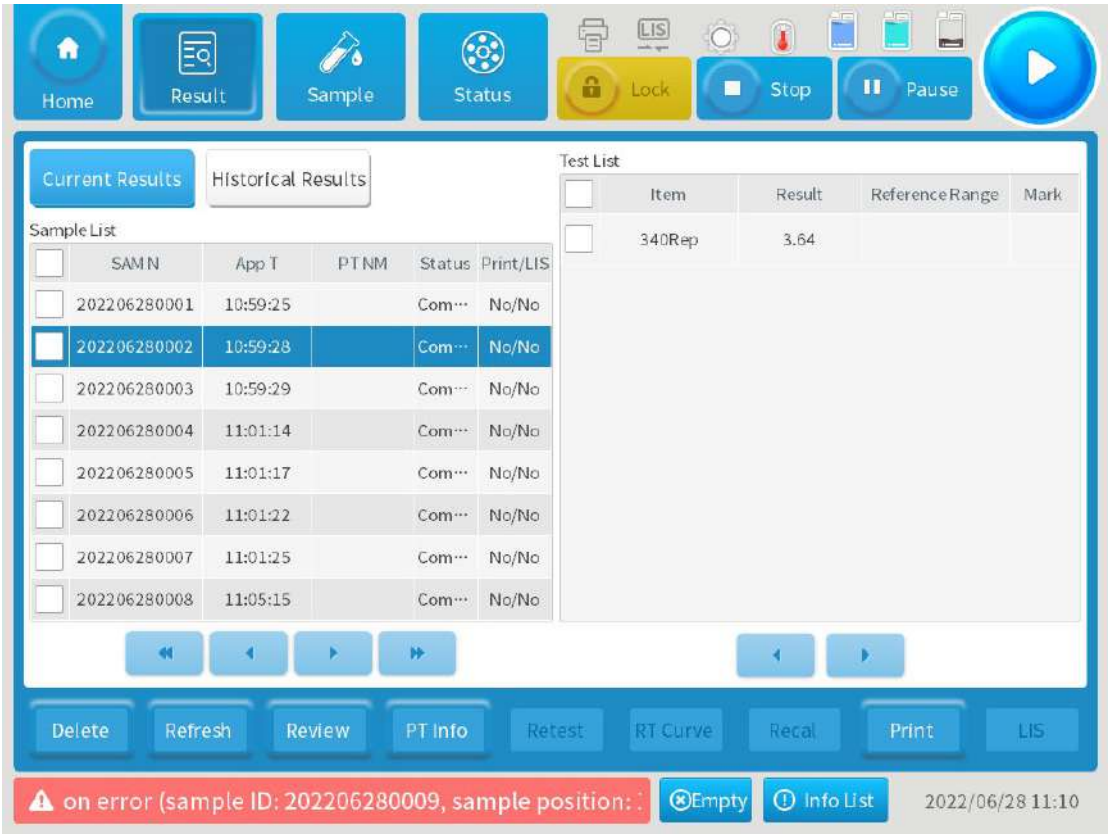


Figure 6-5 Current result

It is divided into current result and historical result which will be operated in the same way shown below:

- Refresh

  Click “Refresh” to refresh the current test results.

- Review

  (1) Select one in the sample list, and then test results of all items of the selected sample

will be displayed in the right test list;

(2) Click "Review", input review conditions in the pop-up window and then click "OK" to view results in the test list.

- Patient information

(1) Select a sample in the sample list and click "PT Info" to enter the patient information interface;

(2) Then, you can view or modify related information and click "Save";

(3) Click "Previous" or "Next" to view information of the previous or next sample;

(4) And in the page, you can also query information of other samples by selecting sample No., barcode and serial code.

- Retest

(1) After searched results are displayed, tick the to-be-retested item in the test list;

(2) Click "Retest" to set the method and position (if it is necessary to change the sample position);

(3) Click "OK" and then the Analyzer will retest.

- Reaction curve

(1) Tick an item in the test list and then click "RT Curve" to enter the reaction curve interface;

(2) And users can also view the original AD value and the reaction curve of sample blank.

- Recalculate

(1) After searched results are displayed, tick the to-be-recalculated item in the test list;

(2) Click "Recal" to start recalculation.

- Delete results

(1) After searched results are displayed, tick a sample in the sample list. Click "Delete" > "Delete the selected sample" to delete all tests for the sample;

(2) Tick the to-be-deleted test from the test list. Click "Delete" > "Delete the selected item" to delete the test;

(3) To delete all results, click "Delete" > "Delete all results".

- Print

(1) After searched results are displayed, select the sample/item to be printed, click "Print" to enter the print interface;

(2) Users can print results of the selected sample/item or all results, tick to ignore printed samples, tick double-row printing, set printing sequence, preview printing, etc.;

(3) After setting, click "OK" to print results.

- LIS

After searched results are displayed, click "LIS" and set the content to be transmitted by selecting "Selected sample", "All smaples", "Latest sample", "SAM N", "SAM BC", "S/C" and "Ignore the sent sample". Then click "OK" to send results to LIS.

6.4 Reagents

In the “Reagent” interface, users can view details of all reagents, load and unload reagents, residue detection, reagent scanning, etc.

Click “Reagent” on the home page to enter the reagent management interface as shown below:

Figure 6-6 Reagent management

Definitions of all parameters and the operation on the reagent interface are shown in the table below:

Parameters	Definition	Operation
Rea T	Reagent types	No operation required
Pos.	Set the tray and cuvette No. for the reagent	No operation required
#of m. R	Number of reagent tests	No operation required
Cal Stat	Status of reagent calibration	No operation required
C. Val Period	Valid period of calibration parameter	No operation required
Batch No.	Batch No. of reagents	No operation required
Vial No.	Vial No. of reagents	No operation required
VD of Rea	Valid days after opening the reagent vial	No operation required
Meas Ite	Number of items that can be tested	No operation required

- Search

(1) Click “Search” to enter the search interface;

(2) Select the tray No. and item, and then click “OK” to search information of loaded reagents.

- Reagent scanning

  See details in the section 5.4.

- Reagent loading

  See details in the section 5.4.

- Residue detection

  (1) Click “Resi D” and drop down to select the tray No. in the pop-up window;

  (2) Click “SEL Pos.” in the designated position box to select the specified cuvette for residue detection;

  (3) Click “SEL Item” in designated item box to perform residue detection of all reagent positions of the specified item;

  (4) To perform residue detection for all positions on the reagent tray, click “All Positions”;

  (5) Click “OK” to start detecting residue. Otherwise, click “Cancel”.

- Reagent unloading

  (1) Click “Rea UNLD” and select the tray No. in the pop-up window;

  (2) Just like the residue detection, reagents can be unloaded based on the designated positions and items or all trays.

- View reagent information

  (1) Click “Rea Info” to enter the reagent information interface;

  (2) Click “Previous” or “Next” to present different reagent information.

6.5 Setup

Click “Setup” on the home page and a pop-up window showing test, system, user and item setup will appear. The details are as follows.

6.5.1 Test setup

The test setup includes two pages (click the “Up” or “Down” button), including basic setup, cleaning setup, result mark, auto retest setup and alarm setup. See the figure below:

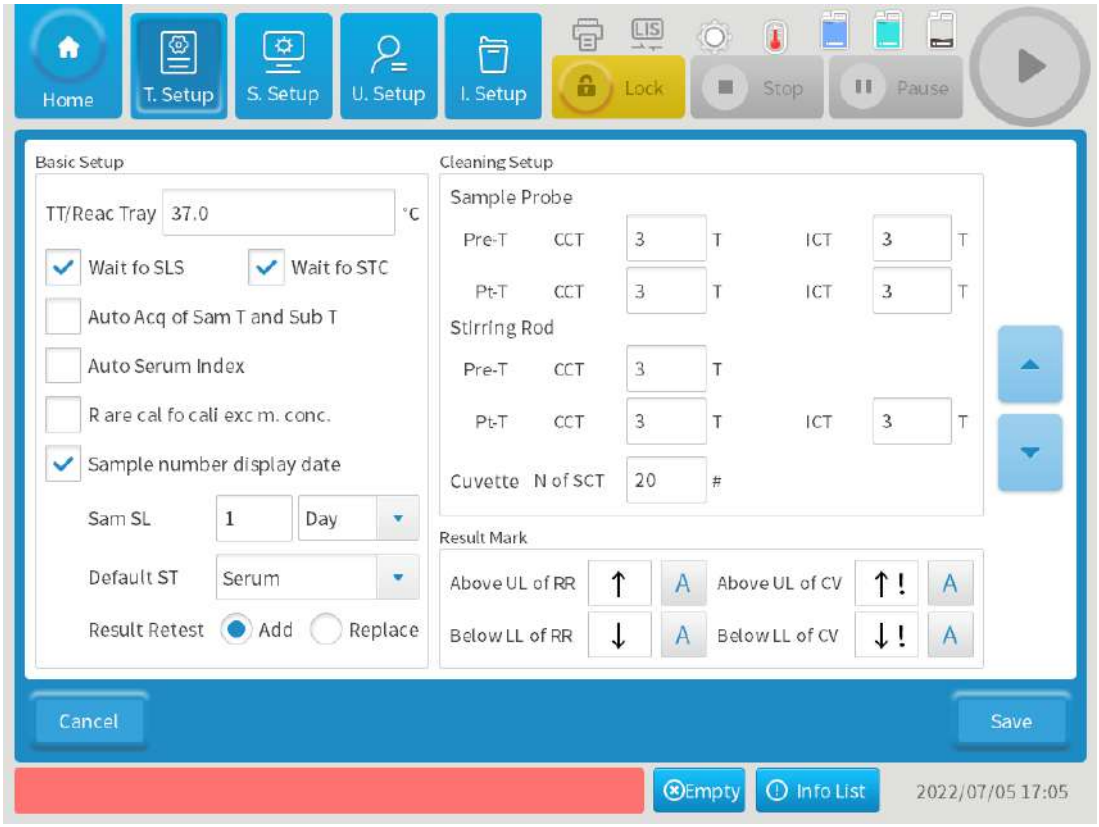


Figure 6-7 Test setup

6.5.1.1 Basic setup

Definitions of all parameters and the operation on the basic setup interface are shown in the table below:

Table 6-2 Basic setup

Parameters	Definition	Operation
TT/Reac Tray	The target temperature when the reaction tray is reacting	Input in the box and the default value is 37°C
Wait fo SLS	Wait for stable light source or not	Tick or cancel ticking, and it is ticked by default
Wait fo STC	Wait for stable temperature control or not	Tick or cancel ticking, and it is ticked by default
Auto Acq of Sam T and Sub T	Automatic acquisition of time	Tick or cancel ticking, and it is not ticked by default
Auto Serum Index	After ticking, the serum index will be tested automatically when the sample type is serum or plasma	Tick or cancel ticking, and it is not ticked by default
R are cal for cali exc m. conc.	Calculate the result or not when exceeding the calibration reactivity of maximum concentration	Tick or cancel ticking, and it is not ticked by default

Parameters	Definition	Operation
Sample number display date	Display year, month and day before the sample number	Tick or cancel ticking, and it is ticked by default
Sam SL	Set the sample shelf life	Select the unit in the drop-down box and input the time number in the box
Default ST	Set the default sample type of the Analyzer	Select in the drop-down ox
Result Retest	Retest results, replace the original result or add it to the result list	Click “Add” or “Replace”

- Click “Save” after entering parameters.
- Click “Save” to save modification of the settings.

Note: the operation of cleaning setup, result mark, auto retest setup and alarm setup are the same as that of basic setup.

6.5.1.2 Cleaning setup

Definitions of all parameters on the cleaning setup interface are shown in the table below:

Table 6-3 Cleaning setup

Parameters	Definition	Operation
Pre-T CCT	Common test times before testing the reagent-sample probe and stirring rod	Input in the box
Pre-T ICT	Intensified test times before testing the reagent-sample probe and stirring rod	Input in the box
Pt-T CCT	Common test times after testing the reagent-sample probe and stirring rod	Input in the box
Pt-T ICT	Intensified test times after testing the reagent-sample probe and stirring rod	Input in the box
Cuvette N of SCT	Number of second cleaning of cuvette	Input in the box

6.5.1.3 Result mark

Definitions of all parameters on the result mark interface are shown in the table below:

Table 6-4 Result mark

Parameters	Definition	Operation
Above UL of RR	Test result is above the upper limit of reference range	Set the color mark for the test result
Above UL of CV	Test result is above the upper limit of critical value	Set the color mark for the test result

Parameters	Definition	Operation
Below LL of RR	Test result is below the lower limit of reference range	Set the color mark for the test result
Below LL of CV	Test result is below the lower limit of critical value	Set the color mark for the test result

6.5.1.4 Auto retest setup

Definitions of all parameters on the auto retest setup interface are shown in the table below:

Table 6-5 Auto retest setup

Parameters	Definition	Operation
Beyond UL of RR	Test result is above the upper limit of reference range	Tick or cancel ticking, and it is not ticked by default
Below LL of RR	Test result is below the lower limit of reference range	Tick or cancel ticking, and it is not ticked by default
Beyond UL of CV	Test result is above the upper limit of critical value	Tick or cancel ticking, and it is not ticked by default
Below LL of CV	Test result is below the lower limit of critical value	Tick or cancel ticking, and it is not ticked by default
Beyond UL of LR	Test result is above the upper limit of linearity range	Tick or cancel ticking, and it is not ticked by default
Below LL of LR	Test result is below the lower limit of linearity range	Tick or cancel ticking, and it is not ticked by default
No Linearity of TR	Linearity is not applicable to the test result	Tick or cancel ticking, and it is not ticked by default
No Calct Int	If the photometric spot is less than 2 during the delayed time and limit of substrate depletion, there will be a mark for no calculation interval.	Tick or cancel ticking, and it is not ticked by default
Substrate Depl	The substrate is depleted in the reaction process	Tick or cancel ticking, and it is not ticked by default
Abn Prozone Exam	Prozone examination is abnormal	Tick or cancel ticking, and it is not ticked by default
Beyond the max. conc cablibration react	The test result is beyond the reactivity of the maximum concentration calibration	Tick or cancel ticking, and it is not ticked by default

6.5.1.5 Alarm setup

Definitions of all parameters on the alarm setup interface are shown in the table below:

Table 6-6 Alarm setup

Parameters	Definition	Operation
Bulb Alarm Limit	That how many hours the bulb lights prompts an alarm	Input hours in the box
Rea Resi Alm LMT	That how many reagent residue is insufficient prompts an alarm	Input in the box
Alm Lmt of Prb Dtg Allow	That how many cleaning solution residue is insufficient prompts an alarm	Input in the box
Rea SL Alarm	Prompt an alarm when the reagent expires or not	Tick or cancel ticking, and it is ticked by default
CV Alarm	Prompt an alarm when the sample test result exceeds the critical value or not	Tick or cancel ticking, and it is ticked by default
AS vol	Volume of alarm sound	Input the volume percentage in the box
AS	Content of alarm sound	Import from a folder, and the listening test is available
Display edited result mark	The mark shown after editing the result	Tick or cancel ticking, and it is ticked by default

6.5.2 System setup

System setup includes device, print, LIS, barcode, DT dictionary and list setup. And details are as follows.

6.5.2.1 Device setup

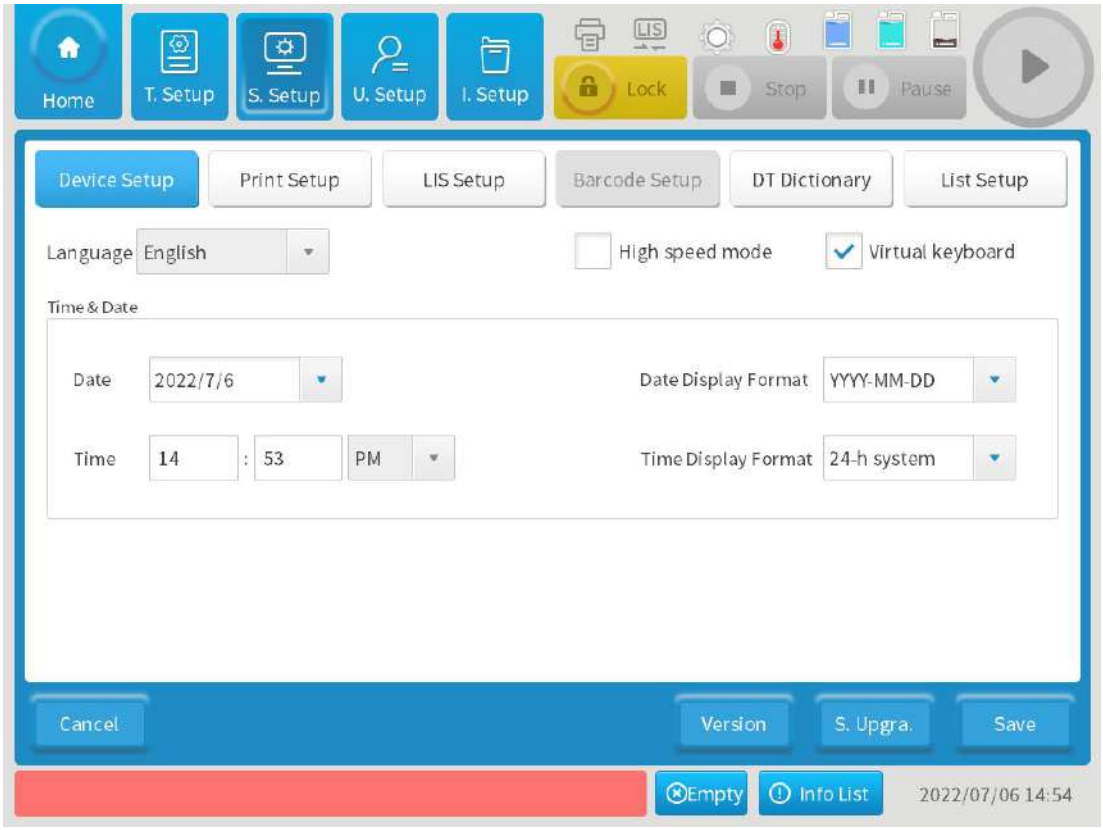


Figure6-8 Device setup

Parameters	Definition	Operation
Language	Software interface language	Drop down to select
Hight speed mode	Test speed is high	Tick or cancel ticking, and it is not ticked by default
Virtual keyboard	The virtual keyboard is shown below the software interface	Tick or cancel ticking, and it is ticked by default
Date	Displayed in the lower right corner of the interface	Select in the drop-down box
Date display format	Select date in the year-month-day order	Select in the drop-down box
Time	Set time	Select “AM” or “PM” in the drop-down list and input the time data in the box
Time display format	12h or 24h system	Select the date in the drop-down box
Version	The current operating software version number	No operation required
S. Upgra.	Upgrade the current software	Click “S. Upgra.” to import the new installation package

- Input the information and then click “Save”;
- Click “Cancel” to cancel modification of the information.

6.5.2.2 Print setup

- Printing

  (1) The software has six report types with six default templates, which cannot be deleted or edited;

  (2) Select the report type for which users want to add a template, and click “Add”. A new template that is the same as the default one will be added. You can edit and design this template. Click “Preview” to preview the template after editing. Click “Save” to save the edited template. Click “Delete” to delete the template;

  (3) Drop down to set the default printer in the “Default Printer” box. Set the default paper type in the “Paper Type” box. And you can tick or cancel ticking the auto print;

  (4) Click “Sequence” to set printing sequence;

  (5) Select a template in the template name list and click “Set as D” to set the selected template as a default one.

- Edit template

  Select a newly added template and click Edit. You can change the font, content, and layout on the template design page that appears.

  There are a toolbar, formula bar and save button on the template design page.

  - Click “Settings” to make general, page and margin settings. General settings include report name, file encoding, default font and font size. Page and margin settings include page size, margin and orientation.
  - Click “Label” to add labels and text boxes in the formula bar and enter text descriptions in the text box. If you want to import related data to the text box, associate the data name and select them from the drop-down list. The data will be automatically imported during printing. If you want to view the ID information of the patient in the text box, double click the text box and select the ID from the associated drop-down box.
  - Click “Field” to add a field text box in the formula bar. Double click the text box to set input text type, field type, value, character format, number, and date in the field setting dialog box.
  - Click “Hline” or “Vline” to add horizontal or vertical lines in the formula bar. The length can be stretched freely.
  - The area on the left of the second line is a tool that applies only to text box. You can set the font, font size, bold, italic, underline, and alignment.
  - The area on the right of the second line is a tool that applies only to line segment. You can set the type and width of a line segment.
  - If you want to set the color of a text box or a line segment, select the text box, click “Color” and “OK”. If you want to delete a text box or a line segment, select it, and click “Delete”. Click “Save” to save the modified template.

- Printer setup

  Users can set the default printer, paper type, sample report type and more from the printer settings. After this, click “Save” to save the set items.

6.5.2.3 LIS setup

Definitions of all parameters on the LIS setup interface are shown in the table below:

Table 6-7 LIS setup

Parameters	Definition	Operation
LIS h Com. Add	LIS host communication IP address	Input in the box
Port No.	The port number of the communication host (No. input should be consistent with the host port No.)	Input in the box
Com. M	Select a communication mode	Select “One-way” or “Two-way”. For two- way, you can choose the acquisition method, including “By S/B”, “By serial code” and “Sample barcode and serial No.”.
LIS Com. P	Select LIS communication process	Select “Add” or “Replace”
Auto-C Af ST	Automatically connect to communication after startup	Tick or cancel ticking, and it is ticked by default
Com. TO	That how many seconds the communication lasts over prompts an automatic connection.	Input in the box
Dis-C AT Recon	Whether to establish communication automatically after it is disconnected	Tick or cancel ticking, and it is ticked by default
Re-C Int	That how many seconds last after communication disconnection prompts an automatic connection.	Input in the box
Send the TR of C sam in real time	Select whether to send the test result of samples in real time or not	Tick or cancel ticking, and it is ticked k by default
Send test results in real time	Select whether to send test results in real time or not	Tick or cancel ticking
Start a sample scan	Select whether to scan sample barcode when a test starts	Tick or cancel ticking
Results beyond range/CV won’t be sent to LIS	Select whether to send results beyond the range or critical value to LIS.	Tick or cancel ticking
TR beyond the linear range is not sent	Select whether to send the test result that exceeds the linearity range	Tick or cancel ticking, and it is ticked by default

- Click “Save” after input of parameters.

- Click “Save” to save modification of the settings.

6.5.2.4 Barcode setup

The “Barcode Setup” interface shows settings for six barcode types. You can choose whether to verify these types or whether to transmit check bits and set coding numbers.

6.5.2.5 Data dictionary

Users can set the result unit, sample note, diagnostic reference and patient information.

- To add new types, select a dictionary type, click “Add” to input information in the blank box, and then click “Save”;
- To delete data from a dictionary type, tick the data box and then click “Delete”;
- To modify data from a dictionary type, click the data and modify it. After this, click “Save”;
- Otherwise, click “Cancel”.

6.5.2.6 List setup

- To set the display format of the list, select or cancel selecting an option for configuration and then click “Preview”;
- To save the setting, click “Save”. If not, click “Cancel”.

6.5.3 User setup

This section introduces information about user setup. User setup includes user management, hospital setup, department setup, and physician setup. See below for details.

6.5.3.1 User management

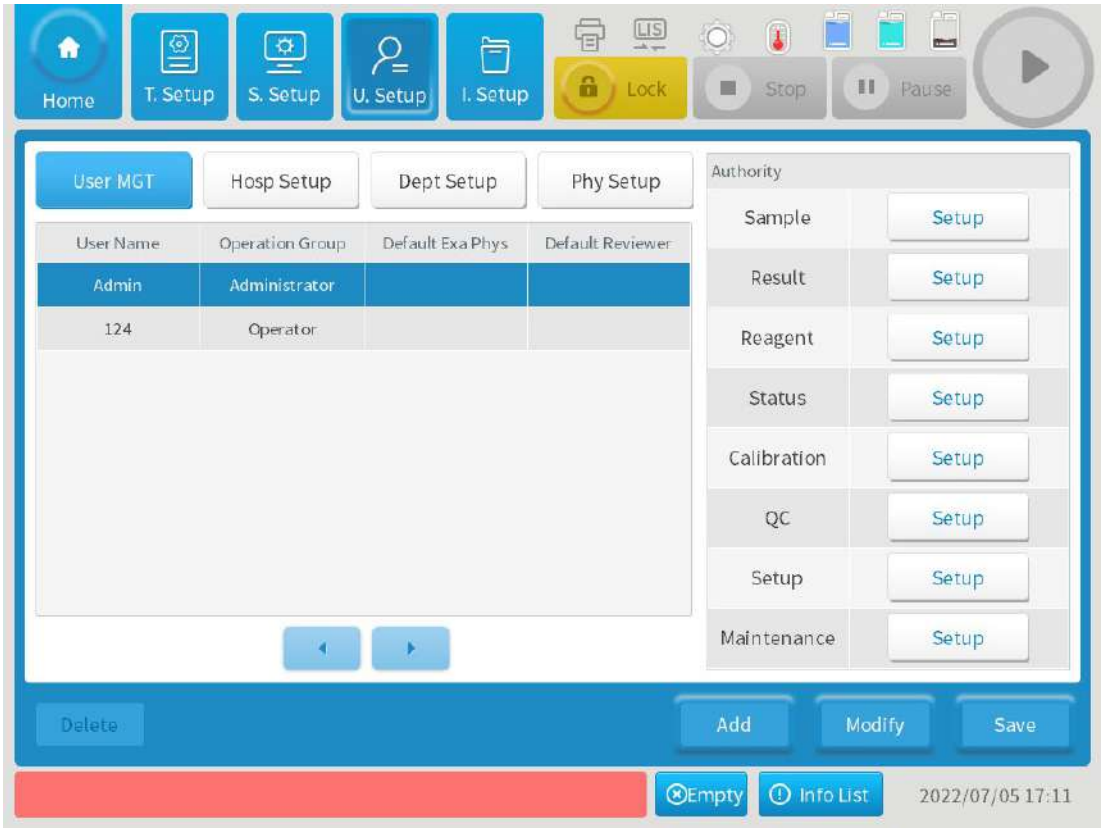


Figure 6-9 User management

Parameters	Definition	Operation
Add	Add user account	Enter the interface of adding new users
Modify	Modify user information	Enter the interface of modifying users
Authority	Set different authority for different user accounts	Enter the authority setup interface

- To add users, click "Add" to pop up the Add User interface to input a new account. First, set the associated physician by clicking "A. Physi." to select examination physician and reviewer and to set them as the default ones. After this, click "Save";
- To delete a user name, select the user, click "Delete", and then click "OK" > "Save" in the pop-up window;
- To modify the user, select the user, click "Modify", modify the content in the pop-up window and then click "OK" > "Save";
- To change the authority, select a user and then an option in the right column. Click "Setup" and tick or cancel ticking an authority. After this, click "Save".

6.5.3.2 Hospital setup

Definitions of all parameters on the hospital setup interface are shown in the table below:

Table 6-8 Hospital setup

Parameters	Definition	Operation
Hospital	Hospital name	Input in the box
Address	Hospital address	Input in the box
Director	Director of hospital	Input in the box
Contact	Contact number of the hospital director or after-sales personnel	Input in the box
ASR Person	After-sales personnel appointed for the product	Input in the box
Inst. Time	The date when the instrument is installed	Select the date in the drop-down box
Remarks	Remarks	Input in the box

Click “Save” after input of parameters.

6.5.3.3 Department setting

Definitions of all parameters on the department setup interface are shown in the table below:

Table 6-9 Department setup

Parameters	Definition	Operation
Department	Display the department name	No operation required
Director	Display the director of the department	No operation required
Note	Display the remarks	No operation required
Add	New department information	Click it to enter the interface of adding new department
Modify	Modify the department information	Click it to enter the interface of modifying the department
Delete	Delete the department information	Click it

- Add: click “Add” to input the parameters in the pop-up window;
- Modify: check the items to be modified and click “Modify” to input the parameters in the pop-up window;
- Delete: check the items to be deleted and click “Delete”.

6.5.3.4 Physician setting

Definitions of all parameters on the physician setup interface are shown in the table below:

Table 6-10 Doctor setup

Parameters	Definition	Operation
Physician	Doctor name	No operation required

Parameters	Definition	Operation
Submitter	Judge if a submitter or not	No operation required
Exa Phys	Judge if an examination physician or not	No operation required
Reviewer	Judge if a reviewer or not	No operation required
Department	The department where the doctor serves	No operation required
Note	Remarks	No operation required
Add	To add doctor information	Click it to enter the interface of Add a doctor
Modify	To modify the doctor information	Click it to enter the interface of Modify doctor
Delete	To delete the doctor information	Click it

- Add: click “Add” to input the parameters in the pop-up window;
- Modify: select the to-be-modified department, click “Modify” and input the information in the pop-up window;
- Delete: tick the box for the to-be-deleted department and click “Delete”.

6.5.4 Item setup

This section introduces information about item setup. Item setup includes routine item, serum index, calculation item, combined item, manual item and cross contamination. See below for details.

6.5.4.1 Routine item

- Add item

  (1) Click “Add” to enter the routine item addition interface;

  (2) Click “Save” after input of parameters.

Definitions of all parameters and the operation for the routine item addition interface are shown in the table below:

Parameters	Definition	Operation
Item Abb	Item abbreviation	Input the start number in the edit box.
FN/Ite	Full name of items	Input it
SAM TYP	Select sample types	Tick the box
Rea O-V SL	The shelf life of the reagent after it is opened	Input in the box and 30 days by default
Test M	Set the measuring method for an item, including endpoint, two-point, two-point endpoint and kinetic methods	Select in the drop-down box

Parameters	Definition	Operation
R. Direc	The change direction of absorbance during reaction, including increase and decrease	Select in the drop-down box
R Unit	Result unit	Select in the drop-down box
R ACC	Decimal places	Select in the drop-down box
Dom WL	The measured dominant wavelength	Select in the drop-down box
Sub-WL	The measured sub-wavelength	Select in the drop-down box
S Vol	The sample volume for the general test, and the unit is μL	Input in the box and range from 2 to 50 μL
R1 Vol	The volume of reagent 1 for the general test, and the unit is μL	Input in the box and range from 90 to 350 μLul
R2 Vol	The volume of reagent 2 for the general test, and the unit is μLul	Input in the box and range from 10 to 250 μL
Bl. Time	The time duration before the reaction of a test starts. For a single-reagent item, blank time lasts from the time when the reagent is added to the time when the sample S is added. For a dual-reagent item, it lasts from the time when the sample S is added to the time when the reagent R2 is added.	Input in the box
Reaction time	The time duration calculated from starting and ending photometry points	Input in the box
CF	Calibrate results according to y=kx+b, where x is the actual result, y is the results after calibration, k is the slope of the calibration formula and b is the intercept of the formula.	Input in the box
RR	The reference range for the sample concentration of test results	Input in the box according to the instruction in the reagent box or professional range
Range/CV	The critical range value for the sample concentration of test results	Input in the box
More	Set the upper and lower limit of the reference range and critical value for more conditions including gender, sample type, age, etc.	Click More to enter the interface of setting reference and critical value ranges
Monitoring parameters	Set monitoring parameters for varied conditions, including detecting linearity limit, substrate depletion limit, linear range, reactivity range, working solution absorbance, R1 blank	Input in the box

Parameters	Definition	Operation
	absorbance, prozone examination parameters, etc.	
Cancel	Do not save this input information	Click it
Close	Close the interface	Click it
Save	Save the parameters currently set up	Click it

- Modify items

  (1) Select the to-be-modified item in the item list, and click “Modify” to enter the routine item modification interface;

  (2) Click “Save” after input of parameters.

- Delete items

  Select the to-be-modified item in the item list, and then click “Delete”.

- Sequence

  (1) Click “Sequence” and select an item that you want to change the sequence in the pop-up window;

  (2) Click “Top” to move the item to the first order, while click “Bottom” to move it to the last one;

  (3) Click “Move Up” to ascend one order, while click “Move Down” to descend one order;

  (4) To move the item to a specified place, input the number in the “Move To” box and then click “OK”;

  (5) To save the setting, click “Save” and click “Close” to return to the routine item interface. Otherwise, click “Cancel”.

- Import

  (1) Click “Import” and a dialog box for importing items will appear;

  (2) Select the excel file in the local folder and then import the parameters to the item list.

- Export

  (1) Select to-be-exported items in the item list;

  (2) Click “Export” and a dialog box for exporting items will appear;

  (3) Select a file path to export parameter in the item list to the local folder.

6.5.4.2 Serum index

Serum refers to the hemolysis, icterus and lipemia level in serum and plasma samples.

Definitions of all parameters on the serum index interface are shown in the table below:

Table 6-11 Serum index

Parameters	Definition	Operation
It Abb	Item abbreviation	No operation required
FN/Ite	Full name of items	No operation required
S Vol	The sample volume is fixed at 10μL	No operation required
Rea V	Reagents are physiological saline, and their volume is fixed at 200μL	No operation required
Q Expression	Adopt qualitative expressions for test results or not	Tick it or cancel ticking
Q Judgment	Determine the qualitative mark by comparing the measured value of hemolysis, icterus or lipemia with the threshold value of the qualitative judgment.	Input it. The threshold value of the qualitative judgment is the five positive integers or decimals in ascending order from up to down. In the six boxes for qualitative marks, any symbols can be input. Take the lipemia as an example. When LI-L5 is input in the qualitative judgment box, 0<L1<L2<L3<L4<L5 is required. When the result L<L1, the qualitative mark is 1; When L1<L<L2, the mark is 2, and so on.
Q Mark	The test result is shown as the mark	
Calc P	Set 6 parameters, including A, B, C, D, E and F, which calculates results of serum indexes	Input it B, E and F cannot be adjusted and fixed as 1.42, 1.31 and 4.55; A, C and D can be adjusted and are 2.20, 1.45 and 250 by default
Corr F	Set the slope and intercept of correction	Input it

- To use qualitative expressions for test result of serum indexes, users need to tick in the related boxes;
- Input five positive integers or decimals in ascending order in five boxes from up to down, and input the customized symbols in the qualitative mark boxes;
- To change calculation parameters, click “Cal P” and input A, C and D values in the pop-up window;
- To change the correction factor, click “Corr F” and input slope and intercept in the pop-up window;
- After these are set, click “Save”.

6.5.4.3 Calculation item

Definitions of all parameters and the operation on the calculation item interface are shown in the table below:

Table 6-12 Calculation item

Parameters	Definition	Operation
S/N	Order of calculation items	No operation required
Calculation Item	Abbreviation of calculation items	No operation required
Calc Form	Formula of calculation items	No operation required
Add	Add calculation items	Click it to enter the interface of adding calculation items
Modify	Modify calculation items	Click it to enter the interface of modifying calculation items
Delete	Delete calculation items	Select an item and then click Delete

- Add calculation items

  (1) Click “Add” to enter the interface of adding calculation items;

  (2) Input or select related information in boxes;

  (3) Click the item in the lower item list and click the number and calculating symbol in the right button area to form a formula. And then you can see the input formula in the “Calc Form” area;

  (4) To save the added calculation items, click “Save”. Otherwise, click “Cancel”.

Definitions of all parameters and the operation on the calculation item addition interface are shown in the table below:

Table 6-13 Calculation item addition

Parameters	Definition	Operation
Ite Abb	Abbreviation of calculation items	Input in the box and support only 8 characters
FN/Ite	Full name of calculation items	Input in the box and support only 256 characters
R Unit	Result unit	Select in the drop-down box
R ACC	Decimal places	Select in the drop-down box with 0, 0.0, 0.00, 0.000, 0.0000 available
RR	The reference range for the sample concentration of test results	Input in the box
R/CV	The critical range value for the sample concentration of test results	Input in the box
More	Set the upper and lower limit of the reference range and critical value for more conditions including gender, sample type, age, etc.	Click More to enter the interface of setting reference and critical value ranges

Parameters	Definition	Operation
Calc Form	Display formula of calculation items	No operation required

- Modify calculation items

  (1) Select the to-be-modified item in the calculation item list, and click “Modify” to enter the calculation item modification interface;

  (2) Input or select related information in boxes;

  (3) To change the formula, click “Clear” and input a new formula;

  (4) To save the modified information, click Save. Otherwise, click “Cancel”.

- Delete calculation items

  (1) Select to-be-deleted items;

  (2) Click “Delete” > “OK”. Otherwise, click “Cancel”.

6.5.4.4 Combined item

Definitions of all parameters and the operation on the combined item addition interface are shown in the table below:

Table 6-14 Combined item

Parameters	Definition	Operation
S/N	Order of combined items	No operation required
Combined Item	Name of combined items	No operation required
Item(s) Included	Items included in the combined item	No operation required
SAM Comb	The combined item is displayed in the sample application list or not	No operation required
QC Comb	The combined item is displayed in the QC application list or not	No operation required
Top	The selected combined item is displayed in the top order	Select an item and then click “Top”
Move Up	The selected combined item is displayed in one ascending order	Select an item and then click “Move Up”
Move Down	The selected combined item is displayed in one descending order	Select an item and then click “Move Down”
Bottom	The selected combined item is displayed in the bottom order	Select an item and then click Bottom
Move To	The selected combined item is moved to the specified place	Select an item, input a number in the box and then click “OK” or the “Enter key”

- Add combined item

  (1) Click “Add” to enter the interface of adding combined items;

(2) Input name of the item;

(3) Click the item in the item list. Select with a click and cancel with another click;

(4) To display the combined item in the sample application list, tick the box of “SAM Comb”;

(5) To display the combined item in the QC application list, tick the box of “QC Comb”;

(6) To save the added combined items, click “Save”.

- Modify combined item

(1) Select one item to be modified;

(2) Click “Modify” to input information in the pop-up window;

(3) Users can delete or add items in the item list;

(4) To save the modified information, click “OK”.

- Delete combined item

(1) Select one item to be deleted;

(2) Click “Delete”.

6.5.4.5 Manual item

The manual item is the item for which item parameters and test results are input manually. It will not be tested and only applicable in storage, display and printing of test results.

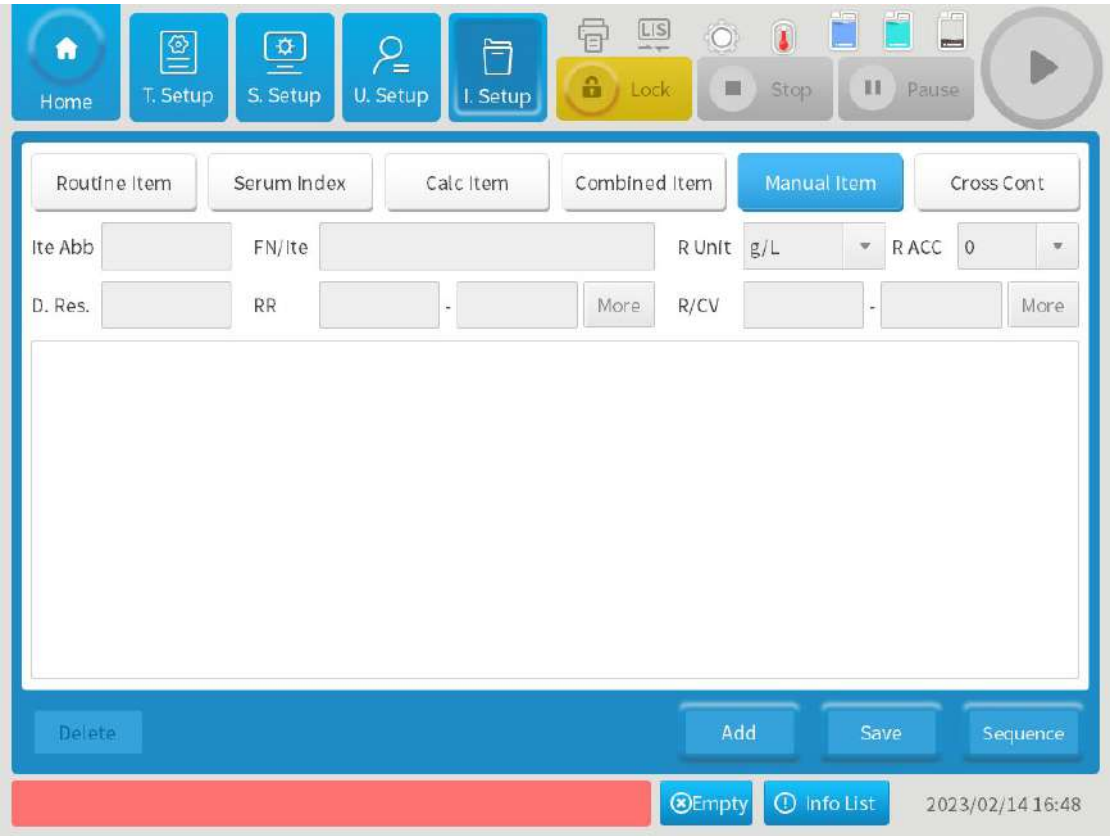


Figure 6-10 Manual item

- Add manual items

(1) Click “Add”;

(2) Input or drop down to select the information in the box, and add the item with input parameters to the lower manual item area;

(3) After this, click “Save”.

- Modify manual items

(1) Select one item to be modified in the manual item area;

(2) Input or drop down to modify in the box;

(3) After this, click “Save”.

- Delete manual item

(1) Select one item to be deleted in the manual item area;

(2) Click “Delete” to delete the item from the area;

(3) After this, click “Save”.

- Manual item sequence

(1) Click “Sequence”;

(2) In the pop-up window, put items you want to adjust in a new order;

(3) Click “Save” to return to the manual item interface.

6.5.4.6 Cross contamination

(1) Select the contamination source item in the “Cont S Item” area;

(2) Select one or multiple contaminated items in the “Cont Item” area. For an item, select it with a click and cancel selecting with another click;

(3) Tick “Rea Cont” and “Cuv Cont” in the right “Contamination List”;

(4) To save the setting, click “Save”. Otherwise, click “Cancel”;

(5) Click “CT Setup” to drop down to select the times for intensified and general cleaning. Then click “OK”;

(6) To delete the set cross contamination item, select one in the contamination list and then click “Delete”.

Note

Please properly determine the cross-contamination relation between items according to the reagent component offered by the manufacturer. Otherwise, cross contamination may affect analysis results.

6.6 Maintenance

This section introduces information about maintenance of the software.

6.6.1 Maintenance interface overview

- Attributes

Display attributes of maintenance items. There are two options, including system and user. System indicates that the item is set when the Analyzer leaves the factory. User is added for the item through customization by users.

- Item

  Display all pre-set system items and customized maintenance items during the current period.

- Operator

  Display the operator executing the corresponding maintenance item, also the login user ID of the software.

- Last maintenance time

  Display the last maintenance time.

- Status

  Display whether the item is expired or delayed and next maintenance time.

- Log

  Record error and other necessary information during maintenance.

- Customize

  Users can add or delete an item for maintenance according to the reagents used by the Analyzer.

- Delete

  If a maintenance item is not necessary, it can be deleted. Please note that only customized maintenance items can be deleted and those pre-set system items can not be deleted.

- Delayed

  One-period delay for the maintenance item time.

- Execution

  Select one or multiple items and click Execution to start checking the selected items.

6.6.2 Daily maintenance

Daily maintenance includes periodical maintenance, troubleshooting, data backup, temperature curve, consumable maintenance and unit status. It is the default page. Click “Maintenance” on the home page to enter this interface.

6.6.2.1 Periodical maintenance

The periodical maintenance divides items that need maintenance made by users into daily, weekly, monthly, and other (irregular) ones by the maintenance period. Other maintenance items are divided into the command-based ones.

The periodical maintenance list includes the following periods:

- Daily - 1 day
- Weekly - 7 days
- Monthly - 30 days

- Other - irregular
- Dirty cuvette detection

6.6.2.2 Trouble shooting

In case of a fault of the running Analyzer, users can view the code, source, unit, level, time, description, and cause of the failure as well as the solution on the trouble shooting interface. This feature allows you to solve simple problems on your own. And fault recover is available.

Definitions of all parameters and the operation on the trouble shooting interface are shown in the table below:

Table 6-15 Trouble shooting

Parameters	Definition	Operation
Code	Fault code	/
Source	The part related to the fault	/
Unit	The unit related to the fault	/
Level	Fault level	/
Time	Fault time	/
Fault Description	Fault description	/
Fault Cause	The preliminarily estimated cause of the fault	/
Processing Method	The recommended solution for the fault	/
Fau. Rec.	Restore the Analyzer in fault to normal status	/
Query	Fault query	Click it to enter the query interface
Warning	A zero-level fault	The √ means selected.
Fault	A non-zero level fault	The √ means selected.
Export Log	Export the fault log	Click it to enter the export interface
Delete	Delete the selected fault information	Select the information you want to delete and then click “Delete”
Back	Return to the daily maintenance interface	Click it

6.6.2.3 Data backup

- Auto Backup
  - “Bakp cyc”: the interval of the backup.
  - “Bakp Lmt”: the number of backup.
  - “Path”: the backup path, or the backup storage location, which can be entered

or selected.

- Click “Save” after setting the cycle, limit, and path. A reminder will notify you when the backup time is approaching. When backing up all the data on software, turn off the software. If the software or data is damaged, users can restore data from the previous backup package.

- Manual Backup

  Enter or select a backup path (storage location). Click “Backup” to start backup.

6.6.2.4 Temperature curve

The temperature control system includes reaction tray temperature control (heating) and reagent refrigeration. The reaction tray has a single temperature sensor for temperature sensing and data feedback. The refrigeration module of the reagent-sample tray contains a refrigeration unit composed of two coolers which work independently and each has a temperature sensor.

Click the “Temp. Curve” button. Users can view the reaction tray temperature, and the reagent-sample tray temperature 1 and 2 on the temperature status interface. Low, normal, and high temperature are respectively shown in blue, green, and red. The displayed parameters include digits and status.

- Opening/closing temperature control means opening/closing temperature control for the reaction tray;
- Click “Back” to return to the daily maintenance interface.

6.6.2.5 Consumable maintenance

It is used to check the status of wash buffer, diluent, liquid waste container, concentrated wash buffer container and deionized water.

Click “Maintenance” > “Consumable Stat” to confirm the displayed status.

Each status is displayed with a color.

Table 6-16 Color for the container status

Container	Status	Colors	Status	Colors
Waste liquid container	Full	Red	Not full	Brown
External deionized water tank	Empty	Red	Not empty	Blue-green
Concentrated wash buffer container	Full	Blue	Not full	Red

The residue of special wash buffer and diluent is displayed by percentage. When the residue is below 10%, the red indicator is on (alarm); when the residue is greater than 10% but less than 25%, the yellow indicator is on (reminder); when the residue is greater than 25%, the blue indicator is on (normal).

6.6.2.6 Unit status

There are these units, including master control unit, photoelectric unit, temperature control unit, reaction unit, reagent-sample probe unit, stirring rob unit, barcode unit, reagent-sample tray unit and liquid circulation unit. Of these, the temperature control unit includes temperature control of the reaction tray and refrigeration of the reagent-sample tray.

Click “Maintenance” > “Unit Status” to confirm the displayed status. Blue is normal, and red is abnormal.

7 Maintenance and care

This chapter introduces maintenance methods of the Analyzer, including general maintenance commands and periodic maintenance. The purpose, timing of use, required supplies, Analyzer status, precautions and operation steps of each maintenance item are described in detail.

To ensure the Analyzer reliability, good working status and its service life, please strictly follow the Manual for operation and periodic maintenance.

Note

- When conducting maintenance, please take necessary protective measures, such as wearing latex gloves, protective suit etc.
- In case of any leakage of hazardous substances on the Analyzer surface or into the Analyzer, please take appropriate disinfection measures.
- Do not use the cleaning agents or disinfectors that may have chemical reactions with the Analyzer parts or materials contained in the Analyzer.
- If there is any doubt about the compatibility of cleaning agents and disinfectors with the Analyzer parts or materials contained in the Analyzer, please contact Zybio or its local distributor.

7.1 Maintenance tools

This section will list tools for maintenance:

- A set of Allen wrenches;
- Cross screwdrivers (Big, medium, and small);
- Stainless steel wire (inner diameter: 0.3 mm and 0.5 mm);
- Plastic syringe (about 10 ml, without needle);
- Clean gauze;
- Clean cotton swabs;
- Brush for cleaning the container;
- Nonionic surfactant cleanser;
- Absolute ethanol;
- 84 disinfectant;
- Medical latex gloves.

7.2 Periodic maintenance items

Periodic maintenance is required according to the condition of the Analyzer parts and the

Analyzer service condition. This requires the trained operators to conduct periodic maintenance strictly following the instructions to ensure the Analyzer performance. Before conducting maintenance, read steps in this section.

Maintenance items defined by the Analyzer are not editable. However, the system provides a user-defined feature, allowing users to customize necessary maintenance items. After maintenance, users can write maintenance logs to record errors and other necessary information about the maintenance.

7.2.1 Maintenance period

The maintenance periods in the periodical maintenance list include:

- Daily - 1 day
- Weekly - 7 days
- Monthly - 30 days
- Other - irregular
- Dirty cuvette detection

The Analyzer counts down from the time of current maintenance.

7.2.2 Maintenance description

The following table will list maintenance items every day and month.

Table 7-1 Maintenance description

Maintenance period	Maintenance items (in sequence)
Daily	● Check the external water pipe connection; ● Check concentrated wash buffer residue; ● Check if there is leakage and bubble for the syringe; ● Check intensified wash buffer residue; ● Check whether the water outlet of the reagent-sample probe is normal (v erify whether the probe inner wall is blocked); ● Check whether the water outlet of the wash well is normal (verify whether the probe outer wall cleaning is functioning properly).
Weekly	● Check and clean the outer wall of the reagent-sample probe and stirring rod ● Intensified cleaning of cuvettes ● Detect dirty cuvettes and light source lamp ● Clean reagent/sample barcode scanning window
Monthly	Clean the wash well of the reagent-sample probe and stirring rod
Others	● System reset ● Mechanical reset ● Regular cleaning of cuvettes ● Intensified cleaning of the reagent-sample probe ● Intensified cleaning of the stirring rod

Maintenance period	Maintenance items (in sequence)
Command operation	Dirty cuvettes detection

7.2.3 Daily maintenance

Daily maintenance must be completed before a test. The reagent-sample probe, wash wells, syringes, external water pipe connection, residue of concentrated wash buffer and more must be checked.

7.2.3.1 Check external water pipe connection

Abnormal deionized water connection may cause insufficient water supply or leakage, affecting the normal operation of the Analyzer.

Make sure that the Analyzer is vacant before performing the maintenance.

(1) Check whether switches of the water machine or other water conservation modules are on;

(2) Check that the liquid pipes are smooth without bends or twists, or leaks;

(3) Select “Maintenance” > “Perd. Maint.” > “Daily”;

(4) Select the corresponding box for checking liquid waste pipe connection;

(5) Click “Execution” to perform maintenance;

(6) Click “Log” to record errors and other necessary information about the maintenance;

(7) Click “Save” to save the log.

7.2.3.2 Check concentrated wash buffer residue

Shortage of concentrated wash buffer residue will cause the Analyzer to stop a test. It is suggested to check every day if there is sufficient concentrated wash buffer residue before a test. If insufficient, replenish it in time.

Make sure that the Analyzer is vacant before performing the maintenance.

(1) Check if there is sufficient concentrated wash buffer residue. If insufficient, replenish it in time;

(2) Select “Maintenance” > “Perd. Maint.” > “Daily”;

(3) Select the corresponding box for checking the concentrated wash buffer residue;

(4) Click “Execution” to perform maintenance;

(5) Click “Log” to record errors and other necessary information about the maintenance;

(6) Click “Save” to save the log.

7.2.3.3 Check if there are leakage and bubble for the syringe

The syringe of the reagent-sample probe is a device of accurately allocating samples and reagents. In case of syringe leakage, allocation will be inaccurate and even the syringe be damaged. Before a test every day, check if there are leakage and bubble for the syringe.

Maintenance tools: clean gauze.

Make sure that the Analyzer is vacant before performing the maintenance.

(1) Open the maintenance window of the Analyzer, and you can see the syringe;

(2) Select “Maintenance” > “Perd. Maint.” > “Daily”;

(3) Select the corresponding box for checking if there are leakage and bubble for the syringe;

(4) Check if there is leakage by using clean gauze to wipe the connection between the syringe and hand-tight joint. See if the gauze is wet to confirm leakage:

1) If no leakage, enter the next step;

2) It there is, tighten the hand-tight joint;

3) Check again if there is still leakage. If there is, unscrew the joint and ensure the gasket is kept well.

(5) Check if there is bubble in the syringe. If there is, contact Zybio or its local distributor;

(6) Close the maintenance window of the Analyzer;

(7) Click “Execution” to perform maintenance;

(8) Click “Log” to record errors and other necessary information about the maintenance;

(9) Click “Save” to save the log.

7.2.3.4 Check intensified wash buffer residue

Shortage of intensified wash buffer residue will cause the Analyzer to stop a test. It is suggested to check every day if there is sufficient intensified wash buffer residue before a test. If insufficient, replenish it in time.

Make sure that the Analyzer is off before performing the maintenance.

(1) Select “Maintenance” > “Perd. Maint.” > “Daily”;

(2) Select the corresponding box for checking the intensified wash buffer residue. Click “Execution” > “Next” to perform rotation descending of the reagent-sample probe to the intensified cleaning position. When descending to the current level, perform mechanical reset;

(3) Click “Execution” to perform maintenance;

(4) Click “Log” to record errors and other necessary information about the maintenance;

(5) Click “Save” to save the log.

7.2.3.5 Check whether the water outlet of the reagent-sample probe is normal (verify whether the probe inner wall is blocked)

There is impurity or abnormality in the reagent-sample probe, which may affect the test and lead to inaccurate results. Before a test every day, check if the water outlet of the probe is normal.

Make sure that the Analyzer is off before performing the maintenance.

(1) Open the upper cover of the Analyzer;

(2) Select “Maintenance” > “Perd. Maint.” > “Daily”;

(3) Select the corresponding check box for checking water outlet of probe;

(4) Click “Execution” and “Next” to clean the inner wall of the probe;

(5) Observe the water outlet when cleaning the inner wall of the probe as shown in the following figure. If the water splashes or does not get out vertically from the probe tip, the probe may be blocked. In this case, select Intensified Cleaning, if water outlet is still abnormal, then replace the reagent-sample probe, or contact Zybio or its local distributor;

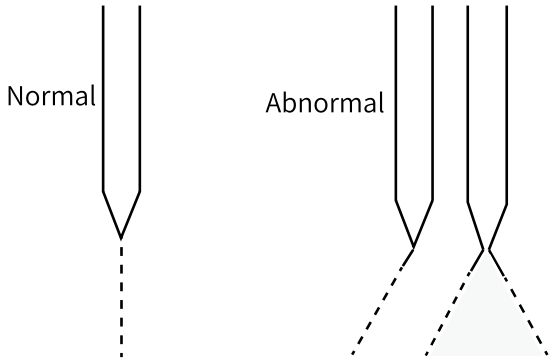


Figure 7-1 Water outlet when cleaning the probe inner wall

(6) Click "Log" to record errors and other necessary information about the maintenance;

(7) Click "Save" to save the log.

7.2.3.6 Check whether the water outlet of the wash well is normal (verify whether the probe outer wall cleaning is normal)

There is impurity or abnormality in the wash well, which may affect the test and lead to inaccurate results. Before a test every day, check if the water outlet of the well is normal.

Make sure that the Analyzer is off before performing the maintenance.

(1) Open the upper cover of the Analyzer;

(2) Select "Maintenance" > "Perd. Maint." > "Daily";

(3) Select the corresponding box for checking and cleaning the wash well;

(4) Click "Execution" and "Next" to clean the outer wall of the reagent-sample probe, and refer to the following figure to check the water flow from the well;

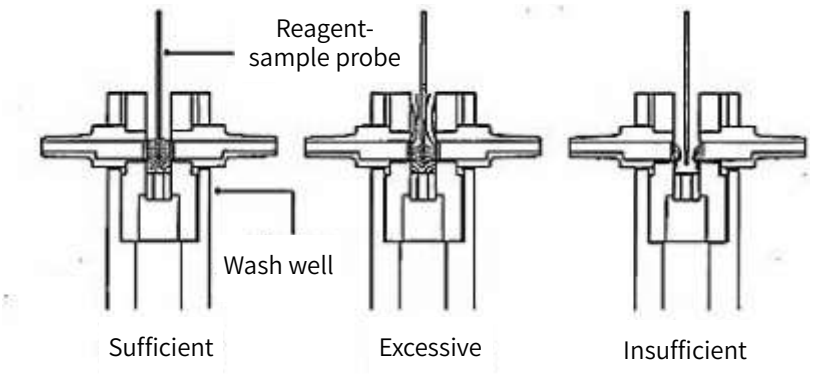


Figure 7-2 Water outlet when cleaning the probe outer wall

(5) If the flow is too small, click "Exit" and clean the well again. Then, repeat the above operations;

(6) Click "Log" to record errors and other necessary information about the maintenance;

(7) Click “Save” to save the log.

7.2.4 Weekly maintenance

Weekly maintenance includes the stirring rod/reagent-sample probe cleaning, intensified cleaning (cuvettes), cuvette detection, and light source lamp detection.

7.2.4.1 Check and clean the outer wall of the reagent-sample probe and stirring rod

If the reagent-sample probe and stirring rod are dirty, samples and reagents may be subject to cross contamination and analysis results are inaccurate. To avoid cross contamination, clean the reagent-sample probe and stirring rod every week.

Maintenance tools: clean gauze, deionized water, and cotton swabs.

Analyzer status: make sure that the Analyzer is off before performing the maintenance.

Please wear protective gloves, as the platform are deemed infectious.

(1) Select “Maintenance” > “Perd. Maint.” > “Weekly”, and select the corresponding box for checking and cleaning the outer wall of the reagent-sample probe and stirring rod;

(2) Click “Execution” and “Next” to perform reset of the reagent-sample probe. Click “Next” to perform reset and descending of the stirring rod to the wash well for the outer wall cleaning. The stirring rod resets to its original position vertically 5s later. Then, click “Next” to perform descending of the probe to the wash well for outer wall cleaning. The probe resets to their original positions vertically 5s later;

(3) Click “Next” to set the reagent-sample probe in the to-be-maintained status;

(4) Dip the clean gauze into the alcohol and wipe the outer wall of the probe until there is no stain;

(5) Click “Next” after the cleaning. Then click “Next” to take the next step. Keep away from the probe motion area;

(6) The maintenance is completed, and click “Next” to finish the maintenance process;

(7) After cleaning, click “Exit”.

7.2.4.2 Intensified cleaning of cuvettes

The acid-base wash buffer is used to clean cuvettes for keeping the cuvettes clean and avoiding cross contamination. It is suggested to do so every week.

Make sure that the Analyzer is off before performing the maintenance.

(1) Prepare a bottle of acid-base water buffer (volume >50ml) in the cleaning position;

(2) Select intensified cleaning and then click “Execution”;

(3) Click “Next”, and the Analyzer will perform intensified cleaning;

(4) Cuvettes are being detected, and please wait. Automatically take the next step after completion;

(5) The maintenance is completed, and click “Next” to finish the maintenance process.

7.2.4.3 Dirty cuvettes and light source lamp detection

Check if cuvettes are dirty and the light is dark by measuring the water blank of each cuvette.

(1) Ensure that the Analyzer is on for over 30 minutes and the light source is stable. Otherwise, exit the detection operation;

(2) Click “Next” to start dirty cuvette detection;

(3) Cuvettes are being detected, and please wait. Automatically take the next step after completion;

(4) The maintenance is completed, and click “Next” to finish the maintenance process.

7.2.4.4 Clean reagent/sample barcode scanning window

You are suggested to clean the reagent/sample barcode scanning window when any dirt is found on the window, so as to avoid cross contamination. It is suggested to do so weekly before a test.

Maintenance tools: clean gauze, alcohol.

Make sure that the Analyzer is off or vacant before performing the maintenance.

(1) Take out the upper cover of the Analyzer;

(2) Use clean gauze dipped with a little amount of alcohol, and wipe the barcode scanning window;

(3) Then, close the upper cover.

7.2.5 Monthly maintenance

This section will introduce details for monthly maintenance.

Clean wash wells of the reagent-sample probe and stirring rod to avoid congestion after a long time of dust sedimentation in wash wells.

(1) Click “Execution” to clean wash wells of the reagent-sample probe and stirring rod according to the following description;

(2) Manually move rocker arms of the reagent-sample probe and stirring rod away from wash wells;

(3) Dip swabs into NaClO (sodium hypochlorite) and wipe wash wells;

(4) Click “Next” after the cleaning. Then click “Next” to take the next step. Keep away from motion areas of the reagent-sample probe and stirring rod;

(5) The maintenance is completed, and click “Next” to finish the maintenance process.

7.3 Irregular maintenance items

This section introduces information about irregular maintenance and related operation steps. Click “Maintenance” > “Perd. Maint.” > “Others” to enter the irregular mechanical item interface. Maintenance items that can be done in the software include system reset, mechanical reset, irregular cleaning of cuvettes, and intensified cleaning of the reagent-sample probe and stirring rod.

Users can contact Zybio or its local distributor to perform the following maintenance items or add them to the irregular maintenance interface. These items include the over

temperature protection unit, wash well cleaning, reaction tank cleaning, drive rod wiping, purified water bucket detection, cuvette probe tube/suction nozzle cleaning, liquid waste container cleaning, reagent-sample probe clearing and replacement, stirring rod replacement, bulb replacement, syringe replacement, peristaltic pump head replacement, and liquid tube cleaning and replacement.

7.3.1 Others

7.3.1.1 System reset

The maintenance item of system reset is forprompting the moving parts to perform reset and cleaning.

(1) Click “System reset”, and the box turns blue;

(2) Click “Execution” to start system reset.

7.3.1.2 Mechanical reset

The maintenance item of mechanical reset is forprompting such moving part as the reagent-sample probe, stirring rod, etc., to perform mechanical reset.

(1) Click “Mechanical reset”, and the box turns blue;

(2) Click “Execution” to start mechanical reset.

7.3.1.3 Routine cleaning of cuvettes

Perform routine cleaning of cuvettes, and irregularly use cuvettes in proper time.

7.3.1.4 Intensified cleaning of the reagent-sample probe

Use the wash buffer to clean the reagent-sample probe, so as to reduce cross contamination. It is suggested to do so whenever necessary.

Make sure that the Analyzer is off before performing the maintenance.

(1) Open the upper cover of the analysis section;

(2) Add sufficient acid-based wash buffer in the acid-base cleaning position of the platform;

(3) Click “Maintenance” > “Perd. Maint.” > “Others”, and select the box for intensified cleaning;

(4) Click “Execution” > “Next”, and the Analyzer will perform intensified cleaning;

(5) Click “Log” to record errors and other necessary information about the maintenance;

(6) Click “Save” to save the log.

7.3.1.5 Intensified cleaning of the stirring rod

Use the wash buffer to clean the stirring rod, so as to reduce cross contamination. It is suggested to do so whenever necessary.

Make sure that the Analyzer is off before performing the maintenance.

(1) Open the upper cover of the analysis section;

(2) Add sufficient acid-based wash buffer in the acid-base cleaning position of the platform;

(3) Click “Maintenance” > “Perd. Maint.” > “Others”, and select the box for intensified

cleaning;

(4) Click “Execution” > “Next”, and the Analyzer will perform intensified cleaning;

(5) Click “Log” to record errors and other necessary information about the maintenance;

(6) Click “Save” to save the log.

7.3.2 Yearly maintenance (Suggested)

7.3.2.1 Over temperature protection unit

To ensure effective operation of the Analyzer, check the safety of the over temperature protection unit every year. The method is as follows:

Put the plastic package of the temperature protection switch in the waster at 90 - 100 °C (boiled water) for 5 minutes. If both ends of the heating wire fuse when using the multimeter to measure the wire, this proves the over temperature protection unit is normal, and vice versa.

Note

When using the method repeatedly, the instrument may be damaged and protection against risks may be reduced.

7.3.2.2 Wash well cleaning

(1) Turn off the Analysis section switch;

(2) Dip the cotton swabs into the wash buffer and wipe the inner and outer walls of the reagent-sample probe and stirring rod. Then, wipe out fluids with clean gauze until there is no visible stain.

Please wear protective gloves, as all dirt is deemed infectious.

7.3.2.3 Reaction tank cleaning

(1) Turn off the Analysis section switch;

(2) Move the cleaning head and the cover away;

(3) Loosen screws of the reaction tray;

(4) Hold both sides of the tray, and lift and take out it with well-distributed strengths;

(5) Dip the swabs into the wash buffer to clean the inner wall of the tank. Then, wipe out fluids with clean gauze until there is no visible stain;

(6) Put the tray back and tighten it with fastening screws;

(7) Cover the tray cover and install the cleaning head.

Please wear protective gloves, as all dirt is deemed infectious.

7.3.2.4 Drive rod wiping

(1) Turn on the analysis section switch;

(2) Move the stirring rod to turn its drive rod to an angle suitable for wiping;

(3) Gently wipe the drive rod up and down with clean gauze until there is no visible dust or stain, then apply the lubricant and pull the drive rod up and down so that the lubricant is evenly distributed on the drive rod;

(4) Wipe the drive rod of the reagent-sample probe in the same way;

(5) Move the reagent-sample probe and stirring rod over the corresponding wash well.

7.3.2.5 Purified water bucket check

A purified water bucket is placed on the left side of the Analyzer.

Check the bucket: check whether the bottom of the bucket is clean. If not, wash the bucket before using it.

7.3.2.6 Cuvette probe tube/suction nozzle cleaning

If the probe tube is not cleaned, there will be residues of reaction liquid and water. Check the probe tube in time after power off every day. If it is not clean, wash them according to the following steps.

(1) Gently wipe the drainage probe tube and tip with clean cotton swabs moistened with absolute ethyl alcohol until there are no visible stains;

(2) Gently wipe the suction probe tube and tip with clean cotton swabs moistened with absolute ethyl alcohol until there are no visible stains;

(3) Gently wipe all sides and the top and bottom parts of the suction nozzle with clean cotton swabs moistened with purified water until there are no visible stains;

(4) Gently wipe all sides and the top and bottom parts of the suction nozzle with clean cotton swabs moistened with absolute ethyl alcohol until there are no visible stains.

Note

Cotton fibers from cotton swabs may get caught between the drainage probe tube and suction probe tube during cleaning. If there are any, remove them promptly.

Please wear protective gloves, as all parts are deemed infectious.

7.3.2.7 Liquid waste container cleaning

Skip this step if the liquid waste is discharged directly into the sewer. Otherwise proceed in

the following order.

(1) Uncover the liquid waste container and remove the liquid waste sensor and pipe;

(2) Clean the container with a brush before putting it back in.

Please wear protective gloves, as all liquid waste is deemed infectious.

7.3.2.8 Reagent-sample probe clearing

The reagent-sample probe needs to be cleared immediately when it becomes clogged. Follow steps below to clear the probe:

(1) Turn off the analysis section switch;

(2) Turn the probe to a suitable position and open the top lid of the probe's rocker arm;

(3) Disconnect the lead from the liquid level detection plate;

(4) Loosen the Teflon tube connected to the probe;

(5) Loosen the compression spring piece;

(6) Remove the probe upwards;

(7) Unclog the probe from the tip upwards with the stainless steel wire (0.3 mm) and repeat the unclogging back and forth several times;

(8) Connect a disposable syringe to the probe through the matching hose and inject water through the syringe. When water can be ejected in a straight line from the tip, the probe has been unclogged;

(9) Attach the sample probe and cover the rocker arm in the reverse order of the above operations;

(10) Move the probe and stirring rod over the corresponding wash well.

Please wear protective gloves, as the reagent-sample probe is deemed infectious.

7.3.2.9 Reagent-sample probe replacement

In case the probe is clogged and cannot be unclogged, broken or bent, it must be replaced immediately. The operation refers to the previous section of Reagent-sample probe clearing.

(1) Turn off the Analysis section switch;

(2) Turn the probe to a suitable position and open the top lid of the probe's rocker arm. Loosen the Teflon tube, and disconnect the liquid level sensor lead;

(3) Loosen the compression spring piece, and take out the probe;

(4) Attach the new probe to the rocker arm and press the spring piece, then connect the Teflon tube and insert the liquid level sensor lead. After that, cover the rocker arm;

(5) Move the probe and stirring rod over the corresponding wash well.

Please wear protective gloves, as the reagent-sample probe is deemed infectious.

7.3.2.10 Stirring rod replacement

In case the stirring rod is broken or bent, or is frequently attached by solution, it needs to be replaced immediately.

(1) Turn off the Analysis section switch;

(2) Move the stirring rod to a suitable position;

(3) Loosen the two jack screws secured to the rotating shaft of the stirring motor;

(4) Remove the stirring rod;

(5) Mount a new stirring rod upwards into the motor's rotating shaft;

(6) Secure the stirring rod to the rotating shaft of the motor with two jack screws.

Please wear protective gloves, as the stirring rod is deemed infectious.

7.3.2.11 Bulb replacement

If the lamp has been used for more than six months, or if the Analyzer prompts that the lamp needs to be replaced, it needs to be replaced immediately.

Note

Before the replacement, make sure that the analysis section is powered off. Otherwise, the light from the lamp will cause eye damage.

Caution

Be careful not to drop the screws when loosening or securing the lamp screws.

(1) Turn off the Analysis section switch and carry out the subsequent steps half an hour later;

(2) Remove the auto-cleaning head and then the reaction tray cover;

(3) Loosen the set screws on the lamp using a M3 inner hexangular screwdriver after removing the tray;

(4) Remove the light source lamp and disconnect the power cable on the binding post;

(5) Remove the used lamp;

(6) Install the new lamp with the set screw and plug the power cable in;

(7) Place the reaction tray and tighten the set screw;

(8) Cover the tray cover and install the cleaning head.

7.3.2.12 Syringe replacement

(1) Open the maintenance window of the Analyzer to view the syringe of the reagent-probe syringe;

(2) Loosen the set screw on the piston end of the syringe and then another two set screws on the tee;

(3) Remove the syringe and tee by pinching the top metal part of the syringe and rotating it counterclockwise to separate the syringe from the tee;

(4) Insert the metal thread at the top of the new syringe into the threaded opening of the tee and rotate it clockwise to secure it;

Caution

There is a sealing washer in the threaded opening of the tee, so be careful not to lose it during disassembly.

(5) Place the syringe in the mounting position with the piston end of the syringe setting into the drive screw. Tighten the set screw of the tee and piston end of the syringe.

7.3.2.13 Peristaltic pump pipe replacement

(1) Turn off the analysis section switch and open the maintenance window of the Analyzer to see the peristaltic pump;

(2) Pull out the peristaltic pump head which is connected with rubber tube from the pipe joint. Then press the buckle on both ends of the head and pull out the head. Replace a new head;

(3) Mount the new head to the original joint, connect the pipe and close the maintenance window.

7.3.2.14 Fluid tube cleaning and replacement

The fluid tube is checked by Zybio or its local distributor every year or half a year. Disassemble the Analyzer shell and check if the fluid liquid is dirty or clogged. If it is, take out the tube, and clean it using 84 disinfectant added with water.

7.4 Dirty cuvette detection

This section introduces information about the command operation. See the following description for details.

Functional buttons on the “Dirty Cuv. Det.” interface will be introduced.

- The cuvette button refers to the cuvette No. 1 to 63. When clicking a button, users will see the window for the cuvette status where you can view the water blank AD values (including 12 wavelength channels for EXC200 or 8 channels for EXC220) of the cuvette in the current and previous tests.
    - The current results

Test Time: the system time when the current test is completed.

Status: the current detection results.

Channel 1-12: indicates wavelength 340-800 (Note: For EXC220, channels 1-8 indicates wavelength 340-700).

Water blank AD value: indicated the AD value of the selected cuvette.

- The previous results

  Test Time: the system time when the previous test is completed.

  Status: the previous detection results.

  Channel 1-12 or 1-8: indicates wavelength 340-800 or 340-700.

  Water blank AD value: indicated the AD value of the selected cuvette.

- The selected cuvette

  The central number is the selected cuvette which can be changed.

- Export

  Export the current and previous detection results, and the format is the same as that displayed.

- Status is displayed via two modes, including normal and abnormal (dirty cuvettes). Blue indicates normal cuvettes, while brown indicates abnormal ones.
- Test time: display the time when the current test is completed.
- Setup: set the initial water blank AD value for a cuvette, and view the currently initial AD value. The initial A can also be set for the current test result and input manually.
- Query Lamp Det. Results: view lamp detection results, and display lamp status and the mean water blank AD value of 12 or 8 channels for 63 cuvettes. The current test results are displayed by default.
- Query Cuv. Det. Result: search test results of all cuvettes for a single test (water blank AD values, including 12 or 8 channels) by the time. The current test results are displayed by default.
- Export: export the current test results of all cuvettes (water blank AD values, including 12 or 8 channels).
- Start: start a new test of dirty cuvette detection. After the test, the test time will be updated to the current system time, and status of 63 cuvetttes is refreshed.
- Stop: stop the current test of cuvette detection. The data of completed tests will be saved, while those of uncompleted tests will be blank.

7.5 List of replaced parts

This section will briefly introduce lists of parts that need to be replaced by users, or Zybio or its local distributor.

7.5.1 Parts replaced by users

This section lists parts that can be replaced by users themselves.

- The reagent-sample probe and stirring rod (See the section 7.3.2.9 and 7.3.2.10);
- Bulb (See the section 7.3.2.11);

- Peristaltic pump head (See the section 7.3.2.13).

7.5.2 Parts replaced by Zybio or its local distributor

This section lists parts that should be replaced by Zybio or its local distributor.

- Main power switch;
- Analysis section power switch;
- Over temperature protection unit;
- Other parts.

7.6 Maintenance log

The list below describes the parts that require maintenance and the recommended maintenance schedule. Please print the tables below each month and make records in the tables every time after finishing maintenance.

Table 7-2 Daily maintenance items

_____(month & year)

	Items (daily)	Maintenance logs																														
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
1	Check external water pipe connection																															
2	Check concentrated wash buffer residue																															
3	Check if there is leakage and bubble for the syringe																															
4	Check intensified wash buffer residue																															

5	Check whether the water outlet of the reagent-sample probe is normal (verify whether the probe inner wall is blocked)																													
6	Check whether the water outlet of the wash well is normal (verify whether the probe outer wall cleaning is functioning properly)																													

Table 7-3 Weekly maintenance items

_____(month & year)

	Items (weekly)	Maintenance logs																													
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
1	Check and clean the outer wall of the reagent-sample probe and stirring rod																															
2	Intensified cleaning of cuvettes																															
3	Dirty cuvettes and light source lamp detection																															
4	Check reagent/sample barcode scanning window																															

Table 7-4 Monthly maintenance items

_____(month & year)

	Items (monthly)	Maintenance logs																													
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
1	Clean the wash well of the reagent-sample probe and stirring rod																															

Table 7-5 Other maintenance items

_____(month & year)

	Items (others)	Maintenance logs																														
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
1	System reset																															
2	Mechanical reset																															
3	Routine cleaning of cuvettes																															
4	Intensified cleaning of the reagent-sample probe																															
5	Intensified cleaning of the stirring rod																															

8 Alarm and error handling

This chapter introduces information about alarm and error handling.

8.1 Alarm display

Data alarm is a kind of mark for abnormal test results displayed on the software interface.

- Choose “Status” > “Sample tray”, where the remark column displays marks that indicate abnormal test results for the current sample/calibrator/control in the current item test. No mark means a normal test result. The marks and the corresponding causes are as follows.

Table 8-1 Mark explanation of the sample tray

No.	Mark	Cause	Calibration	QC	Sample
1	ADE	ADi≤ADid	Applicable	Applicable	Applicable
2	RBK	R1 blank absorbance exceeding limit	Applicable	Applicable	Applicable
3	ABS	Working solution absorbance exceeding limit	Applicable	Applicable	Applicable
4	RCE	Incorrect calculation of reactivity	Applicable	Applicable	Applicable
5	RCT	Working solution reactivity exceeding limit	Applicable	Applicable	Applicable
6	PRO	Abnormal prozone examination	Applicable	Applicable	Applicable
7	PROE	Prozone check calculation error	Applicable	Applicable	Applicable
8	BOE	Substrate depletion	Applicable	Applicable	Applicable
9	NLN	No linear interval	Applicable	Applicable	Applicable
10	ENC	No calculation interval	Applicable	Applicable	Applicable
11	EXP	The reactivity is calculated using the enzyme linear expansion feature	Applicable	Applicable	Applicable
12	LIN	The linearity is below the linearity limit	Applicable	Applicable	Applicable
13	MBK	Mixed blank absorbance exceeding limit	Applicable	/	/
14	BLK	Blank reactivity exceeding limit	Applicable	/	/

No.	Mark	Cause	Calibration	QC	Sample
15	RRN	The reactivity of the sample exceeds that of the calibrator with the maximum concentration	/	Applicable	Applicable
16	RRNE	Concentration calculation error occurs after exceeding reactivity of the calibrator with the maximum concentration	/	Applicable	Applicable
17	LOW	The reactivity of the sample is below that of the calibrator with the minimum concentration	/	Applicable	Applicable
18	LRG	The sample concentration is beyond the upper limit of the linear range	/	Applicable	Applicable
19	LRL	The sample concentration is beyond the lower limit of the linear range	/	Applicable	Applicable
20	↑!	The sample concentration is beyond the upper limit of the critical value range	/	/	Applicable
21	↓!	The sample concentration is beyond the lower limit of the critical value range	/	/	Applicable
22	↑	The sample concentration is beyond the upper limit of the normal reference range	/	/	Applicable
23	↓	The sample concentration is beyond the lower limit of the normal reference range	/	/	Applicable

- “Mark” and “Prompt” on the “Result” interface refer to abnormal test results of samples. And the blank one means normal results. The marks and the corresponding causes are as follows.

Table 8-2 Mark explanation of the result interface

No.	Mark	Cause	Symbol	Prompt
1	ADE	ADi≤ADid	/	Applicable
2	RBK	R1 blank absorbance exceeding limit	/	Applicable
3	ABS	Working solution absorbance exceeding limit	/	Applicable
4	RCE	Incorrect calculation of reactivity	/	Applicable
5	RCT	Working solution reactivity exceeding limit	/	Applicable
6	PRO	Abnormal prozone examination	/	Applicable
7	PROE	Prozone check calculation error	/	Applicable

No.	Mark	Cause	Symbol	Prompt
8	BOE	Substrate depletion	/	Applicable
9	NLN	No linear interval	/	Applicable
10	ENC	No calculation interval	/	Applicable
11	EXP	The reactivity is calculated using the enzyme linear expansion feature	/	Applicable
12	LIN	The linearity is below the linearity limit	/	Applicable
13	RRN	The reactivity of the sample exceeds that of the calibrator with the maximum concentration	/	Applicable
14	RRNE	Concentration calculation error occurs after exceeding reactivity of the calibrator with the maximum concentration	/	Applicable
15	LOW	The reactivity of the sample is below that of the calibrator with the minimum concentration	/	Applicable
16	LRG	The sample concentration is beyond the upper limit of the linear range	/	Applicable
17	LRL	The sample concentration is beyond the lower limit of the linear range	/	Applicable
18	↑!	The sample concentration is beyond the upper limit of the critical value range	Applicable	/
19	↓!	The sample concentration is beyond the lower limit of the critical value range	Applicable	/
20	↑	The sample concentration is beyond the upper limit of the normal reference range	Applicable	/
21	↓	The sample concentration is beyond the lower limit of the normal reference range	Applicable	/
22	ER	Use expired reagents	/	Applicable
23	DCP	Use delayed calibration parameters	/	Applicable

- Marks on the “Calibration” > “Cal R” interface refer to abnormal test results of calibration. And the blank one means normal results. The marks and the corresponding causes are as follows.

Table 8-3 Mark explanation of the calibration result interface

No.	Mark	Cause	Mark
1	DMON	The nonlinear calibration data is not monotonous.	Applicable
2	CDE	The concentration is divided by 0 (the reactivity is 0).	Applicable
3	COV	The nonlinear calibration iteration does not converge.	Applicable
4	CMON	The nonlinear calibration curve is not monotonous.	Applicable

No.	Mark	Cause	Mark
5	ER	Use expired reagents	Applicable

- Remarks on the "Calibration" > "Cal R" > "C. Curve" interface and "Summary" of the calibration test information refer to abnormal test results. And the blank one means normal results. The marks and the corresponding causes are as follows.

Table 8-4 Mark explanation of the calibration curve interface

No.	Mark	Cause	Remarks	Conclusion
1	ADE	ADi≤ADid	Applicable	/
2	RBK	R1 blank absorbance exceeding limit	Applicable	/
3	ABS	Working solution absorbance exceeding limit	Applicable	/
4	RCE	Incorrect calculation of reactivity	Applicable	/
5	RCT	Working solution reactivity exceeding limit	Applicable	/
6	PRO	Abnormal prozone examination	Applicable	/
7	PROE	Prozone check calculation error	Applicable	/
8	BOE	Substrate depletion	Applicable	/
9	NLN	No linear interval	Applicable	/
10	ENC	No calculation interval	Applicable	/
11	EXP	The reactivity is calculated using the enzyme linear expansion feature	Applicable	/
12	LIN	The linearity is below the linearity limit	Applicable	/
13	MBK	Mixed blank absorbance exceeding limit	Applicable	Applicable
14	BLK	Blank reactivity exceeding limit	Applicable	Applicable
15	DUP	Calibration repeatability	Applicable	Applicable
16	SEN	Calibration sensitivity	/	Applicable
17	CSD	High standard deviation of the calibration curve	/	Applicable
18	DET	Low degree of fitting of the calibration curve	/	Applicable
19	FAC	Calibration coefficient difference exceeding limit	/	Applicable
20	ECF	Use expired calibrators	Applicable	/

- Marks on the "QC" > "QC Data" interface refer to abnormal test results of QC. And the blank one means normal results. The marks and the corresponding causes are as follows.

Table 8-5 Mark explanation of the QC data interface

No.	Mark	Cause	Mark
1	ADE	ADi≤ADid	Applicable

No.	Mark	Cause	Mark
2	RBK	R1 blank absorbance exceeding limit	Applicable
3	ABS	Working solution absorbance exceeding limit	Applicable
4	RCE	Incorrect calculation of reactivity	Applicable
5	RCT	Working solution reactivity exceeding limit	Applicable
6	PRO	Abnormal prozone examination	Applicable
7	PROE	Prozone check calculation error	Applicable
8	BOE	Substrate depletion	Applicable
9	NLN	No linear interval	Applicable
10	ENC	No calculation interval	Applicable
11	EXP	The reactivity is calculated using the enzyme linear expansion feature	Applicable
12	LIN	The linearity is below the linearity limit	Applicable
13	RRN	The reactivity of controls exceeds that of the calibrator with the maximum concentration	Applicable
14	RRNE	Concentration calculation error occurs after exceeding reactivity of the calibrator with the maximum concentration	Applicable
15	LOW	The reactivity of the control is below that of the calibrator with the minimum concentration	Applicable
16	LRG	The control concentration is beyond the upper limit of the linear range	Applicable
17	LRL	The control concentration is beyond the lower limit of the linear range	Applicable
18	ER	Use expired reagents	Applicable
19	DCP	Use delayed calibration parameters	Applicable

8.2 Alarm and troubleshooting

When the Analyzer sounds an alarm, the system will, depending on the alarm level, automatically process the alarm in the following seven modes, which will be displayed on the bottom of the software interface with a highlight red bar. When users click the red bar, the detailed error information, possible causes, and solutions will pop up.

- Prohibit tests

  Only diagnostics and maintenance are allowed, and any test is prohibited.

- Turn off

  Stop all the current test, and the Analyzer is on standby waiting for intervention.

- Stop all tests

  All tests that are not started are suspended, but those already in the queue will not stop.

- Stop tests of relevant samples

Tests of certain samples are suspended, but other tests are not.

- Stop tests of relevant reagents

  Tests of certain reagents are suspended, but other tests are not.

- Warning

  A warning message pops up, but the analyzer will not process it.

- Prompt

  A prompt message pops up, but the analyzer will not process it.

8.2.1 Alarm information search

The method of searching a runtime error of the Analyzer is as follows.

- Click “Maintenance” > “Trouble Shooting”. View the alarm information in the pop-up window.

8.2.2 Analyzer operation error table

The following table will list errors, cause and handling measures.

Table 8-6 Analyzer operation error table

Code	Description	Causes	Solutions
F00001	Unit error in periodic tests.	A unit performs incorrectly.	Perform periodic recovery command.
F00002	Unit errors in the recovery period and recovery errors but photoelectric data collection available.	A unit performs incorrectly.	Turn off and restart the master computer for start-up self-check.
F00003	Unit errors in the recovery period and recovery errors, and master computer stop.	A unit performs incorrectly.	Turn off and restart the master computer for start-up self-check.
F00004	Unit error in periodic tests.	A unit performs incorrectly.	Perform periodic recovery command.
F00005	Unit error in periodic tests.	A unit performs incorrectly.	Perform periodic recovery command.
F00006	Unit error in periodic tests.	A unit performs incorrectly.	Perform periodic recovery command.
F00007	Unit error in periodic tests.	A unit performs incorrectly.	Perform periodic recovery command.
F00008	The sample probe is not in the vertical initial position, and it cannot rotate.	1. The sample probe is not in the vertical initial position; 2. The probe vertical initial position sensor errors or lead errors.	Check the wire and joint. First perform probe vertical position recovery, and then the rotation command. If the problem still occurs, contact Zybio or its local distributor.
F00009	The sample probe can detect the liquid level of acid-base wash buffer when descending, but the amount is insufficient (The probe can touch the bottom of the reagent cuvette only with another 5 steps).	Insufficient acid-base wash buffer;	Add acid -base wash buffer. If the problem still occurs, contact Zybio or its local distributor.
F00010	The sample probe cannot detect the liquid level of acid-base wash buffer when descending, which means the probe level	1. No acid-base wash buffer; 2. Liquid level sensor errors.	1. Add reagents; 2. Check the wire and sensor.

Code	Description	Causes	Solutions
	sensor is in trouble or there are no reagents in the wash buffer vial.		If the problem still occurs, contact Zybio or its local distributor.
F00011	The sample probe cannot detect the sensor signal of the initial position after ultimate steps when it vertically moves to the initial position.	1. Strong light or severe electromagnetic interference; 2. Poor wire connection of stepper motor leads to step loss; 3. Stepper motor damage; 4. The initial position sensor is broken or subject to poor wire connection; 5. The motor drive board errors; 6. Sensor wire or plug errors.	When the strong light or severe electromagnetic interference is excluded, check if the sensor plug is loose. If not, check if the wire is broken, and perform restarting. If the problem still occurs, contact Zybio or its local distributor.
F00012	The sample probe is subject to collision when moving vertically.	1. The reagent vial is covered; 2. The sample vial is covered; 3. The reagent-sample tray cover or the reaction tray cover is not placed in the correct position; 4. Severe electromagnetic interference exists; 5. The collided sensor is broken or subject to poor wire connection.	1. Check if the reagent vial is opened and the reagent is placed correctly; 2. Check if the sample vial is opened and the sample is placed correctly; 3. Put the reagent-sample tray cover or the reaction tray cover in the correct position; 4. Exclude possible electromagnetic interference. If the problem still occurs, contact Zybio or its local distributor.
F00013	The sample probe is still in the initial position before finishing specified steps when the probe moves vertically, which means the initial position sensor is in trouble or step loss.	1. Strong light or severe electromagnetic interference; 2. Poor wire connection of stepper motor leads to step loss; 3. Stepper motor damage; 4. The initial position sensor is broken or subject to poor wire connection;	When the strong light or severe electromagnetic interference is exluded, check if the sensor plug is loose. If not, check if the wire is broken, and perform restarting. If the problem still occurs, contact Zybio or its local distributor.

Code	Description	Causes	Solutions
		5. The motor drive board errors; 6. Sensor wire or plug errors.	
F00014	The sample probe detects the liquid level signal before touching the reagent vial mouth when descending, which means the level sensor is in trouble or there are beads around the probe tip.	1. The probe is dirty, so there are beads around the tip; 2. Wash buffer in the container is insufficient, so there are beads around the tip; 3. Liquid level sensor board sensitivity is enhanced; 4. Severe electromagnetic interference.	1. Check the wash buffer container. If insufficient, add some; 2. Check the tip. If it is dirty, use absorbent cotton swabs moistened with absolute ethyl alcohol to wipe it slightly; 3. Exclude severe electromagnetic interference. If the problem still occurs, contact Zybio or its local distributor.
F00015	The sample probe can detect the liquid level when descending, but the reagent is insufficient (The probe can touch the bottom of the reagent cuvette only with another 5 steps.).	Insufficient reagents;	1. Add reagents. If the problem still occurs, contact Zybio or its local distributor.
F00016	The sample probe cannot detect the liquid level when descending, which means the probe level sensor is in trouble or there are no reagents in the wash buffer vial.	1. No reagents; 2. Reagents are placed incorrectly; 3. Liquid level sensor errors.	1. Check the reagent position; 2. Add reagents; 3. Check the wire and sensor. If the problem still occurs, contact Zybio or its local distributor.
F00017	The sample probe is not in the vertical, initial position and can not descend to the specified position. When descending forcibly, the probe will be subject to collision. So the operation cannot be performed.	The sample probe is not in the vertical, initial position;	1. Execute the vertical recovery command for the probe, and then execute the descending command. If the problem still occurs, contact Zybio or its local distributor.

Code	Description	Causes	Solutions
F00018	Although the sample is not aspirated in this period, the sample probe is not in the vertical, initial position when moving downwards to the cuvette.	1. Strong light or severe electromagnetic interference; 2. The initial position sensor is broken or subject to poor wire connection; 3. Not execute the vertical recovery command for the probe firstly.	First execute the vertical recovery command. When the strong light or the severe electromagnetic interference is exluded, perform restarting. If the problem still occurs, contact Zybio or its local distributor.
F00019	Although the sample is aspirated in this period, the sample probe is not in the vertical, initial position when moving downwards to the cuvette.	See F00018	See F00018
F00020	Although the sample is aspirated before, the sample probe is not in the initial position and cannot descend to complete cleaning when start cleaning the probe.	See F00018	See F00018
F00021	Although the sample is not aspirated before, the sample probe is not in the initial position and cannot descend to complete cleaning when start cleaning the probe.	See F00018	See F00018
F00022	The sample probe is not in the initial position and cannot descend to the specfied position and complete cleaning.	See F00018	See F00018
F00023	The sample is aspirated, but the sample probe is not in the initial position and cannot descend to the wash well and discharge wash buffer for cleaning.	See F00018	See F00018
F00024	The sample is not aspirated, but the sample probe is not in the initial position and cannot descend to the wash well and discharge wash buffer for cleaning.	See F00018	See F00018

Code	Description	Causes	Solutions
F00025	The sample probe cannot detect the initial position before ultimate steps when the probe horizontally rotates to the initial position. This may be explained by the initial position sensor errors or step loss.	1. Strong light or severe electromagnetic interference; 2. Poor wire connection of stepper motor leads to step loss; 3. Stepper motor damage; 4. The initial position sensor is broken or subject to poor wire connection; 5. The motor drive board errors; 6. Sensor wire or plug errors.	When the strong light or severe electromagnetic interference is exluded, check if the sensor plug is loose. If not, check if the wire is broken, and perform restarting. If the problem still occurs, contact Zybio or its local distributor.
F00026	The sample probe is in the initial position. To perform horizontal rotation the initial position, the probe must rotate counterclockwise with certain steps and then rotate clockwise to the initial position. The sample probe is kept in the initial position after specified steps. This may be explained by the initial position sensor errors or step loss.	See F00025	See F00025
F00027	The sample probe cannot detect the cleaning position before specified steps when the probe horizontally rotates to the cleaning position. This may be explained by the encoding tray sensor errors or motor step loss.	1. Strong light or severe electromagnetic interference; 2. Poor wire connection of stepper motor leads to step loss; 3. Stepper motor damage; 4. The encoding tray sensor is broken or subject to poor wire connection; 5. The motor drive board errors; 6. Sensor wire or plug errors.	See F00025
F00028	The sample probe cannot arrive the specified position of he reagent cuvette	See F00027	See F00025

Code	Description	Causes	Solutions
	when rotating to this position, which means the encoding tray sensor errors or step loss.		
F00029	The sample probe cannot arrive in the specified position of the sample cuvette when rotating to this position, which means the encoding tray sensor errors or step loss.	See F00027	See F00025
F00030	For not knowing the position where the sample probe arrives before its rotation, it is because that the horizontal rotation recovery is not performed before rotation or the rotation is in trouble. To complete the procedure, please perform the horizontal rotation recovery firstly.	Not execute the rotation recovery command.	1. Execute the rotation recovery command for the probe, and then execute related rotation command. If the problem still occurs, contact Zybio or its local distributor.
F00031	The sample probe cannot find the reaction tray position before specified steps when the probe horizontally rotates to the tray position.	See F00027	See F00025
F00032	The sample probe detects the liquid level before touching the sample cuvette mouth when descending, which means the level sensor is in trouble or there are beads around the probe tip.	1. The probe is dirty, so there are beads around the tip; 2. Wash buffer in the container is insufficient, so there are beads around the tip; 3. Liquid level sensor board sensitivity is enhanced; 4. Severe electromagnetic interference.	1. Check the wash buffer container. If insufficient, add some; 2. Check the tip. If it is dirty, use absorbent cotton swabs moistened with absolute ethyl alcohol to wipe it slightly; 3. Exclude severe electromagnetic interference. If the problem still occurs, contact Zybio or its local distributor.
F00033	When cleaning the inner wall of the sample probe, the electromagnetic valve cannot be opened for the cleaning.	1. Severe electromagnetic interference; 2. The wash buffer valve is broken or subject to poor wire connection;	When the severe electromagnetic interference is excluded, check wire and pump valve and perform

Code	Description	Causes	Solutions
		3. Valve driver board is broken.	restarting. If the problem still occurs, contact Zybio or its local distributor.
F00034	When opening the liquid pump frequently or cleaning the outer wall of the sample probe, the liquid pump cannot be opened.	1. Severe electromagnetic interference; 2. The wash buffer pump is broken or subject to poor wire connection; 3. Pump driver board is broken.	See F00033
F00035	Open the electromagnetic valve firstly when cleaning the inner and outer walls of the sample probe. 0.8 seconds later, the liquid valve cannot be opened. So the electromagnetic valve shall be closed, but it cannot be closed.	1. Severe electromagnetic interference; 2. The liquid valve of cleaning the inner wall is broken or subject to poor wire connection; 3. The wash buffer pump is broken or subject to poor wire connection; 4. Pump valve driver board is broken.	See F00033
F00036	When cleaning the probe is done, the liquid pump and electromagnetic valve cannot be closed.	See F00035	See F00033
F00037	When cleaning the probe is done, the electromagnetic valve cannot be closed.	1. Severe electromagnetic interference; 2. The liquid valve of cleaning the inner wall is broken or subject to poor wire connection; 3. Valve driver board is broken.	See F00033
F00038	When cleaning the probe is done, the liquid pump cannot be closed.	See F00034	See F00033
F00039	When cleaning the inner and outer walls of the sample probe, the cleaning valve cannot be opened.	See F00037	See F00033
F00040	The sample syringe does not stop running before ultimate steps when it vertically	1. Strong light or severe electromagnetic interference;	When the strong light or severe electromagnetic interference is

Code	Description	Causes	Solutions
	moves to the initial position, which means the initial position sensor errors or step loss.	2. Poor wire connection of stepper motor leads to step loss; 3. Stepper motor damage; 4. The initial position sensor is broken or subject to poor wire connection; 5. The motor drive board errors; 6. Sensor wire or plug errors.	exluded, check if the sensor plug is loose. If not, check if the wire is broken, and perform restarting. If the problem still occurs, contact Zybio or its local distributor.
F00041	Unit error in periodic tests.	A unit performs incorrectly.	Perform periodic recovery command.
F00042	Inspection and errors of command frame received by the sample probe unit.	1. Severe electromagnetic interference; 2. Serial cable is loose; 3. Serial cable is connected poorly.	1. Check and tighten the serial cable after shutting down; 2. Exclude severe electromagnetic interference and perform restarting. If the problem still occurs, contact Zybio or its local distributor.
F00043	The sample probe can detect the sample liquid level when descending, but the amount is insufficient (The probe can continue to descend and will touch the bottom of the sample cuvette only with another 5 steps).	Insufficient sample;	1. Add sample. If the problem still occurs, contact Zybio or its local distributor.
F00044	The sample probe cannot detect the sample liquid level when descending, which means the probe level sensor is in trouble or there are no samples in the vial.	1. No samples; 2. Samples are placed incorrectly; 3. Liquid level sensor errors.	1. Check the sample position; 2. Add sample. 3. Check the wire and sensor. If the problem still occurs, contact Zybio or its local distributor.
F00045	Before the sample probe rotates to the specified position of the reagent cuvette, the position transmitted in the command is not 1-60 (1-40 for the 100 series), and the	The command sent includes improper cuvette No.	The command sent by users must be proper cuvette No.

Code	Description	Causes	Solutions
	probe cannot rotate to the specified cuvette.		
F00046	The sample probe arrives in the initial vertical position in advance when moving to this position.	This may be explained by the initial position sensor errors or external light intervening the sensor signal.	Check if there is light interference, Otherwise, contact Zybio or its local distributor.
F00047	The sample syringe arrives in the initial vertical position in advance when moving to this position.	This may be explained by the initial position sensor errors or external light intervening the sensor signal.	See F00046
F00048	The sample syringe is kept in the initial vertical position in the process of its vertical recovery.	See F00040	See F00040
F00049	Before the sample probe rotates to the specified position of the sample cuvette, the position transmitted in the command is not 1-60 (1-40 for the 100 series), and the probe cannot rotate to the specified cuvette.	The command sent includes improper cuvette No.	The command sent by users must be proper cuvette No.
F00050	Unit error in periodic tests.	A unit performs incorrectly.	Perform periodic recovery command.
F00051	Invalid commands of the sample probe unit	The command sent by the master computer is the improper one of the sample probe unit.	Check if the sent command is correct
F00052	Means errors of the probe encoding tray sensor for horizontal rotation or step loss.	1. Strong light or severe electromagnetic interference; 2. Poor wire connection of stepper motor leads to step loss; 3. Stepper motor damage; 4. The encoding tray sensor is broken or subject to poor wire connection; 5. The motor drive board errors;	When the strong light or severe electromagnetic interference is ecluded, check if the sensor plug is loose. If not, check if the wire is broken, and perform restarting. If the problem still occurs, contact Zybio or its local distributor.

Code	Description	Causes	Solutions
		6. Sensor wire or plug errors.	
F00053	Means errors of the probe encoding tray sensor for horizontal rotation or step loss.	See F00052	See F00052
F00054	Means errors of the probe encoding tray sensor for horizontal rotation or step loss.	See F00052	See F00052
F00055	The sample probe can detect the sample liquid level when descending and during on-line dilution, but the amount is insufficient (The probe can continue to descend and will touch the bottom of the sample cuvette only with another 5 steps).	Insufficient sample;	Add sample. If the problem still occurs, contact Zybio or its local distributor.
F00056	The sample probe cannot detect the sample liquid level when descending and during on-line dilution, which means the probe level sensor is in trouble or there are no samples in the vial.	1. Insufficient sample; 2. Samples are placed incorrectly; 3. Liquid level sensor errors.	1. Check the sample position; 2. Add sample. 3. Check the wire and sensor. If the problem still occurs, contact Zybio or its local distributor.
F00057	Means errors of the probe initial position sensor for horizontal rotation or step loss.	1. Strong light or severe electromagnetic interference; 2. Poor wire connection of stepper motor leads to step loss; 3. Stepper motor damage; 4. The initial position sensor is broken or subject to poor wire connection; 5. The motor drive board errors; 6. Sensor wire or plug errors.	When the strong light or severe electromagnetic interference is excluded, check if the sensor plug is loose. If not, check if the wire is broken, and perform restarting. If the problem still occurs, contact Zybio or its local distributor.
F00058	The sample volume is insufficient in the reaction cuvettes, and there may be risks of collision when aspirating samples	The volume set on the software is greater than the largest amount of samples allowed to be aspirated in cuvettes	Contact Zybio or its local distributor.

Code	Description	Causes	Solutions
F00066	The encoding tray detection errors or step loss during rotation of the reagent-sample tray	1. Strong light or severe electromagnetic interference; 2. Poor wire connection of stepper motor leads to step loss; 3. Stepper motor damage; 4. The encoding tray sensor is broken or subject to poor wire connection; 5. The motor drive board errors; 6. Sensor wire or plug errors.	When the strong light or severe electromagnetic interference is excluded, check if the sensor plug is loose. If not, check if the wire is broken, and perform restarting. If the problem still occurs, contact Zybio or its local distributor.
F00067	Means errors of the initial position sensor of the reagent tray or step loss.	See F00057	See F00057
F00068	Means errors of the encoding tray sensor of the reagent tray or step loss.	See F00066	See F00066
F00069	Means errors of the encoding tray of the reagent tray or step loss.	See F00066	See F00066
F00070	The stirring rod does not stop running before ultimate steps when it vertically moves to the initial position, which means the initial position sensor errors or step loss.	See F00057	See F00057
F00071	The stirring rod is kept in the initial position before specified steps when vertically descending from this position.	See F00057	See F00057
F00072	The stirring rod is not in the initial position and can not descend to the specified position. When descending forcibly, the rod will be subject to collision. So the operation cannot be performed.	1. The stirring rod is not in the vertical initial position; 2. The vertical initial position sensor errors or wire errors.	Check the wire or plug, and execute the vertical recovery command of the rod. If the problem still occurs, contact Zybio or its local distributor.

Code	Description	Causes	Solutions
F00073	Cannot open the rod motor.	1. Severe electromagnetic interference; 2. The wire is connected poorly; 3. Drive board is broken.	When the severe electromagnetic interference is excluded, check the wire and circuit board and perform restarting. If the problem still occurs, contact Zybio or its local distributor.
F00074	Cannot close the rod motor.	See F00073	See F00073
F00079	The stirring rod cannot find the initial position before specified steps when the probe horizontally rotates to this position.	See F00057	See F00057
F00080	The stirring rod is in the initial position. When performing horizontal rotation the initial position, the rod must leave this position and then rotate to the position. The stirring rod is still kept in the position after specified steps. This may be explained by initial position sensor errors or step loss.	See F00057	See F00057
F00081	The stirring rod cannot detect the cleaning position before specified steps when the rod horizontally rotates to the position. This may be explained by the encoding tray sensor errors or step loss. Or this is because step loss r the encoding tray signal errors lead to failed detection of signal.	1. Strong light or severe electromagnetic interference; 2. Poor wire connection of stepper motor leads to step loss; 3. Stepper motor damage; 4. The encoding tray sensor is broken or subject to poor wire connection; 5. The motor drive board errors; 6. Sensor wire or plug errors.	When the strong light or severe electromagnetic interference is excluded, check if the sensor plug is loose. If not, check if the wire is broken, and perform restarting. If the problem still occurs, contact Zybio or its local distributor.
F00082	The stirring rod cannot detect the cleaning position before ultimate steps are done in the speed-down area, when the rod horizontally rotates to the position. This	See F00081	See F00081

Code	Description	Causes	Solutions
	may be explained by the encoding tray sensor errors or step loss.		
F00083	The stirring rod cannot detect the reaction tray position before ultimate steps are done, when the rod horizontally rotates to the position. This may be explained by the encoding tray sensor errors or step loss.	See F00081	See F00081
F00084	The stirring rod cannot detect the reaction tray position before ultimate steps are done in the speed-down area, when the rod horizontally rotates to the position. This may be explained by the encoding tray sensor errors or step loss.	See F00081	See F00081
F00085	For not knowing the position where the stirring rod arrives before its rotation,	It is because that the horizontal rotation recovery is not performed before rotation or the rotation is in trouble.	To complete the procedure, please perform the horizontal rotation recovery firstly.
F00086	The sample probe arrives in the initial vertical position in advance when moving to this position.	This may be explained by the initial position sensor errors or external light intervening the sensor signal.	Check if there is light interference, Otherwise, contact Zybio or its local distributor.
F00087	The stirring rod is not in the initial vertical position, and it cannot rotate.	1. The stirring rod is not in the initial vertical position; 2. The initial vertical position sensor errors or wire errors.	First perform the rod vertical position recovery, and check the wire and joint. Then, perform the related rotation command. If the problem still occurs, contact Zybio or its local distributor.
F00088	Inspection and errors of command frame received by the stirring rod unit.	1. Severe electromagnetic interference; 2. Serial cable is loose; 3. Serial cable is connected poorly.	1. Check and tighten the serial cable after shutting down; 2. Exclude severe electromagnetic interference and perform restarting. Start up again

Code	Description	Causes	Solutions
			If the problem still occurs, contact Zybio or its local distributor.
F00089	The cleaning head is not in the initial vertical position, and reaction tray cannot rotate.	1. The cleaning head is not in the initial vertical position; 2. The cleaning head vertical initial position sensor errors or lead errors.	First perform the head vertical position recovery, and check the wire and joint. Then, perform the related command. If the problem still occurs, contact Zybio or its local distributor.
F00090	Efficacy and byte of the command frame are not the same as those computed. There are errors for the returning of the command. Or there is the invaid command.	See F00088	See F00088
F00091	The ultimate steps of a cuvette on the reaction tray are done, but the encoding tray signal is not detected.	1. Strong light or severe electromagnetic interference; 2. Poor wire connection of stepper motor leads to step loss; 3. Stepper motor damage; 4. The encoding tray sensor is broken or subject to poor wire connection; 5. The motor drive board errors; 6. Sensor wire or plug errors.	When the strong light or severe electromagnetic interference is excluded, check if the sensor plug is loose. If not, check if the wire is broken, and perform restarting. If the problem still occurs, contact Zybio or its local distributor.
F00092	The reaction tray does not find the initial position after rotating for 1 circle during the process that the tray passes the initial position and rotates to the specified cuvette.	1. Strong light or severe electromagnetic interference; 2. Poor wire connection of stepper motor leads to step loss; 3. Stepper motor damage; 4. The initial position sensor is broken or subject to poor wire connection; 5. The motor drive board errors; 6. Sensor wire or plug errors.	When the strong light or severe electromagnetic interference is exluded, check if the sensor plug is loose. If not, check if the wire is broken, and perform restarting. If the problem still occurs, contact Zybio or its local distributor.

Code	Description	Causes	Solutions
F00093	The ultimate steps of a cuvette on the reaction tray are done when performing rotation to the static sampling cuvette, but the encoding tray signal is not detected. Means errors of the encoding tray detection or step loss.	See F00091	See F00091
F00094	The cuvette for the reaction tray before the rotating the tray is not sure, so the rotation can not be finished.	The possible cause may be that the tray rotation recovery is not performed or the tray motor rotation is performed after performing the rotation recovery. So the cuvette where the tray is remained may be unknown.	First, execute the tray rotation recovery, and execute the procedure after the recovery is normal. If the problem still occurs, contact Zybio or its local distributor.
F00102	This may be explained by initial position sensor errors or step loss.	See F00092	See F00092
F00103	Initial position sensor errors	See F00092	See F00092
F00104	The cleaning head is kept in the initial position before vertically descending via specified steps from this position.	See F00092	See F00092
F00105	The cleaning head is not in the initial position before movement, when the head moves from the position to the liquid waste suction position.	Not execute the vertical recovery of the cleaning head.	Perform the vertical recovery of the head and then other actions. If the problem still occurs, contact Zybio or its local distributor.
F00106	When the cleaning head moves upwards from the cuvette with 185 steps, it is in the initial position and cannot move upwards.	The head does not perform the action in a correct position, and the initial position sensor is in trouble.	Perform the vertical recovery of the head and then descend to the liquid waste suction position. After this, execute the action. If the problem still occurs, contact Zybio or its local distributor.
F00107	The waiting and operation time of the peristaltic pump exceeds the limit	The waiting time of the pump is set wrongly.	Set the waiting time of the pump again.

Code	Description	Causes	Solutions
F00108	The cleaning head arrived in the vertical initial position when the head performs vertical recovery.	This may be explained by the initial position sensor errors or external light intervening the sensor signal.	Check the head sensor, plug, wire, and then execute the action. If the problem still occurs, contact Zybio or its local distributor.
F00111	The current temperature of the reaction tray exceeds the set 10°C.	1. Severe electromagnetic interference; 2. The temperature sensor wire is loose or separated; 3. Abnormal temperature control.	Exclude severe electromagnetic interference and check the wire. If the problem still occurs, contact Zybio or its local distributor.
F00112	After specified temperature-establishment period (about 14 minutes) of the reaction tray passes, the tray is not within the normal temperature range (The target temperature+/ 2 range).	See F00111	See F00111
F00113	At the normal control temperature, when the temperature-establishment period (about 14 minutes) is finished, the current temperature deviates from the normal range (The target temperature+/ 2 range).	See F00111	See F00111
F00114	The temperature exceeds 10°C for 10 times continuously during the normal control period.	See F00111	See F00111
F00115	The system is running in a status where parameter cannot be changed.	The Analyzer is running.	Turn off the Analyzer, and it is on standby.
F00116	The target temperature is set as more than 95°C.	Target temperature setting errors	Set the target temperature again.
F00119	When the temperature exceeds the target temperature for over 10 times, the temperature control shuts down automatically and AD value of the static	1. The AD value of the static temperature may be FF, which causes the result to be calculated as the negative one and the temperature difference to be reported	Please contact Zybio or its local distributor.

Code	Description	Causes	Solutions
	temperature may be FF. This may cause the result to be calculated as the negative one, which may be explained by 0°C reference resistance errors.	wrongly. This may be explained by 0°C reference resistance errors; 2. The electric network interference leads to fluctuation of the temperature AD.	
F00127	The command received by the master control unit is improper.	The command received by the master control unit is improper.	Check if the command is correct.

Appendix A. Accessory list

Table A-1 Accessory list

No.	Name	Qty.
1	Liquid waste discharge component 1	1 set
2	Liquid waste discharge component 2	1 set
3	Purified water inlet pipe component	1 set
4	Wash buffer inlet pipe component	1 set
5	Float senor component for purified water bucket	1 set
6	Float senor component for wash buffer	1 set
7	The level sensor component for liquid waste bucket	1 set
8	Power cord	1 pc
9	Network cable	1 pc, 3m
10	Scanner	Optional
11	Concentrated wash buffer	5L/bucket
12	Basic wash buffer	35ml/vial
Note: for ordering any wash buffer, users can contact Zybio or its local distributor.		

Appendix B. Terms

- AD value:

  A numerical value (whose size is related to the AD bits selected) converted (digital-to-analog conversion) from photovoltage (analog signal) that is converted from photocurrent (generated by the light reaching the detector) amplified after flowing through a fixed resistance.

- Dark current

  The circuit output which is expressed as an AD value when the light source is not turned on, or when there is no signal light. The dark current corresponds to the circuit background and must be deducted when the absorbance is calculated.

- Water blank

  The absorbance value of the cuvette filled with purified water. Absorbance is a relative value, which must be based on a certain absorbance value. In the Analyzer, with the absorbance of the water blank defined as 0, the water blank value must be subtracted from any other absorbance.

- Photometric spot

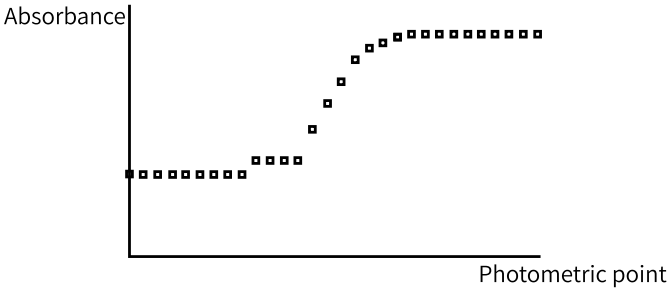
  The specific moment of photoelectric colorimetry. It is usually expressed as a specific value. There is a strict and fixed time relationship among photometric spots.

- Absorbance

  The negative common logarithm of the transmittance divided by the incident light intensity. In the Analyzer, the incident light intensity is the AD value when the cuvette is filled with deionized water and the displayed absorbance value is the calculated absorbance value multiplied by 10000.

- Reaction curve:

  A series of points consisting of the photometric spots as the abscissa and the absorbance as the coordinate. A typical reaction curve of the Analyzer is as follows:



- Reaction rate

  The change or change rate of absorbance before, during, or after the reaction.

- Calibration

  To determine the reaction rate of one or more samples (also calibrators) with a known

concentration (or activity) and fit the data set (concentration and reaction rate) with an optimal curve based on the user-selected calibration method (linear or non-linear), and calculate the mathematical expression for this curve. This curve is used to determine the reaction rate of the sample with unknown concentration (or activity), thus calculating the concentration (or activity) of this sample.

- Calibration curve

  A curve formed with a series of points (concentration or activity as the abscissa and reaction rate as the coordinate) and fitted with the best mathematical equation.

- Calibration parameters

  Other terms in the calibration curve expression other than concentration and reaction rate.

- Dead volume

  The volume of solution that remains in a tube after the needle or syringe dispenses all solution.

Appendix C. Literature

1 Christopher-John L Farrell, Andrew C Carter, Serum indices: managing assay interference. SAGE Journals. 2016; 10: 1-12.

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4 Muravskaya N P, Gryazskikh N Y. Metrological Support for Automatic Biochemical Analyzers. Measurement Techniques, 2014, 56(11): 1296-1301.

5 LEONARD T. SKEGGS, An Automatic Method for Colorimetric Analysis. Technical Section. 1957, 28: 311-322.

P/N: 02-70-01-1062-01[04]

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Chemistry

zybio

Chemistry Analyzer EXC 200

A cost-effective choice dedicated for small healthcare sites

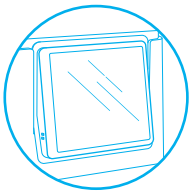
Chemistry

www.zybio.com

Chemistry Analyzer EXC 200

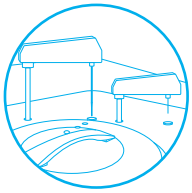
EXC 200 combines versatile advanced functions that facilitate high quality testing, which is a discrete and random-access clinical chemistry analyzer offering a throughput of 240 T/H for single reagent and 160 T/H for dual reagents. Working with 97 original chemistry reagents, EXC 200 isan ideal clinical solution for small healthcare sites.

Function



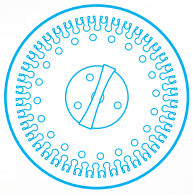
User Friendly

- 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 97 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 97 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, AAG, HAP, AFU

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, sdLDL-C, Lp(a)

Cardiac & Cardiovascular Panel

ACE, LDH, LDH1, CK, CK-MB, α-HBDH, IMA, MYO, cTnI, H-FABP, hs-CRP, HCY, Lp-PLA_2, MPO

Diabetes

GLU, HbA1c, GA, GSP, LAC, β-HB

Tumor

PGI, PGII, SA, Fer

Coagulation

D-D, FIB, FDP

Specific Proteins

IgA, IgG, IgM, IgE, C3, C4, C1q, CSF/UTP, TRF, SOD, IgG4

Rheumatic & Rheumatoid Panel

anti-CCP, RF, ASO

Electrolytes

Fe, Zn, CO_2, 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	65 kg

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EN-C-SH-EXC200-I-20210922H

Chemistry

CE IVD

zybio

Instructions for Use of Clinical Chemistry Multi-Analyte Calibrator

Package Specification

REF	Specification
01.09.0D.00.CA.02	1 Level × 5 mL × 10
012212047	1 Level × 5 mL × 6
01.09.0D.00.CA.04	1 Level × 5 mL × 1

Intended Use

This product is matched for the calibration of 31 biochemical items of Zybio Inc. (albumin, alkaline phosphatase, alanine aminotransferase, aspartate aminotransferase, calcium, cholinesterase, total cholesterol, creatine kinase, carbon dioxide, creatinine, direct bilirubin, ferrum, γ-glutamyl transferase, glutamate dehydrogenase, glucose, lactate, leucine amino peptidase, lactate dehydrogenase, lipase, magnesium, inorganic phosphorus, total bile acid, total bilirubin, triglyceride, total protein, uric acid, urea, zinc, α-amylase, α-hydroxybutyrate dehydrogenase and β-hydroxybutyrate).

Principle

A detection system is calibrated through the measurement on the calibrators with known concentration, so as to establish the metrological traceability of the measurement results for our system.

Reagents Components and Concentration

Human serum matrix.

It contains 31 biochemical items: Albumin (ALB), alkaline phosphatase (ALP), alanine aminotransferase (ALT), aspartate aminotransferase (AST), calcium (Ca), cholinesterase (ChE), total cholesterol (CHOL), creatine kinase (CK), carbon dioxide (CO_2), creatinine (CREA), direct bilirubin (DBIL), ferrum/iron (Fe), γ-glutamyl transferase (GGT), glutamate dehydrogenase (GLDH), glucose (GLU), lactate (LAC), leucine amino peptidase (LAP), lactate dehydrogenase (LDH), lipase (LPS), magnesium (Mg), inorganic phosphorus (P), total bile acid (TBA), total bilirubin (TBIL), triglyceride (TG), total protein (TP), uric acid (UA), urea (UREA), zinc (Zn), α-amylase (α-AMY), α-hydroxybutyrate dehydrogenase (α-HBDH) and β-hydroxybutyrate (β-HB).

Note: The traceability information is shown in the attached form, and the labeled value is shown in the target value list.

Storage and Validity

1. The product should be stored at 2 - 8 °C and kept away from direct light. The unopened product is valid for 24 months.
2. The re-dissolved components are stable for 2 days at 2 - 8 °C and 28 days at (-15) - (- 25) °C. (Freeze/thaw only once).
3. Alkaline phosphatase levels will increase during the stabilization time. It is recommended to stabilize at 15 - 25 °C for 1 hour after re-dissolution before detection. It is necessary to timely screw the bottle cap for preservation when CO_2 is not used after re-dissolution. And also it is necessary to kept away from direct light when direct bilirubin and total bilirubin are re-dissolved and subsequent preservation.
4. The production date and expiration date are available on package label.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Warnings and Precautions

1. For calibration during in vitro diagnostic clinical chemistry analysis. Do not be used for other purposes.
2. If the results are inconsistent with the specified values, the experiment should be stopped, and retested after the possible causes were analyzed.
3. This product can only be frozen and thawed once after re-constitution, avoiding repeatedly frozen and thawed.
4. Please use this product according to the specified method. The use of non-specified method and purpose cannot ensure the accuracy of the results.
5. If the product is contaminated with bacteria, the stability of many components will be reduced. If there are obvious signs that the product has been contaminated with microorganism, do not use it.
6. It is necessary to follow the routine precautions for the laboratory operation when using this product.
7. If the product accidentally enters the eyes, mouth or sticks to the skin, immediately wash thoroughly with water and go to the hospital if necessary.
8. The opened product shall be stored sealed according to the specified method. Do not use after the expiration date.
9. This product shall be stored according to the specified method and kept away from direct light.
10. Warning: This product contains human-derived or animal-derived ingredients. At present, there is no way to completely ensure that it is free of infectious substances, and there is also the possibility of contamination during use; this product and samples should be regarded as potential sources of infection, operators should take protective measures and follow the laboratory safe operation regulations; all wastes should be disposed of in accordance with local regulatory requirements.

Test Process

1. Take out the calibrator, carefully open the cap to avoid loss of contents, and accurately reconstitute with purified water marked on the label.
2. Carefully tighten the cap and place it at room temperature, out of direct light for 30 minutes. During reconstitution, gently rotate the vial several times to ensure complete dissolution of the contents. Do not shake the vial vigorously to avoid foam.
3. After the completion of reconstitution, please immediately operate according to the instructions for use (ALP should be stable for 1 hour before detection), add the calibrator according to the instructions for use of reagent, and calibrate in the linear calibration mode.
4. If it cannot be used immediately or after use, please timely put it back to the specified storage conditions.

Performance Characteristics

1. Appearance: yellowish lyophilized powder, and yellowish or yellow liquid after re-dissolution.
2. Moisture content: ≤ 5%.
3. Trueness: the trueness of the measurement value shall meet | En | ≤ 1.
4. Homogeneity:

4.1 within-vial homogeneity: within-vial $CV \leq 10\%$.

4.2 Between-vial homogeneity: between-vial $CV \leq 15\%$.

Materials Required (but not provided)

Chemistry analyzer, reagents, control, general lab equipment and consumable.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community
	Biological Risks		

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EC REP
Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Current Version: 02 Date of Issue: May, 2022

CE IVD

zybio

Instructions Attached Form

Serial Number	Substance Detected	Project Name	Traceability Information
1	ALB	Albumin (ALB) Kit (Bromocresol Green Method)	ERM-DA470k/IFCC
2	ALP	Alkaline Phosphatase (ALP) Kit (Enzymatic Method)	IFCC reference measurement procedure (37℃) for ALP
3	ALT	Alanine Aminotransferase (ALT) Kit (Enzymatic Method)	IFCC reference measurement procedure (37℃) for ALT
4	AST	Aspartate Aminotransferase (AST) Kit (Enzymatic Method)	IFCC reference measurement procedure (37℃) for AST
5	Ca	Calcium (Ca) Kit (Arsenazo III Method)	SRM 909c NIST
6	CHE	Choline Esterase (ChE) Kit (Butyryl Thiocholine Method)	manufacturer's working calibrator
7	CHOL	Total Cholesterol (CHOL) Kit (Enzymatic Method)	SRM 909c NIST
8	CHOL	Total Cholesterol (CHOL) Kit (Single) (Enzymatic Method)	SRM 909c NIST
9	CK	Creatine Kinase (CK) Kit (Rate Method)	IFCC reference measurement procedure (37℃) for CK
10	CO_2	Carbon Dioxide (CO2) Kit (Enzymatic Method)	manufacturer's working calibrator
11	CREA	Creatinine (CREA) Kit (Enzymatic Method)	SRM 909c NIST
12	DBIL	Direct Bilirubin (DBIL) Kit (Vanadate Oxidation Method)	manufacturer's working calibrator
13	Fe	Ferrum (Fe) Kit (5-Br-PADAP Chromogenic Method)	SRM 909c NIST
14	Fe	Iron (Fe) Kit (Ferrozine Method)	SRM 909c NIST
15	GGT	Gamma-Glutamyl Transferase (GGT) Kit (Enzymatic Method)	IFCC reference measurement procedure (37℃) for GGT
16	GLDH	Glutamate Dehydrogenase (GLDH) Kit (Rate Method)	manufacturer's working calibrator
17	GLU	Glucose (GLU) Kit (Hexokinase Method)	GBW(E)091043
18	LAC	Lactate (LAC) Kit (Lactate Oxidase Method)	manufacturer's working calibrator
19	LAP	Leucine Amino Peptidase (LAP) Kit (Rate Method)	manufacturer's working calibrator
20	LDH	Lactate Dehydrogenase (LDH) Kit (Rate Method)	IFCC reference measurement procedure (37℃) for LDH
21	LPS	Lipase (LPS) Kit (Colorimetric Method)	manufacturer's working calibrator
22	Mg	Magnesium (Mg) Kit (Xylidyl Blue Method)	SRM 909c NIST
23	P	Inorganic Phosphorus (P) Kit (Direct UV Method)	manufacturer's working calibrator
24	TBA	Total Bile Acids (TBA) Kit (Enzymatic Cycling Method)	manufacturer's working calibrator
25	TBIL	Total Bilirubin (TBIL) Kit (Vanadate Oxidation Method)	manufacturer's working calibrator
26	TG	Triglyceride (TG) Kit (Enzymatic Method)	SRM 909c NIST
27	TG	Triglyceride (TG) Kit (Single) (Enzymatic Method)	SRM 909c NIST
28	TP	Total Protein (TP) Kit (Biuret Method)	SRM 909c NIST
29	UA	Uric Acid (UA) Kit (Uricase Method)	SRM 909c NIST
30	UREA	Urea (UREA) Kit (Urease-GLDH Method)	SRM 909c NIST
31	Zn	Zinc (Zn) Kit (Colorimetric Method)	manufacturer's working calibrator
32	α-AMY	α-Amylase (α-AMY) Kit (E-pNP-G7 Method)	IFCC reference measurement procedure (37℃) for AMY
33	α-HBDH	α-Hydroxybutyric Acid Dehydrogenase (α-HBDH) Kit (Rate Method)	manufacturer's working calibrator
34	β-HB	β-Hydroxybutyrate (β-HB) Kit (Enzymatic Method)	manufacturer's working calibrator

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Concentrated Detergent

【Product Name】

Concentrated Detergent

【Package】

480 mL/box, 500 mL/bottle, 1 L/bottle, 2 L/bottle, 5 L/bottle × 1, 5 L/bottle × 2, 5 L/bottle × 4.

【Intended Use】

This product is used for cleaning of chemistry analyzer.

【Principle】

This product is a detergent for chemistry analyzer cleaning, it is mainly used for cleaning the sample probe, reagent probe, pipeline system, stirring system and colorimetric system of the analyzer. Its main principle is that the surfactant in the detergent can effectively reduce the surface tension of the residue in the analyzer, so that the residue can be easily cleaned out.

【Main Component】

Potassium hydroxide, surfactant.

【Storage and Validity】

Stored at 2～35℃ for 24 months. Do not freeze.

Validity period is 60 days after opening.

【Applicable Instrument】

Chemistry Analyzer

【Usage】

The detergent is a necessary reagent for cleaning the reaction system of the chemistry analyzer. As different instruments apply to different methods, please refer to insert while using.

【Performance Index】

pH≥12.50(25.0℃±1.0℃)

【Warnings and Precautions】

1. If the detergent gets into your mouth or contacts with your eyes or skin, rinse with plenty of water immediately or consult a doctor if necessary.

2. Avoid freezing during transportation and storage; prevent dust from entering the reagents and use up within 60 days after opening.

3. This product is for in vitro diagnostic use only. Please properly dispose of waste liquid and packaging in accordance with local regulations.

【Explanations on Symbols】

Symbol	Explanation
	CORROSIVE
LOT	LOT CODE
	CONSULT INSTRUCTIONS FOR USE
	PRODUCTION DATE
	USE-BY DATE
	TEMPERATURE LIMIT
	MANUFACTURER

【Manufacturer Information】

Supplier/manufacturer: Zybio Inc.

Address: Floor 1 to Floor 4, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, Chongqing, China 400082

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E-mail: info@zybio.com

Tel: +86(0)23 6865 5509

Fax: +86(0)23 6869 9779

Probe Detergent

【Product Name】

Probe Detergent

【Package】

240 mL/box, 480 mL/box, 500 mL/bottle, 1 L/bottle, 2 L/bottle, 5 L/bottle.

【Intended Use】

This product is used for cleaning of chemistry analyzer.

【Principle】

This product is a detergent for chemistry analyzer cleaning, it is mainly used for cleaning the sample probe, reagent probe, pipeline system, stirring system and colorimetric system of the analyzer. Its main principle is that the surfactant in the detergent can effectively reduce the surface tension of the residue in the analyzer, so that the residue can be easily cleaned out.

【Main Component】

Potassium hydroxide, surfactant.

【Storage and Validity】

Stored at 2～35℃ for 24 months. Do not freeze.

Validity period is 60 days after opening.

【Applicable Instrument】

Chemistry Analyzer

【Usage】

The detergent is a necessary reagent for cleaning the reaction system of the chemistry analyzer. As different instruments apply to different methods, please refer to insert while using.

【Performance Index】

pH≥11.50(25.0℃±1.0℃)

【Warnings and Precautions】

1. If the detergent gets into your mouth or contacts with your eyes or skin, rinse with plenty of water immediately or consult a doctor if necessary.

2. Avoid freezing during transportation and storage; prevent dust from entering the reagents and use up within 60 days after opening.

3. This product is for in vitro diagnostic use only. Please properly dispose of waste liquid and packaging in accordance with local regulations.

【Explanations on Symbols】

Symbol	Explanation
	CORROSIVE
	LOT CODE
	CONSULT INSTRUCTIONS FOR USE
	PRODUCTION DATE
	USE-BY DATE
	TEMPERATURE LIMIT
	MANUFACTURER

【Manufacturer Information】

Supplier/manufacturer: Zybio Inc.

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CE IVD

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Instructions for Use of α-Amylase (α-AMY) Kit

(E-pNP-G7 Method)

Package Specification

REF	Reagent	Systems
01.09.0B.00.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	Zybio EXC200/220
01.09.0B.00.EC.02	R1 48 mL × 2 R2 12 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of the catalytic activity concentration of α-amylase (α-AMY) in human samples (serum, plasma or urine).

Summary

α-Amylase activity is one of the important diagnostic markers of acute pancreatitis. Serum amylase can be increased in diseases such as chronic pancreatitis, pancreatic cancer, acute appendicitis, ulcerative perforation, intestinal obstruction, mumps, and salivary gland suppuration. When renal function decreased, serum amylase increased and urine amylase decreased. Patients with various liver diseases will show a simultaneous decrease in serum and urine amylase.

Principle

This kit uses E-pNP-G7 method (IFCC recommended method) to determine the activity of α-amylase (α-AMY) in samples. α-AMY in the sample hydrolyzes 4, 6-ethylene-4-nitrophenyl-4-a-D-maltoheptaose (E-pNP-G7) to generate 4, 6-ethylene-maltopentaose (E-G5), 4, 6-ethylene-maltotetraose (E-G4), 4, 6-ethylene-maltotriose (E-G3), and 4-nitrophenyl-maltose (G2-NP), 4-nitrophenyl-maltotriose (G3-NP), 4-nitrophenyl-maltotetraose (G4-NP) and other fragments, and the three 4-nitrophenyl-maltopolysaccharides generated are hydrolyzed to glucose and 4-nitrophenol under the action of α-glucosidase, causing an increase in absorbance at a rate directly proportional to the activity of α-AMY in the sample. The activity of α-AMY in the sample can be calculated from the working curve by continuously monitoring and comparing with the calibrator treated in the same manner.

$$\text{E-pNP-G7} + H_2O \xrightarrow{\alpha\text{-AMY}} \text{E-G5} + \text{E-G4} + \text{E-G3} + \text{G2-NP} + \text{G3-NP} + \text{G4-NP}$$

$$\text{G2-NP} + \text{G3-NP} + \text{G4-NP} + H_2O \xrightarrow{\alpha\text{-Glucosidase}} \text{Glucose (G)} + \text{4-NP}$$

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	HEPES	50 mmol/L
	Glucosidase	5.5 - 6.5 KU/L
R2	HEPES	50 mmol/L
	Ethylene-pNP-G7	7.5 - 9.5 mmol/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 °C and kept away from freezing. The unopened reagents are valid for 18 months.
2. Once opened, the reagents are stable for 30 days at 2 - 8 °C. For reagents not in use, the cap should be tightened to avoid contamination.
3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Sample types are serum, plasma (heparin), or urine (random or timed). Serum and plasma are stable for 4 days at room temperature, 2 weeks at 2 - 8 °C, and 1 year at - 20 °C to avoid repeated freezing and thawing. Urine is stable for 7 days at 2 - 8 °C with pH adjusted to 7.0 prior to storage.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When the blank absorbance > 0.35, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. The same sample tested with reagents from different manufacturers may lead to different measured values.
7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	Rate Method	**Sample/Reagent**	1/50
Main Wavelength	405 nm	**Reaction Temperature**	37 °C
Sub Wavelength	505 nm	**Reaction Time**	10 min
Reaction Direction	+		

2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	5
Calibrator (μL)	/	5	/
Purified Water (μL)	5	/	/
Reagent 1 (μL)	200	200	200
Mix well, incubate at 37 °C for 5 min			
Reagent 2 (μL)	50	50	50
Mix well, incubate at 37 °C for 1 min, measure the average absorbance change rate ΔA/min within 2 min.			

3. Calibration

Use Randox multi-analyte calibrator or Zybio Clinical Chemistry Multi-analyte Calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it

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is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The catalytic activity concentration of α-Amylase (α-AMY) in the sample can be calculated on the working curve based on its absorbance change rate.

Reference Intervals

Serum: < 140 U/L

Urine: < 640 U/L

This reference interval is determined according to the 95% distribution area of 200 healthy human specimens without related diseases in each group, and is only for reference. It is recommended that each laboratory establish its own reference interval.

Explanation of Results

1. If the catalytic activity concentration of α-AMY in the sample exceeds 1000 U/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.
2. The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by re-measuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.
3. The results obtained from tests using reagents from different manufacturers or methodologies should not be directly compared to each other to avoid incorrect medical interpretation; it is recommended that the laboratory indicate the characteristics of the reagents used in the test report sent to the clinician.

Limitations

1. The deviation of test results caused by interferents is less than 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Vc	0.3 g/L
Hemoglobin	1.25 g/L
Bilirubin	342 μmol/L
Triglyceride	10 mmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 0.35; the reagent blank absorbance change rate (ΔA/min) ≤ 0.002.
2. Analytical sensitivity: at the test catalytic activity concentration of 140 U/L, the reagent absorbance change rate (ΔA/min) ≥ 0.01.
3. Accuracy: relative deviation ≤ 10%.
4. Precision: within-run *CV* ≤ 5%, between-run relative range ≤ 10%.
5. Linear Range:

[5, 1000] U/L, the correlation coefficient (r) ≥ 0.990.

[5, 50] U/L, the absolute deviation ≤ 5 U/L;

(50, 1000] U/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

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Current Version: 02 Date of Issue: May, 2022

CE IVD

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Instructions for Use of Albumin (ALB) Kit (Bromocresol Green Method)

Package Specification

REF	Reagent	Systems
01.09.00.04.EC.01	R 30 mL × 6	Zybio EXC200/220
01.09.00.04.EC.03	R 60 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of albumin (ALB) concentration in human samples (serum). Clinically, it is mainly used as an aid to evaluation of liver function as well as nutritional assessment.

Summary

Albumin is a carbohydrate-free protein, which constitutes 55 - 65% of total plasma protein. It maintains plasma oncotic pressure, and is also involved in the transport and storage of a wide variety of ligands and is a source of endogenous amino acids. Albumin binds and solubilizes various compounds, e g. bilirubin, calcium and long-chain fatty acids. Furthermore, albumin is capable of binding toxic heavy metal ions as well as numerous pharmaceuticals, which is the reason why lower albumin concentrations in blood have a significant effect on pharmacokinetics.

Hyperalbuminemia is of little diagnostic significance except in the case of dehydration. Hypoalbuminemia occurs during many illnesses and is caused by several factors: compromised synthesis due either to liver disease or as a consequence of reduced protein uptake; elevated catabolism due to tissue damage (severe burns) or inflammation; malabsorption of amino acids (Crohn's disease); proteinuria as a consequence of nephrotic syndrome; protein loss via the stool (neoplastic disease). In severe cases of hypoalbuminemia, the maximum albumin concentration of plasma is 2.5 g/dL (380 µmol/L). Due to the low osmotic pressure of the plasma, water permeates through blood capillaries into tissue (edema). The determination of albumin allows monitoring of a controlled patient dietary supplementation and serves also as an excellent test of liver function.

Principle

Albumin in serum binds to bromocresol green to form a blue-green complex at pH 4.2, which has an absorption peak at the wavelength of 630 nm, and the change in color intensity is directly proportional to the albumin concentration. The albumin concentration in the serum can be obtained by comparing with that in calibrator treated in the same manner.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R	Bromocresol Green	0.15 mmol/L
	Succinic Acid buffer	74.9 mmol/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 12 months.
2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Non-hemolytic serum is suitable for samples, which are stable at 2 - 8 ℃ for 14 days.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When reagent becomes turbid or the blank absorbance > 0.500, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. The same sample tested with reagents from different manufacturers may lead to different measured values.
7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	End-Point Method	**Sample/Reagent**	1/100
Main Wavelength	630 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	700 nm	**Reaction Time**	2 min
Reaction Direction	+		

2. Operation

Addition	Blank	Calibration	Detection
Sample (µL)	/	/	3
Calibrator (µL)	/	3	/
Purified Water (µL)	3	/	/
Reagent (µL)	300	300	300
Mix well, measure absorbance *A* after 2 min.			

3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality

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control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The concentration of albumin (ALB) in the sample can be calculated on the working curve based on its absorbance change value.

Reference Intervals

35.0~55.0 g/L

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of ALB in the sample exceeds 60.00 g/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is less than 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Vc	0.5 g/L
Chyle	0.30%
Bilirubin	342 μmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 0.500.
2. Analytical sensitivity: at the test concentration of 40.0 g/L, the reagent absorbance change (ΔA) ≥ 0.50.
3. Accuracy: relative deviation ≤ 6.0%.
4. Precision: within-run *CV* ≤ 2.0%, between-run relative range ≤ 5.0%.
5. Linear Range:

[10.0, 60.0] g/L, the correlation coefficient (*r*) ≥ 0.990.

[10.0, 20.0] g/L, the absolute deviation ≤ 4.0 g/L;

(20.0, 60.0] g/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Guo J, Xie J, Zhao H. Design of method comparison study and bias estimation for albumin assays[J]. Chin J Lab Med, 2000, 23:343-345.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

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Instructions for Use of Alkaline Phosphatase (ALP) Kit (Enzymatic Method)

Package Specification

REF	Reagent	Systems
01.09.00.13.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	Zybio EXC200/220
01.09.00.13.EC.03	R1 48 mL × 2 R2 12 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of the catalytic activity concentration of alkaline phosphatase (ALP) in human samples (serum or plasma). Clinically, it is mainly used as an aid to diagnosis of hepatobiliary diseases and bone diseases.

Summary

Alkaline phosphatase in serum consists of four structural genotypes: the liver-bone-kidney type, the intestinal type, the placental type and the variant from the germ cells. It occurs in osteoblasts, hepatocytes, leukocytes, the kidneys, spleen, placenta, prostate and the small intestine. The liver-bone-kidney type is particularly important.

A rise in the alkaline phosphatase occurs with all forms of cholestasis, particularly with obstructive jaundice. It is also elevated in diseases of the skeletal system, such as Paget's disease, hyperparathyroidism, rickets and osteomalacia, as well as with fractures and malignant tumors. A considerable rise in the alkaline phosphatase activity is sometimes seen in children and juveniles. It is caused by increased osteoblast activity following accelerated bone growth.

Principle

P-nitrophenyl phosphate + H_2O $\xrightarrow{ALP}$ P-Nitrophenol + Phosphate

The catalytic activity concentration of alkaline phosphatase in the sample shall be calculated by measuring the increasing rate of the absorbance at 405 nm.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	2-Amino-2-methyl-1-propanol (AMP) buffer	597 mmol/L
	Magnesium Acetate	2.0 mmol/L
R2	Disodium 4-nitrophenylphosphate (PNPP)	81.5 mmol/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 12 months.
2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Non-hemolytic serum or plasma (heparin anticoagulation) is suitable for samples, which are stable for 2 days at 2 - 8 ℃ and for 1 month at - 20 ℃.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When reagent becomes turbid or the blank absorbance > 1.000, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. The same sample tested with reagents from different manufacturers may lead to different measured values.
7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	Rate Method	Sample/Reagent	1/50
Main Wavelength	405 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	505 nm	**Reaction Time**	10 min
Reaction Direction	+		

2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	5
Calibrator (μL)	/	5	/
Purified Water (μL)	5	/	/
Reagent 1 (μL)	200	200	200
Mix well, incubate at 37 ℃ for 5 min			
Reagent 2 (μL)	50	50	50
Mix well, after 2 min, measure the absorbance change within 3 min, and calculate the absorbance change rate Δ*A*/ min.			

3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The catalytic activity concentration of alkaline phosphatase (ALP) in the sample can be calculated on the working curve based on its absorbance change rate.

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Reference Intervals

Age: 1 - 12, < 500 U/L

Male (Age: 12 - 15): < 750 U/L Adult Male: 45 - 125 U/L

Female (Age: 15 - 20): 40 - 150 U/L Female (Age: 20 - 49): 35 - 100 U/L

Female (Age: 50 - 79): 50 - 135 U/L

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases per group, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the catalytic activity concentration of ALP in the sample exceeds 1000 U/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is less than 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Vc	0.5 g/L
Chyle	0.30%
Bilirubin	342 μmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 1.000, the reagent blank absorbance change rate (ΔA/min) ≤ 0.005.

2. Analytical sensitivity: at the test catalytic activity concentration of 120 U/L, the reagent absorbance change rate (ΔA/min) ≥ 0.010.

3. Accuracy: the relative deviation ≤ 10%.

4. Precision: within-run CV ≤ 5%, between-run relative range ≤ 10%.

5. Linear range:

[25, 1000] U/L, the correlation coefficient (r) ≥ 0.990.

[25, 100] U/L, the absolute deviation ≤ 10 U/L;

(100, 1000] U/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Bowers G, McComb R. Measurement of total alkaline phosphatase activity in human serum[J]. Clin Chem, 1975, 21:1988-1995.

[2] Price P, Toroian D, Chan W. Tissue-nonspecific alkaline phosphatase is required for the calcification of collagen in serum: a possible mechanism for biomineralization[J]. J Biol Chem, 2009, 284:4594-46.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

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Current Version: 02 Date of Issue: May, 2022

CE IVD

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CE IVD

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Instructions for Use of Aspartate Aminotransferase (AST) Kit (Enzymatic Method)

Package Specification

REF	Reagent	Systems
01.09.00.16.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	Zybio EXC200/220
01.09.00.16.EC.02	R1 48 mL × 2 R2 12 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of aspartate aminotransferase activity in human samples (serum or plasma). Clinically, it is mainly used as an aid to diagnosis of viral hepatitis, obstructive jaundice, and myocardial infarction.

Summary

The enzyme aspartate aminotransferase (AST) is widely distributed in tissue, principally hepatic, cardiac, muscle, and kidney. Elevated serum levels are found in diseases involving these tissues. Hepatobiliary diseases, such as cirrhosis, metastatic carcinoma, and viral hepatitis also increase serum AST levels. Following myocardial infarction, serum AST is elevated and reaches a peak two days after onset. In patients undergoing renal dialysis or those with vitamin B6 deficiency, serum AST may be decreased. The apparent reduction in AST may be related to decreased pyridoxal phosphate, the prosthetic group for AST, resulting in an increase in the ratio of apoenzyme to holoenzyme. Two isoenzymes of AST have been detected, cytoplasmic and mitochondrial. Only the cytoplasmic isoenzyme occurs in normal serum, while the mitochondrial, together with the cytoplasmic isoenzyme, has been detected in the serum of patients with coronary and hepatobiliary disease.

Principle

This kit uses the method recommended by the International Federation of Clinical Chemistry (IFCC):

1. Aspartic Acid + α-Ketoglutaric Acid $\xrightarrow{AST}$ Oxaloacetic Acid + L-Glutamic Acid

2. Oxaloacetic Acid + NADH + H^+ $\xrightarrow{MDH}$ L-Lactic Acid + NAD^+ + H_2O

Oxidation of NADH to NAD^+ causes a decrease in absorbance at 340 nm, which is directly proportional to the AST activity in the sample.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	Trometamol (Tris) buffer	62 mmol/L
	Nicotinamide adenine dinucleotide (NADH)	0.4 mmol/L
R2	Trometamol (Tris) buffer	439 mmol/L
	α-Ketoglutaric Acid	37.1 mmol/L
	L-Aspartic Acid	>800 mmol/L
	Malate Dehydrogenase (MDH)	>2.5 kU/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 12 months.

2. Once opened, the reagents are stable for 4 weeks at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.

3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Non-hemolytic serum or plasma is suitable for samples, which are stable for 3 days at 2 - 8 ℃. Avoid repeated freezing and thawing.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.

2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.

3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.

4. When reagent becomes turbid or the blank absorbance < 1.000, the reagent is failed and should be discarded.

5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.

6. The same sample tested with reagents from different manufacturers may lead to different measured values.

7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	Rate Method	Sample/Reagent	6/125
Main Wavelength	340 nm	Reaction Temperature	37 ℃
Sub Wavelength	405 nm	Reaction Time	10 min
Reaction Direction	-		

2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	12
Calibrator (μL)	/	12	/
Purified Water (μL)	12	/	/
Reagent 1 (μL)	200	200	200
Mix well, incubate at 37 ℃ for 5 min			
Reagent 2 (μL)	50	50	50
Mix well, after 2 min, measure the average absorbance change rate ΔA/min within 3 min.			

3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

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4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The concentration of aspartate aminotransferase (AST) in the sample can be calculated on the working curve based on its absorbance change rate.

Reference Intervals

≤ 40 U/L

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of AST in the sample exceeds 1000 U/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is less than 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Chyle	0.30%
Bilirubin	300 μmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≥ 1.000; the reagent blank absorbance change rate (Δ*A*/min) ≤ 0.004.

2. Analytical sensitivity: at the test concentration of 130.0 U/L, the reagent absorbance change rate (Δ*A*/min) ≥ 0.01.

3. Accuracy: relative deviation ≤ 10%.

4. Precision: within-run *CV* ≤ 5%, between-run relative range ≤ 10%.

5. Linear Range:

[10, 1000] U/L, the correlation coefficient (*r*) ≥ 0.990.

[10, 100] U/L, the absolute deviation ≤ 10 U/L;

(100, 1000] U/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Abdalla D. Clinical chemistry: theory, analysis, correlations[J]. Revista Brasileira de Ciências Farmacêuticas, 2003, 39:348-349.

[2] Tietz N. Fundamentals of clinical chemistry[M]. Saunders, 1987.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

Zybio Inc.

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EC REP Lotus NL B.V.

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

Current Version: 02 Date of Issue: May, 2022

CE IVD

zybio

Instructions for Use of Calcium (Ca) Kit (Arsenazo III Method)

Package Specification

REF	Reagent	Systems
01.09.0C.01.EC.01	R 30 mL × 6	Zybio EXC200/220
01.09.0C.01.EC.02	R 60 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of calcium (Ca) concentration in human samples (serum or plasma). Clinically, it is mainly used as an aid to diagnosis of calcium metabolism disorders.

Summary

Calcium is the most abundant mineral element in the body with about 99% in the bones primarily as hydroxyapatite. The remaining calcium is distributed between the various tissues and the extracellular fluids where it performs a vital role for many life sustaining processes. Among the extra skeletal functions of calcium are involvement in blood coagulation, neuromuscular conduction, excitability of skeletal and cardiac muscle, enzyme activation, and the preservation of cell membrane integrity and permeability. Serum calcium levels and hence the body content are controlled by parathyroid hormone (PTH), calcitonin, and vitamin D. An imbalance in any of these modulators leads to alterations of the body and serum calcium levels. Increases in serum PTH or vitamin D are usually associated with hypercalcemia. Increased serum calcium levels may also be observed in multiple myeloma and other neoplastic diseases. Hypocalcemia may be observed e g. in hypoparathyroidism, nephrosis, and pancreatitis.

Principle

The Arsenazo III is combined with calcium ions, forming a purple-colored complex. The color of the complex is proportional to the concentration of calcium ion in the sample, which can be calculated by measuring the absorbance change at 660 nm.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R	Arsenazo III	129 μmol/L
	MES Buffer	4.25 g/L
	Surfactant	0.2% (v/v)

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 12 months.
2. Once opened, the reagents are stable for 4 weeks at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

1. Fresh and nonhemolytic serum or plasma (heparin) is suitable for samples.
2. Samples should be analyzed as soon as possible after collection, which can be stable for 2 days at 20 - 25 ℃, for 14 days at 2 - 8 ℃, and for 3 months at - 20 ℃. Repeated freezing and thawing should be avoided.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. Strict measures shall be taken to avoid contamination since calcium ion is almost omnipresent.
4. When reagent becomes turbid or the blank absorbance > 1.500, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. Trace chelating agents (such as EDTA) present in the detergent can hinder the generation of chromogens. It is recommended to use disposable tubes and pipettes, etc.
7. The same sample tested with reagents from different manufacturers may lead to different measured values.
8. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	End-Point Method	**Sample/Reagent**	1/100
Main Wavelength	660 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	700 nm	**Reaction Direction**	+

2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	3
Calibrator (μL)	/	3	/
Purified Water (μL)	3	/	/
Reagent (μL)	300	300	300
Mix well, incubate at 37 ℃ for 2 min, then zero the system at 660 nm as blank and measure absorbance *A*.			

3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

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5. Calculation

Linear calibration was used to draw the working curve. The concentration of calcium ion (Ca) in the sample can be calculated on the working curve based on its absorbance change value.

Reference Intervals

Adults Serum: 2.10 - 2.60 mmol/L

Children Serum: 2.50 - 3.00 mmol/L

This reference interval is determined based on 95% distribution interval obtained from 210 healthy human specimens without related diseases per group, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of Ca in the sample exceeds 4.00 mmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is within ± 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Bilirubin	280 μmol/L
Mg^{2+}	3 mmol/L
K^{+}	8 mmol/L
Na^{+}	180 mmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 1.500.
2. Analytical sensitivity: at the test concentration of 2.50 mmol/L, the absorbance change (ΔA) ≥ 0.20.
3. Accuracy: relative deviation ≤ 5%.
4. Precision: within-run *CV* ≤ 3%, between-run relative range ≤ 5%.
5. Linear range:

[1.00, 4.00] mmol/L, the correlation coefficient (r) ≥ 0.990.

Within the specified test range, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Massry S, Coburn J, Chapman L, et al. Role of serum Ca, parathyroid hormone, and NaCl infusion on renal Ca and Na clearances[J]. Am J Physiol, 1968, 214:1403-1409.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

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EC REP Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Current Version: 02 Date of Issue: May, 2022

CE IVD

zybio

Instructions for Use of Total Cholesterol (CHOL) Kit (Enzymatic Method)

Package Specification

REF	Reagent	Systems
01.09.02.10.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	Zybio EXC200/220
01.09.02.10.EC.02	R1 48 mL × 2 R2 12 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of total cholesterol (CHOL) concentration in human samples (serum).

Summary

Total cholesterol is the sum of cholesterol contained in all lipoproteins in the blood and is an important index for the prevention and treatment of dyslipidemia. There are primary hypercholesterolemia and secondary hypercholesterolemia. Primary hypercholesterolemia is mainly caused by genetic factors, while secondary hypercholesterolemia is common in diabetes mellitus, nephrotic syndrome, fatty liver, and hypothyroidism. Hypercholesterolemia is one of the major risk factors for coronary heart disease.

The kit uses enzymatic method to determine the concentration of total cholesterol (CHOL) in the sample. The cholesterol ester in the sample was hydrolyzed by cholesterol esterase into free fatty acid and free cholesterol, the latter was oxidized by cholesterol oxidase to cholestenone and produces H_2O_2. Finally, the Trinder reaction was coupled to produce a colored quinonimine, causing an increase in absorbance. The degree of increase is proportional to the concentration of CHOL in the sample. By monitoring the change of absorbance and comparing with the calibrator of the same treatment, the concentration of CHOL in the sample can be calculated according to the working curve.

Principle

1. Cholesteryl Ester + H_2O $\xrightarrow{\text{Cholesterol Esterase}}$ Cholesterol + Fatty Acid
2. Cholesterol + O_2 $\xrightarrow{\text{Cholesterol Oxidase}}$ Cholestenone + H_2O_2
3. $2H_2O_2$ + 4-AAP + TOOS $\xrightarrow{\text{Peroxidase}}$ Quinonimine + $4H_2O$

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	N-2-hydroxyethylpiperazine-N'-2-ethanesulfonic acid	40-60 mmol/L
	Phenol	1-2 mmol/L
	Cholesterol Esterase	2-4 kU/L
R2	N-2-hydroxyethylpiperazine-N'-2-ethanesulfonic acid	40-60 mmol/L
	Peroxidase	8-12 kU/L
	Cholesterol Esterase	2-4 kU/L
	Cholesterol Oxidase	1-2 kU/L
	4-Aminoantipyrine (4-AAP)	1-2 mmol/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 18 months.
2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Serum is suitable for samples, which shall be separated in time after collection to avoid hemolysis. Samples are stable for 3 days at 2 - 8 ℃ and 30 days at - 20 ℃. Avoid repeated freezing and thawing.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When reagent becomes turbid or the blank absorbance > 0.080, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. The same sample tested with reagents from different manufacturers may lead to different measured values.
7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	End-Point Method	**Sample/Reagent**	1/100
Main Wavelength	546 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	700 nm	**Reaction Time**	10 min
Reaction Direction	+		

2. Operation

Addition	**Blank**	**Calibration**	**Detection**
Sample (μL)	/	/	3
Calibrator (μL)	/	3	/
Purified Water (μL)	3	/	/
Reagent 1 (μL)	240	240	240
Mix well, incubate at 37 ℃ for 5 min, and measure absorbance A_1			
Reagent 2 (μL)	60	60	60
Mix well, measure absorbance A_2 after 5 min, calculate $\Delta A = A_2 - A_1$.			

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3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The concentration of total cholesterol (CHOL) in the sample can be calculated on the working curve based on its absorbance change value.

Reference Intervals

≤ 5.2 mmol/L (≤ 200 mg/dL)

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of CHOL in the sample exceeds 20.0 mmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is less than 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
VC	0.5 g/L
Hemoglobin	5 g/L
Bilirubin	342 μmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 0.080.

2. Analytical sensitivity: at the test concentration of 5.0 mmol/L, the reagent absorbance change (ΔA) > 0.10.

3. Accuracy: relative deviation ≤ 10%.

4. Precision: within-run *CV* ≤ 3%, between-run relative range ≤ 5%.

5. Linear Range:

[1.0, 20.0] mmol/L, the correlation coefficient (*r*) ≥ 0.990.

[1.0, 4.0] mmol/L, the absolute deviation ≤ 0.4 mmol/L;

(4.0, 20.0] mmol/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Allain C, Poon L, Chan C, et al. Enzymatic Determination of Total Serum Cholestero[J]. Clinical Chemistry, 1974, 20:470-475.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
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REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

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CE IVD

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Instructions for Use of Creatinine (CREA) Kit (Enzymatic Method)

Package Specification

REF	Reagent	Systems
01.09.01.05.EC.01	R1 30 mL × 2 R2 10 mL × 2	Zybio EXC200/220
01.09.01.05.EC.02	R1 30 mL × 1 R2 10 mL × 1	Zybio EXC200/220
01.09.01.05.EC.03	R1 45 mL × 2 R2 15 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of creatinine (CREA) concentration in human samples (serum, plasma or urine). Clinically, it is mainly used as one of the evaluation indicators of renal function.

Summary

Chronic kidney disease is a worldwide problem that carries a substantial risk for cardiovascular morbidity and death. Current guidelines define chronic kidney disease as kidney damage or glomerular filtration rate (GFR) less than 60 mL/min per 1.73 m^2 for three months or more, regardless of cause. The assay of creatinine in serum or plasma is the most commonly used test to assess renal function. Creatinine is a break-down product of creatine phosphate in muscle, and is usually produced at a fairly constant rate by the body (depending on muscle mass). It is freely filtered by the glomeruli and, under normal conditions, is not re-absorbed by the tubules to any appreciable extent. A small but significant amount is also actively secreted. Since a rise in blood creatinine is observed only with marked damage of the nephrons, it is not suited to detect early stage kidney disease. A considerably more sensitive test and better estimation of glomerular filtration rate (GFR) is given by the creatinine clearance test based on creatinine's concentration in urine and serum or plasma, and urine flow rate. For this test a precisely timed urine collection (usually 24 hours) and a blood sample are needed. However, since this test is prone to error due to the inconvenient collection of timed urine, mathematical attempts to estimate GFR based only on the creatinine concentration in serum or plasma have been made. Among the various approaches suggested, two have found wide recognition: that of Cockroft and Gault and that based on the results of the MDRD trial. While the first equation was derived from data obtained with the conventional Jaffé method, a newer version of the second is usable for IDMS-traceable creatinine methods. Both are applicable for adults. In children, the Schwartz formula should be used. In addition to the diagnosis and treatment of renal disease, the monitoring of renal dialysis, creatinine measurements are used for the calculation of the fractional excretion of other urine analytes (e g, albumin, α -amylase). Numerous methods were described for determining creatinine. Automated assays established in the routine laboratory include the Jaffé alkalinepicrate method in various modifications, as well as enzymatic tests.

Principle

This kit uses an enzymatic method to determine the concentration of creatinine (CREA) in samples.

Creatinine (CREA) in the sample is hydrolyzed by creatininase to creatine, which is hydrolyzed to sarcosine and carbamide catalyzed by creatinase. Sarcosine is oxidized to glycine, formaldehyde, and H_2O_2 catalyzed by sarcosine oxidase, and finally coupled with Trinder reaction to form colored quinonimine, causing an increase in absorbance. The degree of increase is proportional to the concentration of CREA in the sample. By monitoring the change of absorbance and comparing it with that of the calibrator treated in the same manner, the concentration of CREA in the sample can be calculated according to the working curve.

1. Creatinine + H_2O $\xrightarrow{\text{Creatininase}}$ Creatine
2. Creatine + H_2O $\xrightarrow{\text{Creatinase}}$ Sarcosine + Carbamide
3. Sarcosine + H_2O + O_2 $\xrightarrow{\text{Sarcosine Oxidase}}$ Glycine + HCHO + H_2O_2
4. $2H_2O_2$ + 4-AAP + TOOS $\xrightarrow{\text{Peroxidase}}$ Quinonimine + $4H_2O$

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	Creatinase	≥10 kU/L
	Sarcosine Oxidase	≥7.5 kU/L
	Sodium 3-(N-Ethyl-3-Methylanilino)-2-Hydroxypro Panesulfonate（TOOS）	≥1 mmol/L
R2	Creatininase	≥100 kU/L
	4-Aminoantipyrine (4-AAP)	≥1 mmol/L
	Peroxidase	≥2 kU/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from freezing. The unopened reagents are valid for 12 months.
2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Serum, plasma (heparin for anticoagulation) or urine is suitable for samples, which shall be separated as soon as possible after collection to avoid hemolysis.

Serum or plasma (heparin for anticoagulation) are stable for 7 days at 2 - 8 ℃ and for 30 days at - 20 ℃. Avoid repeated freezing and thawing.

Urine are stable for 3 days at room temperature, for 6 days at 2 - 8 ℃ and for 30 days at - 20 ℃. Avoid repeated freezing and thawing.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When the blank absorbance > 0.300, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. The same sample tested with reagents from different manufacturers may lead to different measured values.
7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

(1) Basic parameters (Blood)

Method	End-Point Method	Sample/Reagent	1/60
Main Wavelength	540 nm	Reaction Temperature	37 ℃
Sub Wavelength	700 nm	Reaction Time	10 min
Reaction Direction	+		

(2) Basic parameters (Urine)

Method	End-Point Method	Sample/Reagent	1/160
Main Wavelength	600 nm	Reaction Temperature	37 ℃
Sub Wavelength	700 nm	Reaction Time	10 min
Reaction Direction	+		

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2. Operation

(1) Operation (Blood)

Addition	Blank	Calibration	Detection
Sample (Blood) (μL)	/	/	5
Calibrator (μL)	/	5	/
Purified Water (μL)	5	/	/
Reagent 1 (μL)	225	225	225
Mix well, incubate at 37 ℃ for 5 min, and measure absorbance A_1			
Reagent 2 (μL)	75	75	75
Mix well, incubate at 37 ℃ for 5 min, then measure absorbance A_2, calculate $\Delta A = A_2 - A_1$.			

(2) Operation (Urine)

Addition	Blank	Calibration	Detection
Sample (Urine) (μL)	/	/	2
Calibrator (μL)	/	2	/
Purified Water (μL)	2	/	/
Reagent 1 (μL)	240	240	240
Mix well, incubate at 37 ℃ for 5 min, and measure absorbance A_1			
Reagent 2 (μL)	80	80	80
Mix well, incubate at 37 ℃ for 5 min, then measure absorbance A_2, calculate $\Delta A = A_2 - A_1$.			

3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The concentration of creatinine (CREA) in the sample can be calculated on the working curve based on its absorbance change value.

Reference Intervals

Serum: Male: 44~97 μmol/L; Female: 35~80 μmol/L;
Morning urine: Male: 3540~24600 μmol/L; Female: 2550~20000 μmol/L;
24-hour urine: Male: 9000~19000 μmol/L; Female: 6000~13000 μmol/L;

Explanation of Results

1. If the concentration of CREA in the blood sample exceeds 2000 μmol/L or the concentration of CREA in the urine sample exceeds 40000 μmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.
2. The system can be configured to initiate automatic repetition, and setting the automatic repetition conditions (when the test result exceeds 40000 μmol/L, it is recommended to use a triple dilution for automatic repeated detection) can extend the urine detection range to 120000 μmol/L. Automatic repetition results will be marked as automatic repetition.
3. The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is ≤ 10% if the concentrations of the following interferents are at or below the given values:

Sample	Substances	Concentrations
Blood	Bilirubin	342 μmol/L
	Hemoglobin	1 g/L
	Triglyceride	10 mmol/L
	Vc	500 mg/L
Urine	Bilirubin	342 μmol/L
	Hemoglobin	5 g/L
	Triglyceride	11 mmol/L
	Vc	4 g/L
	Glucose	150 mmol/L
	Urea	1600 mmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 0.300.
2. Analytical sensitivity:
Blood: at the test concentration of 100 μmol/L, the reagent absorbance change (ΔA) ≥ 0.010.
Urine: at the test concentration of 2000 μmol/L, the reagent absorbance change (ΔA) ≥ 0.040.
3. Accuracy: relative deviation ≤ 10%.
4. Precision: within-run CV ≤ 3%, between-run relative range ≤ 6%.
5. Linear Range:
Correlation coefficient:
Blood: [20, 2000] μmol/L, the correlation coefficient (r) ≥ 0.990.
Urine: [100, 40000] μmol/L, the correlation coefficient (r) ≥ 0.990.
Linearity deviation:
Blood: [20, 70) μmol/L, the absolute deviation ≤ 7 μmol/L;
[70, 2000] μmol/L, the relative deviation ≤ 10%.
Urine: [100, 3000) μmol/L, the absolute deviation ≤ 300 μmol/L;
[3000, 40000] μmol/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Huidobro E, Tagle R, Guzmán A. Estimation of glomerular filtration rate with creatinine[J]. Rev Med Chil, 2018, 146:344-350.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
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Current Version: 02 Date of Issue: May, 2022

CE IVD

Instructions for Use of Direct Bilirubin (DBIL) Kit (Vanadate Oxidation Method)

Package Specification

REF	Reagent	Systems
01.09.00.20.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	Zybio EXC200/220
01.09.00.20.EC.02	R1 48 mL × 2 R2 12 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of direct bilirubin concentration in human samples (serum or plasma). Clinically, it is mainly used as an evaluation indicator of bilirubin metabolism disorders.

Summary

Bilirubin is formed in the reticuloendothelial system during the degradation of aged erythrocytes. The heme portion from hemoglobin and from other heme-containing proteins is removed, metabolized to bilirubin, and transported as a complex with serum albumin to the liver. In the liver, bilirubin is conjugated with glucuronic acid for solubilization and subsequent transport through the bile duct and elimination via the digestive tract.

Diseases or conditions which, through hemolytic processes, produce bilirubin faster than the liver can metabolize it, cause the levels of unconjugated (indirect) bilirubin to increase in the circulation. Liver immaturity and several other diseases in which the bilirubin conjugation mechanism is impaired cause similar elevations of circulating unconjugated bilirubin. Bile duct obstruction or damage to hepatocellular structure causes increases in the levels of both conjugated (direct) and unconjugated (indirect) bilirubin in the circulation.

Principle

The direct bilirubin in the sample is oxidized to biliverdin, which causes a decrease in absorbance at 450 nm.

1. Bilirubin $\xrightarrow{\text{Vanadate}}$ Biliverdin

The concentration of direct bilirubin in the sample shall be calculated by measuring the absorbance change at 450 nm and comparing with that in calibrator treated in the same manner.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	Citric Acid buffer	100 mmol/L
	Surfactant 1	>0.1% (v/v)
R2	Citric Acid buffer	4.9 mmol/L
	Sodium Metavanadate	>5 mmol/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 12 months.
2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Serum or plasma (heparin anticoagulation) is suitable for samples, which are stable for 3 days at 2 - 8 ℃. Samples should be protected from direct light.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When reagent becomes turbid or the blank absorbance > 0.300, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. The same sample tested with reagents from different manufacturers may lead to different measured values.
7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	End-Point Method	**Sample/Reagent**	1/35
Main Wavelength	450 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	546 nm	**Reaction Time**	10 min
Reaction Direction	-		

2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	10
Calibrator (μL)	/	10	/
Purified Water (μL)	10	/	/
Reagent 1 (μL)	280	280	280
Mix well, incubate at 37 ℃ for 5 min, and measure absorbance A_1			
Reagent 2 (μL)	70	70	70
Mix well, measure absorbance A_2 after 5 min, calculate $\Delta A = A_2 - A_1$.			

3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is

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out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The concentration of direct bilirubin (DBIL) in the sample can be calculated on the working curve based on its absorbance change value.

Reference Intervals

≤ 6.89 μmol/L (≤ 0.4mg/dL)

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of DBIL in the sample exceeds 300.00 μmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is less than 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Vc	0.5 g/L
Hemoglobin	5 g/L
Chyle	0.30%

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 0.300.
2. Analytical sensitivity: at the test concentration of 15.00 μmol/L, the reagent absorbance change (ΔA) ≥ 0.008.
3. Accuracy: relative deviation ≤ 10%.
4. Precision: within-run *CV* ≤ 5%, between-run relative range ≤ 10%.
5. Linear Range:

[2.00, 300.00] μmol/L, the correlation coefficient (r) ≥ 0.990.

[2.00, 20.00] μmol/L, the absolute deviation ≤ 2.00 μmol/L;

(20.00, 300.00] μmol/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Gu D, Wang Y, Ren B, et al. Comparison of Three Routine Methods for the Measurement of Serum Bilirubin in a China Laboratory[J]. Clin Lab, 2018, 64:1485-1490.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

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EC REP Lotus NL B.V.
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Current Version: 02 Date of Issue: May, 2022

Instructions for Use of Ferrum (Fe) Kit
(5-Br-PADAP Chromogenic Method)

Package Specification

REF	Reagent
01.09.0C.03. EC.01	R1 30 mL × 3 R2 7.5 mL × 3
01.09.0C.03. EC.02	R1 48 mL × 2 R2 12 mL × 2
Calibrator(s) (Optional)	1 Level × 0.6 mL or 1 Level × 1.0 mL

Intended Use

In vitro test for the quantitative assay of ferrum ion in human samples (serum). Clinically, it is mainly used as an aid to diagnosis of anemia.

Summary

Ingested iron is mainly absorbed in the form of Fe^{2+} in the duodenum and upper jejunum. The trivalent form and the heme-bound Fe^{3+} component of iron in food has to be reduced by vitamin C. About 1 mg of iron is assimilated daily. Upon reaching the mucosal cells, Fe^{2+} ions become bound to transport substances. Before passing into the plasma, these are oxidized by ceruloplasmin to Fe^{3+} and bound to transferrin in this form. The transport of Fe ions in blood plasma takes place via transferrin-iron complexes. A maximum of 2 Fe^{3+} ions per protein molecule can be transported. Serum iron is almost completely bound to transferrin. Iron (non-heme) measurements are used in the diagnosis and treatment of diseases such as iron deficiency anemia, hemochromatosis (a disease associated with widespread deposit in the tissue of the two iron-containing pigments, hemosiderin and hemofuscin, and characterized by pigmentation of the skin), and chronic renal disease. Iron determinations are performed for the diagnosis and monitoring of microcytic anemia (e g. due to iron metabolism disorders and hemoglobinopathy), macrocytic anemia (e g. due to vitamin B12 deficiency, folic acid deficiency and drug-induced metabolic disorders of unknown origin) as well as normocytic anemias such as renal anemia (erythropoetin deficiency), hemolytic anemia, hemoglobinopathy, bone marrow disease and toxic bone marrow damage.

Principle

This kit uses chromogenic endpoint method to combine 5-Br-PADAP with iron ion to generate a purple red complex. The color formed in the reaction is directly proportional to the concentration of iron ion in the sample, which can be calculated by measuring the absorbance change at 546 nm.

Reagents Components and Concentration

Composition: R1 & R2; Calibrator(s) (optional)

R1	HAc-NaAc Buffer	0.2 mmol//L
R2	5-Br-PADAP Chromogenic Solution	0.2 mmol/L
Calibrator(s) (Optional)	$FeCl_3$	Refer To The Label For The Marked Value

The calibrator(s) can be traceable to SRM®3126a.

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The reagents are valid for 12 months.
2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. The reagents could be stable for 2 weeks at 2 - 8 ℃ in transportation.
4. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400, EXC200/220 Chemistry Analyzer. Other models shall be used after verification.

Specimen Information

1. Serum should be separated in time after fasting blood collection to avoid hemolysis and lipemia.
2. The iron in the serum could be stable for one week at 2 - 8 ℃.
3. Repeated freezing and thawing should be avoided.

Warnings and Precautions

1. For in vitro diagnostic use only. It is often used as an aid of diagnosis of iron deficiency anemia.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When reagent becomes turbid or blank absorbance > 0.800, the reagent is invalid and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. Recalibration is recommended after reagents are replaced. Reagents of different batches should not be mixed for use.
7. It is recommended that medical institutions purchase the kit containing calibrator(s) when using the kit for the first time.
8. The same sample tested with reagents from different manufacturers may lead to different measured values.
9. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	End-Point Method	**Sample / Reagent**	3/25
Main Wavelength	546 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	700 nm	**Reaction Time**	10 min
Reaction Direction	+		

2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	30
Calibrator(s) (μL)	/	30	/
Purified Water (μL)	30	/	/

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Reagent 1 (μL)	200	200	200
Mix well, incubate at 37 ℃ for 5 min, and measure absorbance A_1			
Reagent 2 (μL)	50	50	50
Mix well, measure absorbance A_2 after 5 min, calculate $\Delta A = A_2 - A_1$.			

3. Calibration

Use Zybio clinical chemistry multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

4. Quality Control

Indoor quality control is recommended. Values obtained should fall within the limited range. If there is a failure of any of controls, the laboratory should take appropriate corrective measures.

5. Calculation

Fe (μmol/L) = (Δ*A* Sample / Δ*A* Calibrator(s)) × C Calibrator(s)

Reference Intervals

Male: 10.80 - 29.66 μmol/L

Female: 9.10 - 26.90 μmol/L

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration exceeds 60.0 μmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional shall be responsible for the review of the test result, which may be affected by the subject's age, gender, or weight. The measured values within the critical range should be re-determined and confirmed, if it is obviously beyond the reference range or if it is still beyond the reference range after confirmation, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations-Interference

The deviation of test results caused by interferents is within ± 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Mg^{2+}	4 mmol/L
Cu^{2+}	60 mmol/L
Zn^{2+}	45 mmol/L
VC	105 mmol/L
Ca^{2+}	5 mmol/L
Bilirubin	280 μmol/L

Performance Characteristics

1. The reagent blank absorbance: ≤ 0.800.
2. Analytical sensitivity: at the test concentration of 20 μmol/L, the absorbance change (Δ*A*) ≥ 0.01.
3. Accuracy: relative deviation ≤ 10%.
4. Precision: within-run *CV* ≤ 5%, between-run relative range ≤ 10%.
5. Linear range:

[2.0, 60.0] μmol/L, the correlation coefficient (*r*) ≥ 0.990.

[2.0, 10.0) μmol/L, the absolute deviation ≤ 1.0 μmol/L;

[10.0, 60.0] μmol/L, the relative deviation ≤ 10%.

6. Calibrator(s) accuracy: the relative deviation ≤ 10%.
7. Calibrator(s) uniformity: within-vial *CV* ≤ 10%.

References

[1] Wick M, Pinggera W, Lehmann P. Eisenstoffwechsel, Anämien Diagnostik und Therapie [M]. 1999.

Label Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture

Manufacturer Information

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CE IVD

Instructions for Use of Gamma-Glutamyl Transferase (GGT) Kit (Enzymatic Method)

Package Specification

REF	Reagent	Systems
01.09.00.03.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	Zybio EXC200/220
01.09.00.03.EC.02	R1 48 mL × 2 R2 12 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of the catalytic activity concentration of γ-glutamyl transferase in human samples (serum or plasma). Clinically, it is mainly used as an aid to diagnosis of hepatobiliary diseases.

Summary

γ-Glutamyl transferase is used in the diagnosis and monitoring of hepatobiliary diseases. Enzymatic activity of GGT is often the only parameter with increased values when testing for such diseases, and is one of the most sensitive indicators known. γ-Glutamyl transferase is also a sensitive screening test for occult alcoholism. Elevated GGT activities are found in the serum of patients requiring long-term medication with phenobarbital and phenytoin. In 1969, Szasz published the first kinetic procedure for GGT in serum using γ-glutamyl-p-nitroanilide as substrate and glycylglycine as acceptor. In order to circumvent the poor solubility of γ-glutamyl-p-nitroanilide, Persijn and van der Slik investigated various derivatives and found the water soluble substrate L-γ-glutamyl-3-carboxy-4-nitroanilide to be superior in terms of stability and solubility. The results correlate with those derived using the original substrate. In 2002, the International Federation of Clinical Chemistry (IFCC) recommended the standardized method for determining GGT including optimization of substrate concentrations, employment of NaOH, glycylglycine buffer and sample start.

Principle

The kit uses a modified version of the method recommended by the International Federation of Clinical Chemistry (IFCC):

L-γ-Glutamyl-3-Carboxy-4-Nitroaniline + Glycylglycine $\xrightarrow{\text{GGT}}$ L-γ-Glutamyl Glycylglycine + 5-Amino-2-Nitrobenzoate

This causes an increase in absorbance at 405 nm, which is directly proportional to the catalytic activity concentration of GGT in the sample.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	Glycylglycine	127.8 mmol/L
	Trometamol (Tris) buffer	154.6 mmol /L
R2	L-γ-Glutamyl-3-Carboxy-4-Nitroaniline	6 g/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 12 months.
2. Once opened, the reagents are stable for 4 weeks at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Non-hemolytic serum or plasma (EDTA for anticoagulation) is suitable for samples. The γ-glutamyl transferase in samples is stable for 7 days at 2 - 8 ℃.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When reagent becomes turbid or the blank absorbance > 0.800, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. Considering the reaction solution turbidity caused by heparin and inhibition of GGT by citrate, oxalate, and fluoride, plasma with these substances as anticoagulant is not suitable for GGT determination.
7. The same sample tested with reagents from different manufacturers may lead to different measured values.
8. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	Rate Method	**Sample/Reagent**	1/10
Main Wavelength	405 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	505 nm	**Reaction Time**	10 min
Reaction Direction	+		

2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	25
Calibrator (μL)	/	25	/
Purified Water (μL)	25	/	/
Reagent 1 (μL)	200	200	200
Mix well, incubate at 37 ℃ for 3 ~ 5 min			
Reagent 2 (μL)	50	50	50
After 1 min, continuously monitor the absorbance change within 2 min, and calculate the absorbance change rate ΔA/min.			

3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

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4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The catalytic activity concentration of γ-glutamyl transferase (GGT) in the sample can be calculated on the working curve based on its absorbance change rate.

Reference Intervals

Male: 11 - 50 U/L Female: 7 - 32 U/L

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases per group, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the catalytic activity concentration of GGT in the sample exceeds 600 U/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is less than 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Hemoglobin	5 g/L
Bilirubin	684 μmol/L
Triglyceride	10 g/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 0.800, the reagent blank absorbance change rate (Δ*A*/min) ≤ 0.005.

2. Analytical sensitivity: at the test catalytic activity concentration of 50 U/L, the absorbance change rate (Δ*A*/min) ≥ 0.010.

3. Accuracy: relative deviation ≤ 10%.

4. Precision: within-run *CV* ≤ 5%, between-run relative range ≤ 10%.

5. Linear range:

[10, 600] U/L, the correlation coefficient (*r*) ≥ 0.990.

[10, 50] U/L, the absolute deviation ≤ 5 U/L;

(50, 600] U/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Szasz G. A kinetic photometric method for serum gamma-glutamyl transpeptidase[J]. Clin Chem, 1969, 15:124-136.

[2] Schumann G, Bonora R, Ceriotti F, et al. IFCC primary reference procedures for the measurement of catalytic activity concentrations of enzymes at 37 degrees C. International Federation of Clinical Chemistry and Laboratory Medicine. Part 4. Reference procedure for the measurement of catalytic concentration of alanine aminotransferase[J]. Clin Chem Lab Med, 2002, 40:718-724.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

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Current Version: 02 Date of Issue: May, 2022

CE IVD

Instructions for Use of Glucose (GLU) Kit (Hexokinase Method)

Package Specification

REF	Reagent	Systems
1080201	R1 30 mL × 1 R2 7.5 mL × 1	Zybio EXC200/220
1080202	R1 30 mL × 3 R2 7.5 mL × 3	Zybio EXC200/220
1080203	R1 48 mL × 2 R2 12 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of glucose in human samples (serum or plasma). Clinically, the measurements are used as an aid to diagnosis of diabetes mellitus.

Summary

Glucose(GLU) is a kind of hexose containing aldehyde group, whose molecular formula is $C_6H_{12}O_6$, and it is the most important monosaccharide in organisms. Its main function is to provide energy needed for physiological activities.

Glucose and energy homeostasis are maintained through multiple interacting complex feed-back systems that involves neuronal, hormonal, and metabolic components.

Glucose is of central metabolic importance in virtually all organisms, from microbes to humans. Glycolytic metabolism of glucose is a major pathway for the generation of energy (ATP). The phosphorylation of glucose is the first step in glycolysis. A family of hexose phosphorylating enzymes, the hexokinases, carry out this important process. Glucose, glucose 6-phosphate (G-6-P), and α-glucose 1-phosphate (α-G1P) are three essential molecules. When glucose enters a cell, it is first converted to G-6-P upon phosphorylation at C6 by hexokinase (HK).

Principle

The kit uses hexokinase method to determine glucose in serum or plasma.

1. GLU + ATP $\xrightarrow{\text{Hexokinase}}$ G-6-P + ADP

2. G-6-P + NAD^+ $\xrightarrow{\text{G6PDH}}$ 6-Phosphogluconic Acid + NADH + H^+

The glucose content in the sample could be calculated by comparing the variation value of NADH absorbance measured at 340 nm with calibrator treated by the same way.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	Adenosine triphosphate (ATP)	8-10 mmol/L
R2	Nicotinamide adenine dinucleotide (NAD^+)	5-8 mmol/L
	Hexokinase	5-10 kU/L
	Glucose-6-phosphate dehydrogenase (G6PDH)	8-15 kU/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 18 months.
2. Once opened, the reagents are stable for 35 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Serum and plasma (Na-heparin or K_2-EDTA) are the recommended specimen types. The serum and plasma (Na-heparin) samples are stable for 24 hours at 2 - 8 °C, for 30 days at - 20 °C, and for 3 freezing-thawing cycles.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When reagent becomes turbid or the blank absorbance > 0.600, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. The same sample tested with reagents from different manufacturers may lead to different measured values.
7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	End-Point Method	**Sample/Reagent**	1/100
Main Wavelength	340 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	405 nm	**Reaction Time**	10 min
Reaction Direction	+		

2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	3
Calibrator (μL)	/	3	/
Purified Water (μL)	3	/	/
Reagent 1 (μL)	240	240	240
Mix well, incubate at 37 ℃ for 5 min, and measure absorbance A_1			
Reagent 2 (μL)	60	60	60
Mix well, measure absorbance A_2 after 5 min, calculate $\Delta A = A_2 - A_1$.			

3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

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4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The concentration of glucose (GLU) in the sample can be calculated on the working curve based on its absorbance change value.

Reference Intervals

3.9~6.1 mmol/L

This reference interval is determined based on 95% distribution interval obtained from 132 healthy human specimens without related diseases and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of GLU in the sample exceeds 40.0 mmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is within ± 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Hemoglobin	5 g/L
Chyle	0.30%
Bilirubin	342 μmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests, and treatment response. To achieve diagnostic purposes, the test results should be combined with clinical tests, medical history, and other test results.

Performance Characteristics

1. The product has a limit of blank (LoB) of 0.06 mmol/L.
2. The product has a limit of detection (LoD) of 0.13 mmol/L.
3. Accuracy: relative deviation ≤ 10%.
4. Precision: ≤ 5%CV for specimen from 2.0 - 7.0 mmol/L, and ≤ 4%CV for specimen > 7.0 mmol/L.
5. Linear Range:

[2.0, 40.0] mmol/L, the correlation coefficient (r) ≥ 0.990.

[2.0, 4.0) mmol/L, the absolute deviation ≤ 0.4 mmol/L;

[4.0, 40.0] mmol/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Marco V, Zhao F. Viriyapong R, et al. The impact of ageing, fasting and high-fat diet on central and peripheral glucose tolerance and glucose-sensing neural networks in the arcuate nucleus [J]. J Neuroendocrinol, 2017, 29:10.1111/jne.12528.

[2] Wilson J. Isozymes of mammalian hexokinase: structure, subcellular localization and metabolic function[J]. J Exp Biol, 2003, 206:2049-2057.

[3] Middleton R. Hexokinases and glucokinases[J]. Biochem Soc Trans, 1990, 18: 180-183.

[4] Tang Y, Cheng F, Feng Z, et al. Stereostructural Elucidation of Glucose Phosphorylation by Raman Optical Activity[J]. J Phys Chem B, 2019, 123:7794-7800.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

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Current Version: 02 Date of Issue: May, 2022

CE IVD

zybio

Instructions for Use of Lipase (LPS) Kit (Colorimetric Method)

Package Specification

REF	Reagent	Systems
01.09.0B.01.EC.01	R1 30 mL × 3 R2 10 mL × 3 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1	Zybio EXC200/220
01.09.0B.01.EC.02	R1 45 mL × 2 R2 15 mL × 2 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of the catalytic activity concentration of lipase (LPS) in human samples (serum or plasma). Clinically, it is used as the most important evaluation indicator for differential diagnosis of pancreatic diseases.

Summary

Lipases are glycoproteins with a molecular weight of 47000 Da. They are defined as triglyceride hydrolases which catalyze the cleavage of triglycerides to diglycerides with subsequent formation of monoglycerides and fatty acids. In addition to α-amylase, pancreatic lipases have for many years been undeniably the most important clinical chemistry parameters for the differential diagnosis of diseases of the pancreas. The lipase activity determination has gained increasing international recognition because of its high specificity and rapid response. After acute pancreatitis the lipase activity increases within 4 - 8 hours, reaches a peak after 24 hours and decreases after 8 - 14 days.

Numerous methods have been described for the determination of lipase which determine the decrease in substrate turbidimetrically or nephelometrically or determine degradation products.

The methylresorufin substrate method is based on the cleavage of a specific chromogenic lipase substrate 1,2-dilauryl glycerol-3-glutaric acid-(6-methylresorufin)-ester emulsified with bile acids. The pancreatic enzyme activity is determined specifically by the combination of bile acid and colipase used in this assay.

Virtually no lipase activity is detected in the absence of colipase. Colipase only activates pancreatic lipase, but not other lipolytic enzymes found in serum. The high amount of cholate ensures that the esterases present in the serum do not react with the chromogenic substrate due to the highly negative surface charge.

Principle

Lipase, in the presence of co-lipase and bile acids, can hydrolyze 1,2-Di-O-Lauryl-Rac-Glycero-3-Glutaric Acid-(6-Methylresorufin)-Ester to generate 1,2-O-Dilauryl-Rac-Glycerol and Glutaric Acid-(6-Methylresorufin)-Ester, and the latter continues to decompose under alkaline conditions to form glutaric acid and red methylresorufin. The increase in absorbance caused by this red dye is directly proportional to the lipase catalytic activity concentration in the sample.

1. 1,2-Di-O-Lauryl-Rac-Glycero-3-Glutaric Acid-(6-Methylresorufin)-Ester + H_2O $\xrightarrow{LPS}$ 1,2-O-Dilauryl-Rac-Glycerol + Glutaric Acid-(6-Methylresorufin)-Ester

2. Glutaric Acid-(6-Methylresorufin)-Ester + H_2O $\xrightarrow{OH^-}$ glutaric acid + Methylresorufin

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	N,N-Bis(2-hydroxyethyl)glycine	> 130 mmol/L
	Co-lipase	> 0.5 mg/L
R2	Tartaric acid buffer	9 mmol/L
	Lipase substrate	> 0.10 g/L
Calibrator	Lipase Bovine Serum	Refer to the label for marked value
Control	Lipase Bovine Serum	Refer to the label for marked value

The components in different batches are non-interchangeable.

The measurement system can be traceable to enterprise standard.

The target value of control has batch specificity.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 18 months.
2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. In order to ensure the accuracy of test results, calibrator and control are stable for 7 days at 2 - 8 ℃ after reconstitution.
4. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Serum or plasma (heparin for anticoagulation) is suitable for samples, which are stable for 3 days at 2 - 8 ℃ and for 90 days at - 20 ℃. Avoid repeated freezing and thawing.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When reagent becomes turbid or the blank absorbance > 0.800, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. Dedicated calibrator and control are recommended for use to ensure the accuracy of test values.
7. The same sample tested with reagents from different manufacturers may lead to different measured values.
8. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	Rate Method	**Sample/Reagent**	1/100
Main Wavelength	570 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	700 nm	**Reaction Time**	10 min
Reaction Direction	+		

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2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	3
Calibrator (μL)	/	3	/
Purified Water (μL)	3	/	/
Reagent 1 (μL)	225	225	225
Mix well, incubate at 37 ℃ for 5 min			
Reagent 2 (μL)	75	75	75
Mix well, incubate at 37 ℃ for 1.5 min, then continuously monitor the absorbance change rate (ΔA/min) within 2 min.			

3. Calibration

Use Zybio matched calibrator or Zybio Clinical Chemistry Multi-analyte Calibrator.
Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.
Calibrator reconstitution: Reconstitution with the amount of purified water labeled on the bottle accurately absorbed, leave for 30 minutes, and mix well before use.

4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.
Control reconstitution: Reconstitution with the amount of purified water labeled on the bottle accurately absorbed, leave for 30 minutes, and mix well before use.

5. Calculation

Linear calibration was used to draw the working curve. The catalytic activity concentration of lipase (LPS) in the sample can be calculated on the working curve based on its absorbance change rate.

Reference Intervals

≤ 60 U/L

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the catalytic activity concentration of LPS in the sample exceeds 300 U/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.
The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is ≤ 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Hemoglobin	1 g/L
Chyle	0.30%
Bilirubin	342 μmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 0.800, the reagent blank absorbance change rate (Δ*A*/min) ≤ 0.010.
2. Analytical sensitivity: at the test catalytic activity concentration of 100 U/L, the reagent absorbance change rate (Δ*A*/min) ≥ 0.015.
3. Accuracy: the relative deviation ≤ 10%.
4. Precision: within-run *CV* ≤ 5%; between-run relative range ≤10%.
5. Linear range:
[8, 300] U/L, the correlation coefficient (*r*) ≥ 0.990.
[8, 40] U/L, the absolute deviation ≤ 8 U/L;
(40, 300] U/L, the relative deviation ≤ 10%.
6. Calibrator accuracy: the relative deviation ≤ 10%.
7. Calibration homogeneity: between-vial *CV* shall be ≤ 10%.
8. Control accuracy: test value is within the allowable range of the marked value.
9. Control homogeneity: between-vial *CV* shall be ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, General lab equipment and consumable.

References

[1] Kazmierczak S, Catrou P, Lente F. Diagnostic accuracy of pancreatic enzymes evaluated by use of multivariate data analysis[J]. Clin Chem, 1993, 39:1960-1965.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
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Current Version: 02 Date of Issue: May, 2022

CE IVD

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Instructions for Use of Magnesium (Mg) Kit (Xylidyl Blue Method)

Package Specification

REF	Reagent	Systems
01.09.0C.02.EC.01	R 30 mL × 6	Zybio EXC200/220
01.09.0C.02.EC.02	R 60 mL × 2	Hitachi 7180 Zybio EXC400/420
01.09.0C.02.EC.03	R 30 mL × 6 Calibrator 1 Level × 1.0 mL × 1	Zybio EXC200/220
01.09.0C.02.EC.04	R 60 mL × 2 Calibrator 1 Level × 1.0 mL × 1	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of magnesium concentration in human samples (serum or plasma). Clinically, it is mainly used as an aid to diagnosis of magnesium metabolism disorders.

Summary

Magnesium along with potassium is a major intracellular cation. Mg^{2+} is a cofactor of many enzyme systems. Thus, all ATP-dependent enzymatic reactions require Mg^{2+} as a cofactor in the ATP-magnesium complex. Approximately 69% of magnesium are stored in bone. The rest are part of the intermediary metabolism, about 70% being present in free form while the other 30% is bound to proteins (especially albumin), citrates, phosphate, and other complex formers. The Mg^{2+} serum level is kept constant within very narrow limits (0.65-1.05 mmol/L).

Regulation takes place mainly via the kidneys, especially via the ascending loop of Henle.

This assay is used as an aid to diagnosis of hypomagnesemia (magnesium deficiency) and hypermagnesemia (magnesium excess). Numerous studies have shown a correlation between magnesium deficiency and changes in calcium-, potassium- and phosphate-homeostasis which are associated with cardiac disorders such as ventricular arrhythmias that cannot be treated by conventional therapy, increased sensitivity to digoxin, coronary artery spasms, and sudden death. Additional concurrent symptoms include neuromuscular and neuropsychiatric disorders.

Hypermagnesemia is found in acute and chronic renal failure, magnesium excess, and magnesium release from the intracellular space.

The method described here is based on the reaction of magnesium with xylidyl blue in alkaline solution containing EGTA to mask the calcium in the sample.

Urine magnesium levels are determined in magnesium depletion tests.

Principle

This kit uses xylidyl blue method to determine the content of magnesium. In the alkaline solution, magnesium in the serum combine with xylidyl blue dye to generate a purple complex. The absorbance of this complex at 505 nm is directly proportional to the concentration of magnesium in the sample.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R	Sodium Hydroxide	77 mmol/L
	Xylidyl Blue	0.14 mmol/L
	Polyvinylpyrrolidone	0.03 mmol/L
Calibrator (Optional)	Magnesium Chloride	Refer to the label for marked value

The components in different batches are non-interchangeable.

The measurement system can be traceable to enterprise standard.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 12 months.
2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Serum or plasma is suitable for samples, which are stable for 1 week at 2 - 8 ℃ and for 1 month at - 20 ℃. Avoid repeated freezing and thawing.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When reagent becomes turbid or the blank absorbance > 0.800, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. It is recommended that medical institutions purchase the kit containing calibrator when using the kit for the first time.
7. The same sample tested with reagents from different manufacturers may lead to different measured values.
8. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	End-Point Method	**Sample/Reagent**	1/100
Main Wavelength	505 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	700 nm	**Reaction Time**	8 min
Reaction Direction	+		

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2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	3
Calibrator (μL)	/	3	/
Purified Water/Saline (μL)	3	/	/
Reagent (μL)	300	300	300
Mix well, incubate at 37 ℃ for 8 min, and measure absorbance *A*.			

3. Calibration

Use Zybio matched calibrator, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The concentration of magnesium (Mg) in the sample can be calculated on the working curve based on its absorbance change value.

Reference Intervals

0.8~1.0 mmol/L

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of Mg^{2+} in the sample exceeds 2.0 mmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is < 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Bilirubin	280 μmol/L
Ca^{2+}	3 mmol/L
K^{+}	8 mmol/L
Na^{+}	180 mmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 0.800.
2. Analytical sensitivity: at the test concentration of 1.00 mmol/L, the reagent absorbance change (Δ*A*) ≥ 0.05.
3. Accuracy: relative deviation ≤ 10%.
4. Precision: within-run *CV* ≤ 4%, between-run relative range ≤ 6%.
5. Linear Range:

[0.20, 2.0] mmol/L, the correlation coefficient (*r*) ≥ 0.990.

[0.20, 0.80) mmol/L, the absolute deviation ≤ 0.08 mmol/L;

[0.80, 2.0] mmol/L, the relative deviation ≤ 10%.

6. Calibrator accuracy: relative deviation ≤ 10%.
7. Calibrator homogeneity: within-vial *CV* ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Ehrhardt V, Paschen K, Vogt W, et al. Magnesium-Bestimmung im Serum und Urin mit einer verbesserten Xylidyl-Blau-Methode[C]. Workshop Kaiserslautern, 1989.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
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CE IVD

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Instructions for Use of Total Bilirubin (TBIL) Kit (Vanadate Oxidation Method)

Package Specification

REF	Reagent	Systems
01.09.00.21.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	Zybio EXC200/220
01.09.00.21.EC.03	R1 48 mL × 2 R2 12 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of total bilirubin concentration in human samples (serum or plasma). Clinically, it is mainly used as one of the evaluation indicators for bilirubin metabolism diseases.

Summary

Measurement of the levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, is used in the diagnosis and treatment of liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gall bladder blockage.

Bilirubin is formed in the reticuloendothelial system during the degradation of aged erythrocytes. The heme portion from hemoglobin and from other heme-containing proteins is removed, metabolized to bilirubin, and transported as a complex with serum albumin to the liver. In the liver, bilirubin is conjugated with glucuronic acid for solubilization and subsequent transport through the bile duct and elimination via the digestive tract.

Diseases or conditions which, through hemolytic processes, produce bilirubin faster than the liver can metabolize it, cause the levels of unconjugated (indirect) bilirubin to increase in the circulation. Liver immaturity and several other diseases in which the bilirubin conjugation mechanism is impaired cause similar elevations of circulating unconjugated bilirubin. Bile duct obstruction or damage to hepatocellular structure causes increases in the levels of both conjugated (direct) and unconjugated (indirect) bilirubin in the circulation.

Principle

The total bilirubin in the sample is oxidized to biliverdin, which causes a decrease in absorbance at 450 nm.

1. Bilirubin $\xrightarrow{\text{Vanadate}}$ Biliverdin

The concentration of total bilirubin in the sample shall be calculated by measuring the absorbance change at 450 nm and comparing with that in calibrator treated in the same manner.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	Citric Acid buffer	100 mmol/L
	Surfactant 1	0.2% (v/v)
R2	Citrate Buffer	18.36 mmol/L
	Sodium Metavanadate	6.56 mmol/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 12 months.

2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.

3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Serum or plasma (heparin anticoagulation) is suitable for samples, which are stable for 3 days at 2 - 8 ℃. Samples should be protected from direct light.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.

2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.

3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.

4. When reagent becomes turbid or the blank absorbance > 0.050, the reagent is failed and should be discarded.

5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.

6. The same sample tested with reagents from different manufacturers may lead to different measured values.

7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	End-Point Method	**Sample/Reagent**	1/35
Main Wavelength	450 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	546 nm	**Reaction Time**	10 min
Reaction Direction	-		

2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	10
Calibrator (μL)	/	10	/
Purified Water (μL)	10	/	/
Reagent 1 (μL)	280	280	280
Mix well, incubate at 37 ℃ for 5 min, and measure absorbance A_1			
Reagent 2 (μL)	70	70	70
Mix well, measure absorbance A_2 after 5 min, calculate $\Delta A = A_2 - A_1$.			

3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

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4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The concentration of total bilirubin (TBIL) in the sample can be calculated on the working curve based on its absorbance change value.

Reference Intervals

3.4~20.5 μmol/L (0.2~1.2mg/dL)

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of TBIL in the sample exceeds 500 μmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is less than 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Vc	0.5 g/L
Hemoglobin	5 g/L
Chyle	0.30%

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 0.050.

2. Analytical sensitivity: at the test concentration of 30 μmol/L, the reagent absorbance change (ΔA) > 0.003.

3. Accuracy: relative deviation ≤ 10%.

4. Precision: within-run *CV* ≤ 4%, between-run relative range ≤ 10%.

5. Linear Range:

[3, 500] μmol/L, the correlation coefficient (r) ≥ 0.990.

[3, 20] μmol/L, the absolute deviation ≤ 2 μmol/L;

(20, 500] μmol/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Doumas B, Cheung P, Perry B. Candidate reference method for determination of total bilirubin in serum: development and validation[J]. Clin Chem, 1985, 31:1779-1789.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

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Current Version: 02 Date of Issue: May, 2022

CE IVD

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Instructions for Use of Triglyceride (TG) Kit (Enzymatic Method)

Package Specification

REF	Reagent	Systems
01.09.02.02.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	Zybio EXC200/220
01.09.02.02.EC.02	R1 48 mL × 2 R2 12 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of triglyceride concentration in human samples (serum). Clinically, it is mainly used for auxiliary diagnosis of hypertriglyceridemia.

Summary

Triglycerides are esters of the trihydric alcohol glycerol with 3 long-chain fatty acids. They are partly synthesized in the liver and partly ingested in food.

The determination of triglycerides is utilized in the diagnosis and treatment of patients having diabetes mellitus, nephrosis, liver obstruction, lipid metabolism disorders and numerous other endocrine diseases.

Using a lipoprotein lipase from microorganisms for the rapid and complete hydrolysis of triglycerides to glycerol followed by oxidation to dihydroxyacetone phosphate and hydrogen peroxide. The hydrogen peroxide produced then reacts with 4-aminophenazone and TOPS under the catalytic action of peroxidase to form a red dyestuff (Trinder endpoint reaction). The color intensity of the red dyestuff formed is directly proportional to the triglyceride concentration and can be measured photometrically.

Principle

1. Triglyceride + H_2O $\xrightarrow{\text{Lipase}}$ Glycerol + Fatty Acid
2. Glycerol + ATP $\xrightarrow{\text{Glycerol kinase}}$ Glycerin-3- Phosphoric Acid + ADP
3. Glycerol-3-Phosphoric Acid + O_2 $\xrightarrow{\text{GPO}}$ Dihydroxyacetone Phosphate + H_2O_2
4. $2H_2O_2$ + 4-AAP + TOPS $\xrightarrow{\text{Peroxidase}}$ Quinonimine + $4H_2O$

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	3-Morpholinepropanesulfonic acid buffer	200 mmol/L
	Lipoprotein Lipase (LPL)	2-3 kU/L
	3-(N-Ethyl-3-methylanilino) propanesulfonic acid sodium salt (TOPS)	7-11 mmol/L
R2	3-Morpholinepropanesulfonic acid buffer	200 mmol/L
	Peroxidase	4-6 kU/L
	Glycerophosphate Oxidase (GPO)	6.5-8.5 kU/L
	Glycerokinase	4-6 kU/L
	Adenosine 5'-triphosphate (ATP) disodium salt	1.8-2.8 mmol/L
	4-Aminoantipyrine (4-AAP)	1-2 mmol/L

The components in different batches are non-interchangeable.

The measurement system can be traceable to ERM-DA470k/IFCC.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 12 months.
2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Serum is suitable for samples, which shall be separated in time after collection to avoid hemolysis. Samples are stable for 3 days at 2 - 8 ℃ and 30 days at - 20 ℃. Avoid repeated freezing and thawing.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When reagent becomes turbid or the blank absorbance > 0.200, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. The same sample tested with reagents from different manufacturers may lead to different measured values.
7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	End-Point Method	**Sample/Reagent**	1/100
Main Wavelength	546 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	700 nm	**Reaction Time**	10 min
Reaction Direction	+		

2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	3
Calibrator (μL)	/	3	/
Purified Water (μL)	3	/	/
Reagent 1 (μL)	240	240	240
Mix well, incubate at 37 ℃ for 5 min, and measure absorbance A_1			
Reagent 2 (μL)	60	60	60
Mix well, measure absorbance A_2 after 5 min, calculate $\Delta A = A_2 - A_1$.			

3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

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4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The concentration of triglyceride (TG) in the sample can be calculated on the working curve based on its absorbance change value.

Reference Intervals

≤ 2.30 mmol/L

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of TG in the sample exceeds 10.00 mmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is less than 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Vc	0.5 g/L
Hemoglobin	5 g/L
Bilirubin	342 μmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 0.200.
2. Analytical sensitivity: at the test concentration of 1.0 mmol/L, the reagent absorbance change (ΔA) > 0.03.
3. Accuracy: relative deviation ≤ 10%.
4. Precision: within-run *CV* ≤ 5%, between-run relative range ≤ 8%.
5. Linear Range:

[0.50, 10.00] mmol/L, the correlation coefficient (r) ≥ 0.990.

[0.50, 2.00] mmol/L, the absolute deviation ≤ 0.20 mmol/L;

(2.00, 10.00] mmol/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Toth P. Triglyceride-rich lipoproteins as a causal factor for cardiovascular disease[J]. Vasc Health Risk Manag, 2016, 12: 171-183.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

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Instructions for Use of Total Protein (TP) Kit (Biuret Method)

Package Specification

REF	Reagent	Systems
01.09.00.23.EC.01	R 30 mL × 6	Zybio EXC200/220
01.09.00.23.EC.02	R 60 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of total protein concentration in human samples (serum). Clinically, it is mainly used for liver function evaluation.

Summary

Serum total protein (TP) can be divided into two categories: albumin and globulin, which have important physiological functions in the body. The determination of serum total protein is one of the important items of clinical biochemical tests. Serum proteins have many functions such as maintaining normal colloid osmotic pressure and pH of blood, transporting a variety of metabolites, regulating the physiological effects of transported substances and relieving their toxicity, immune effects and nutritional effects. Serum total protein can be used not only for monitoring the nutritional status of the body, but also for the diagnosis and differential diagnosis of diseases.

After fresh adoption, serum is naturally coagulated and precipitated to remove fibrous protein with a content of 2 to 4 g/L, and the rest is serum total protein. At present, the determination of serum total protein content by biuret method is a routine method in clinical laboratories, and its precision is also very high. The biuret reaction calculates the protein content from the measured absorbance value, which can be used as an ideal method for the determination of total serum protein.

Principle

In alkaline solution, peptide bonds in protein molecules are complexed with divalent copper ions to form a blue-violet complex (biuret reaction). The complex has an absorption peak at 546 nm, and its color depth is directly proportional to the concentration of total protein in the sample. The concentration of total protein in the sample can be calculated by comparing with that in the calibrator treated in the same manner.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R	Cupric Sulfate	12 mmol/L
	Potassium Sodium Tartrate	31.9 mmol/L
	Potassium Iodide	30 mmol/L
	Sodium Hydroxide	600 mmol/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 12 months.
2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Non-hemolytic serum is suitable for samples, which are stable for 7 days at 2 - 8 ℃.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When reagent becomes turbid or the blank absorbance > 0.200, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. The same sample tested with reagents from different manufacturers may lead to different measured values.
7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	End-Point Method	**Sample/Reagent**	1/60
Main Wavelength	546 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	700 nm	**Reaction Time**	10 min
Reaction Direction	+		

2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	5
Calibrator (μL)	/	5	/
Purified Water (μL)	5	/	/
Reagent (μL)	300	300	300
Mix well, measure absorbance *A* after 10 min.			

3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

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5. Calculation

Linear calibration was used to draw the working curve. The concentration of total protein (TP) in the sample can be calculated on the working curve based on its absorbance change value.

Reference Intervals

60~83 g/L

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of TP in the sample exceeds 120 g/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor. The recommended dilution factor is not to exceed four times.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is less than 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Vc	0.5 g/L
Chyle	0.30%
Bilirubin	342 μmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 0.200.
2. Analytical sensitivity: at the test concentration of 70 g/L, the reagent absorbance change (ΔA) ≥ 0.150.
3. Accuracy: relative deviation ≤ 5%.
4. Precision: within-run *CV* ≤ 2%, between-run relative range ≤ 5%.
5. Linear range:

[10, 120] g/L, the correlation coefficient (r) ≥ 0.995.

[10, 30] g/L, the absolute deviation ≤ 3 g/L;

(30, 120] g/L, the relative deviation ≤ 6%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator , Control, General lab equipment and consumable.

References

[1] Gregor A, Kostrzewska E, Godorowska W. Determination of serum proteins in the presence of dextran by means of the biuret reaction[J]. Infusionsther Klin Ernahr, 1977, 4:48-50.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

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Instructions for Use of Uric Acid (UA) Kit (Uricase Method)

Package Specification

REF	Reagent	Systems
01.09.01.07.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	Zybio EXC200/220
01.09.01.07.EC.02	R1 48 mL × 2 R2 12 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of uric acid concentration in human samples (serum or plasma). Clinically, it is mainly used as an aid to diagnosis of hyperuricemia.

Summary

Uric acid is the final product of purine metabolism in the human organism. Uric acid measurements are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions, and of patients receiving cytotoxic drugs.

The oxidation of uric acid provides the basis for two approaches to the quantitative determination of this purine metabolite. One approach is the reduction of phosphotungstic acid in an alkaline solution to tungsten blue, which is measured photometrically. The method is, however, subject to interferences from drugs and reducing substances other than uric acid.

A second approach, described by Praetorius and Poulson, utilizes the enzyme uricase to oxidize uric acid; this method eliminates the interferences intrinsic to chemical oxidation. Uricase can be employed in methods that involve the UV measurement of the consumption of uric acid or in combination with other enzymes to provide a colorimetric assay.

Another method is the colorimetric method developed by Town et al. The sample is initially incubated with a reagent mixture containing ascorbate oxidase and a clearing system. In this test system it is important that any ascorbic acid present in the sample is eliminated in the preliminary reaction; this precludes any ascorbic acid interference with the subsequent POD indicator reaction. Upon addition of the starter reagent, oxidation of uric acid by uricase begins.

Principle

1. Uric acid + O_2 + H_2O $\xrightarrow{\text{Uricase}}$ Allantoin + CO_2 + H_2O_2

2. H_2O_2 + 4-AAP + TOOS $\xrightarrow{\text{Peroxidase}}$ Quinoneimine + H_2O

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	Sodium 3-(N-ethyl-3-methylanilino)-2-hydroxypropanesulfonate (TOOS)	1.11 mmol/L
	Ascorbate Oxidase	10 kU/L
R2	Trometamol (Tris) buffer	200 mmol/L
	Uricase	1.5 kU/L
	Peroxidase	5 kU/L
	4-Aminoantipyrine (4-AAP)	4 mmol/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 12 months.
2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Serum or plasma (heparin or EDTA anticoagulation) is suitable for samples, which are stable for 3 days at 2 - 8 ℃ and for 30 days at - 20 ℃. Avoid repeated freezing and thawing.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When reagent becomes turbid or the blank absorbance > 0.200, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. The same sample tested with reagents from different manufacturers may lead to different measured values.
7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	End-Point Method	Sample/Reagent	1/50
Main Wavelength	546 nm	Reaction Temperature	37 ℃
Sub Wavelength	700 nm	Reaction Time	10 min
Reaction Direction	+		

2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	5
Calibrator (μL)	/	5	/
Purified Water (μL)	5	/	/
Reagent 1 (μL)	200	200	200
Mix well, incubate at 37 ℃ for 5 min, and measure absorbance A_1			
Reagent 2 (μL)	50	50	50
Mix well, measure absorbance A_2 after 5 min, calculate $\Delta A = A_2 - A_1$.			

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3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The concentration of uric acid (UA) in the sample can be calculated on the working curve based on its absorbance change value.

Reference Intervals

Male: 202~416 μmol/L

Female: 140~380 μmol/L

This reference interval is determined based on 95% distribution interval obtained from 210 healthy males and 210 healthy females specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of UA in the sample exceeds 1190 μmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is less than 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Vc	0.5 g/L
Hemoglobin	5 g/L
Chyle	0.30%
Bilirubin	342 μmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 0.200.

2. Analytical sensitivity: at the test concentration of 360 μmol/L, the reagent absorbance change (ΔA) ≥ 0.03.

3. Accuracy: relative deviation ≤ 10%.

4. Precision: within-run *CV* ≤ 4%, between-run relative range ≤ 6%.

5. Linear Range:

[100, 1190] μmol/L, the correlation coefficient (*r*) ≥ 0.990.

[100, 300] μmol/L, the absolute deviation ≤ 30 μmol/L;

(300, 1190] μmol/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Young D. Effects of drugs on clinical laboratory tests[J]. Ann Clin Biochem, 1997, 34:579-581.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

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CE IVD

Instructions for Use of Urea (UREA) Kit (Urease-GLDH Method)

Package Specification

REF	Reagent	Systems
01.09.01.06.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	Zybio EXC200/220
01.09.01.06.EC.02	R1 48 mL × 2 R2 12 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of urea concentration in human samples (serum or plasma). Clinically, it is mainly used as one of the evaluation indicators of renal function.

Summary

Urea is the major end product of protein nitrogen metabolism. It is synthesized by the urea cycle in the liver from ammonia which is produced by amino acid deamination. Urea is excreted mostly by the kidneys but minimal amounts are also excreted in sweat and degraded in the intestines by bacterial action. Determination of blood urea nitrogen is the most widely used screening test for renal function. When used in conjunction with serum creatinine determinations it can aid in the differential diagnosis of the three types of azotemia: prerenal, renal and postrenal. Elevations in blood urea nitrogen concentration are seen in inadequate renal perfusion, shock, diminished blood volume (prerenal causes), chronic nephritis, nephrosclerosis, tubular necrosis, glomerular nephritis (renal causes) and urinary tract obstruction (postrenal causes). Transient elevations may also be seen during periods of high protein intake. Unpredictable levels occur with liver diseases.

Principle

1. $Urea + H_2O \xrightarrow{Urease} 2NH_3 + CO_2$

2. $NH_3 + \alpha\text{-Ketoglutaric Acid} + NADH + H^+ \xrightarrow{GLDH} Glutamic\ Acid + NAD^+ + H_2O$

Oxidation of NADH to NAD^+ causes a decrease in absorbance at 340 nm, which is directly proportional to the Urea concentration in the sample.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	Trometamol (Tris) buffer	100 mmol/L
	Nicotinamide adenine dinucleotide (NADH)	0.3 mmol/L
R2	α-Ketoglutaric Acid	10 mmol/L
	Urease	6.0 kU/L
	Glutamate dehydrogenase (GLDH)	2.0 kU/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 12 months.
2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Serum or plasma (heparin or EDTA anticoagulation) is suitable for samples, which are stable for 3 days at 2 - 8 ℃ and for 30 days at - 20 ℃. Avoid repeated freezing and thawing.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When reagent becomes turbid or the blank absorbance < 1.000, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. The same sample tested with reagents from different manufacturers may lead to different measured values.
7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	Rate Method	**Sample/Reagent**	1/100
Main Wavelength	340 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	405 nm	**Reaction Time**	10 min
Reaction Direction	-		

2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	3
Calibrator (μL)	/	3	/
Purified Water (μL)	3	/	/
Reagent 1 (μL)	240	240	240
Mix well, incubate at 37 ℃ for 5 min			
Reagent 2 (μL)	60	60	60
Mix well, after 1 min, measure the absorbance change within 2 min, and calculate the absorbance change rate ΔA/ min.			

3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

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4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The concentration of urea (UREA) in the sample can be calculated on the working curve based on its absorbance change rate.

Reference Intervals

1.7~8.3 mmol/L (10~50 mg/dL)

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of UREA in the sample exceeds 40.0 mmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is less than 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Vc	0.5 g/L
Hemoglobin	5 g/L
Chyle	0.30%
Bilirubin	342 μmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≥ 1.000; the reagent blank absorbance change rate (ΔA/min) ≤ 0.04.
2. Analytical sensitivity: at the test concentration of 7.5 mmol/L, the reagent absorbance change rate (ΔA/min) ≥ 0.008.
3. Accuracy: relative deviation ≤ 10%.
4. Precision: within-run *CV* ≤ 5%, between-run relative range ≤ 6%.
5. Linear Range:

[0.5, 40.0] mmol/L, the correlation coefficient (*r*) ≥ 0.990.

[0.5, 5.0] mmol/L, the absolute deviation ≤ 0.5 mmol/L;

(5.0, 40.0] mmol/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Ai H, Chen K. Diagnostic Value of Blood Urea Nitrogen and Serum Creatinine in the Diagnosis of Early Diabetic Nephropathy[J]. Journal of Practical Medical Techniques, 2008, 15:431-433.

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