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.

Digitally signed by Dolgopol Iulian
Date: 2025.12.24 09:19:18 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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:	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

By Royal Charter

Certificate of Registration

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

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

This is to certify that:
兹证明

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

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

Holds Certificate No:
持有证书

MD 782925

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

Please see scope page.

For and on behalf of BSI:
BSI代表:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

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

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The information of this certificate can also be found on the official website of the National Certification and Accreditation Administration (www.cnca. gov.cn)
本证书信息亦可在国家认证认可监督管理委员会官方网站 (www.cnca.gov.cn) 上查询。
The certified organization shall be subject to surveillance audit periodically with acceptable results for maintaining the validity of this certificate.
获证组织必须定期接受监督审核并经审核合格此证书方继续有效。
Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
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信息查询及联系方式：BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. 电话： + 44 345 080 9000 BSI保证英国有限公司，注册地英国，注册号码7805321，地址：389 Chiswick High Road, London W4 4AL, UK.
China Headquarters (Beijing): 2008 East Ocean Centre, 24A Jianguomenwai, Beijing, 10004, China, Tel: +86 10 85073000, A Member of the BSI Group of Company. 中国总部（北京）：北京市建国门外大街甲24号东海中心2008室 邮编：100004 电话：+86 10 85073000 BSI集团公司成员。

Certificate No. **MD 782925**
持有证书：

Registered Scope:

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

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

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

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

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打印的证书可以通过网站 http://www.bsi-global.com/ClientDirectory或者致电 +86 10 8507 3000 查询。
The information of this certificate can also be found on the official website of the National Certification and Accreditation Administration (www.cnca. gov.cn)
本证书信息亦可在国家认证认可监督管理委员会官方网站 (www.cnca.gov.cn) 上查询。
The certified organization shall be subject to surveillance audit periodically with acceptable results for maintaining the validity of this certificate.
获证组织必须定期接受监督审核并经审核合格此证书方继续有效。
Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
信息查询及联系方式：BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. 电话： + 44 345 080 9000 BSI保证英国有限公司，注册地英国，注册号码7805321，地址：389 Chiswick High Road, London W4 4AL, UK.
China Headquarters (Beijing): 2008 East Ocean Centre, 24A Jianguomenwai, Beijing, 10004, China, Tel: +86 10 85073000, A Member of the BSI Group of Company. 中国总部（北京）：北京市建国门外大街甲24号东海中心2008室 邮编：100004 电话：+86 10 85073000 BSI集团公司成员。

Certificate No. **MD 782925**
持有证书：

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

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

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打印的证书可以通过网站 http://www.bsi-global.com/ClientDirectory或者致电 +86 10 8507 3000 查询。
The information of this certificate can also be found on the official website of the National Certification and Accreditation Administration (www.cnca. gov.cn)
本证书信息亦可在国家认证认可监督管理委员会官方网站 (www.cnca.gov.cn) 上查询。
The certified organization shall be subject to surveillance audit periodically with acceptable results for maintaining the validity of this certificate.
获证组织必须定期接受监督审核并经审核合格此证书方继续有效。
Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
信息查询及联系方式：BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. 电话： + 44 345 080 9000 BSI保证英国有限公司，注册地英国，注册号码7805321，地址：389 Chiswick High Road, London W4 4AL, UK.
China Headquarters (Beijing): 2008 East Ocean Centre, 24A Jianguomenwai, Beijing, 10004, China, Tel: +86 10 85073000, A Member of the BSI Group of Company. 中国总部（北京）：北京市建国门外大街甲24号东海中心2008室 邮编：100004 电话：+86 10 85073000 BSI集团公司成员。

Certificate No. **MD 782925**
持有证书：

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

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

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Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +86 10 8507 3000.
打印的证书可以通过网站 http://www.bsi-global.com/ClientDirectory或者致电 +86 10 8507 3000 查询。
The information of this certificate can also be found on the official website of the National Certification and Accreditation Administration (www.cnca. gov.cn)
本证书信息亦可在国家认证认可监督管理委员会官方网站 (www.cnca.gov.cn) 上查询。
The certified organization shall be subject to surveillance audit periodically with acceptable results for maintaining the validity of this certificate.
获证组织必须定期接受监督审核并经审核合格此证书方继续有效。
Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
信息查询及联系方式：BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. 电话： + 44 345 080 9000 BSI保证英国有限公司，注册地英国，注册号码7805321，地址：389 Chiswick High Road, London W4 4AL, UK.
China Headquarters (Beijing): 2008 East Ocean Centre, 24A Jianguomenwai, Beijing, 10004, China, Tel: +86 10 85073000, A Member of the BSI Group of Company. 中国总部（北京）：北京市建国门外大街甲24号东海中心2008室 邮编：100004 电话：+86 10 85073000 BSI集团公司成员。

Certificate No. **MD 782925**
持有证书：

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

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

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

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An electronic certificate can be authenticated online. 可以 在线 查询电子证书的有效性。
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The information of this certificate can also be found on the official website of the National Certification and Accreditation Administration (www.cnca. gov.cn)
本证书信息亦可在国家认证认可监督管理委员会官方网站 (www.cnca.gov.cn) 上查询。
The certified organization shall be subject to surveillance audit periodically with acceptable results for maintaining the validity of this certificate.
获证组织必须定期接受监督审核并经审核合格此证书方继续有效。
Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
信息查询及联系方式：BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. 电话： + 44 345 080 9000 BSI保证英国有限公司，注册地英国，注册号码7805321，地址：389 Chiswick High Road, London W4 4AL, UK.
China Headquarters (Beijing): 2008 East Ocean Centre, 24A Jianguomenwai, Beijing, 10004, China, Tel: +86 10 85073000, A Member of the BSI Group of Company. 中国总部（北京）：北京市建国门外大街甲24号东海中心2008室 邮编：100004 电话：+86 10 85073000 BSI集团公司成员。

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 001708 0001 Rev. 04

Holder of Certificate: **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

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of Clinical Chemistry Diagnostic Kit, Immunochromatography Diagnostic Kit, Nucleic Acid Isolation Reagent, Hematology Analysis Reagent, Chemiluminescence Reagent, Nucleic Acid Detection Kit, Microbial Sample Treatment Kit, Disposable Virus Sampling Tube, Blood Culture Reagent Kit, Pathological Reagent Kit, Urine Test Strip, Mass Spectrometry System, Blood Culture System, Urine Analyzer, Immune Quantitative Analyzer, Fully Automatic Chemistry Analyzer, Nucleic Acid Isolation System, Hematology Analyzer, Chemiluminescence Immunoassay Analyzer, Immunohistochemistry Autostainer**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 001708 0001 Rev. 04

Report No.: SH21101401 / SH21101401-CN

Valid from: 2022-02-25
Valid until: 2025-02-24

Date, 2022-02-24

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 001708 0001 Rev. 04

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

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

Design and Development, Production and Distribution of Blood Culture System, Urine Analyzer, Immune Quantitative Analyzer, Fully Automatic Chemistry Analyzer, Nucleic Acid Isolation Systems, Hematology Analyzer, Chemiluminescence Immunoassay Analyzer

Design and Development of Nucleic Acid Isolation Reagent, Nucleic Acid Detection Kit, Mass Spectrometry System, Immunohistochemistry Autostainer

Zybio Inc.
Floor 1 to Floor 4, Building 27/28, No. 10 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of Clinical Chemistry Diagnostic Kit, Immunochromatography Diagnostic Kit, Nucleic Acid Isolation Reagent, Hematology Analysis Reagent, Chemiluminescence Reagent, Nucleic Acid Detection Kit, Microbial Sample Treatment Kit, Disposable Virus Sampling Tube, Blood Culture Reagent Kit, Pathological Reagent Kit, Urine Test Strip

Zybio Inc.
Floor 2, Building 24-25, No. 3 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA

Production and Distribution of Nucleic Acid Isolation Reagent

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DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 001708 0001 Rev. 04

Facility(ies):

Zybio Inc.
Floor 3, Building 35, No. 1 of No. 17 of Shilin Avenue, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA

Production and Distribution of Disposable Virus Sampling Tube

Zybio Inc.
Floor 1 to Floor 5, Building 38, No. 5 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA

Production and Distribution of Pathological Reagent, Chemiluminescence Reagent, Microbial Sample Treatment Kit, Mass Spectrometry System, Immunohistochemistry Autostainer

.

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America

CERTIFICATE

No. QS5 001708 0003 Rev. 03

Certificate Holder: **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

Certification Mark:

Scope of Certificate: **See Page 2 for Overall Scope Statement.**

Standard(s): **ISO 9001:2015**

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.: **SH21101401**

Effective Date: **2022-01-24**

Expiry Date: **2025-01-23**

Date of Issue: 2022-02-03

(Michael Ogunleye)
Manager, US Certification Body,
Medical and Health Services

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SCC Accredited CB-MS
OCSM Accrédité CCN

America

CERTIFICATE

No. QS5 001708 0003 Rev. 03

Overall Scope Statement: **Design and Development, Production and Distribution of Clinical Chemistry Diagnostic Kit, Immunochromatography Diagnostic Kit, Nucleic Acid Isolation Reagent, Hematology Analysis Reagent, Chemiluminescence Reagent, Nucleic Acid Detection Kit, Microbial Sample Treatment Kit, Disposable Virus Sampling Tube, Blood Culture Reagent Kit, Pathological Reagent Kit, Urine Test Strip, Mass Spectrometry System,Blood Culture System, Urine Analyzer, Immune Quantitative Analyzer, Fully Automatic Chemistry Analyzer, Nucleic Acid Isolation System, Hematology Analyzer, Chemiluminescence Immunoassay Analyzer, Immunohistochemistry Autostainer**

Facility(ies): **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

Facility Scopes: Design and Development, Production and Distribution of Blood Culture System, Urine Analyzer, Immune Quantitative Analyzer, Fully Automatic Chemistry Analyzers, Nucleic Acid Isolation Systems, Hematology Analyzers, Chemiluminescence Immunoassay Analyzers; Design and Development Nucleic Acid Isolation Reagent, Nucleic Acid Detection Kit, Mass Spectrometry System, Immunohistochemistry Autostainer

Date of Issue: 2022-02-03

(Michael Ogunleye)
Manager, US Certification Body,
Medical and Health Services

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

SCC Accredited CB-MS OCSM Accrédité CCN

America

CERTIFICATE

No. QS5 001708 0003 Rev. 03

Facility(ies): **Zybio Inc.**
Floor 1 to Floor 4, Building 27/28, No. 10 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA

Facility Scopes: Design and Development, Production and Distribution of Clinical Chemistry, Immunochromatography Diagnostic Kit, Nucleic Acid Isolation Reagent, Hematology Analysis Reagent, Chemiluminescence Reagent, Nucleic Acid Detection Kit, Microbial Sample Treatment Kit, Disposable Virus Sampling Tube, Pathological Reagent Kit, Urine Test Strip

Facility(ies): **Zybio Inc.**
Floor 2, Building 24-25, No. 3 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA

Facility Scopes: Production and Distribution of Nucleic Acid Isolation Reagent

Facility(ies): **Zybio Inc.**
Floor 3, Building 35, No. 1 of No. 17 of Shilin Avenue, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA

Facility Scopes: Production and Distribution of Disposable Virus Sampling Tube

Facility(ies): **Zybio Inc.**
Floor 1 to Floor 5, Building 38, No. 5 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA

Facility Scopes: Production and Distribution of Pathological Reagent, Chemiluminescence Reagent, Microbial Sample Treatment Kit, Mass Spectrometry System, Immunohistochemistry Autostainer

Date of Issue: 2022-02-03

Michael Ogunleye

(Michael Ogunleye)
Manager, US Certification Body,
Medical and Health Services

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

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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.

zybio

Chemistry Analyzer EXC 200

A cost-effective choice dedicated for small healthcare sites

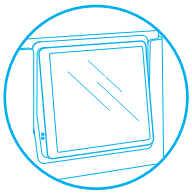
Chemistry

www.zybio.com

Chemistry Analyzer EXC 200

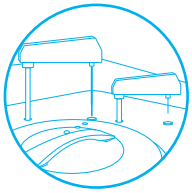
EXC 200 combines versatile advanced functions that facilitate high quality testing, which is a discrete and random-access clinical chemistry analyzer offering a throughput of 240 T/H for single reagent and 160 T/H for dual reagents. Working with 97 original chemistry reagents, EXC 200 isan ideal clinical solution for small healthcare sites.

Function



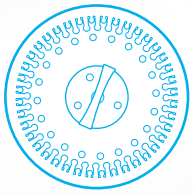
User Friendly

- 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

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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

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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.

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

Current Version: 02 Date of Issue: May, 2022

CE IVD

zybio

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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Current Version: 02 Date of Issue: May, 2022

CE IVD

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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
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Current Version: 02 Date of Issue: May, 2022

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CE IVD

zybio

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

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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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Current Version: 02 Date of Issue: May, 2022

CE IVD

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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
	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 Creatine Kinase (CK) Kit (Rate Method)

Package Specification

REF	Reagent	Systems
01.09.04.03.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	Zybio EXC200/220
01.09.04.03.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 creatine kinase (CK) in human samples (serum or plasma). Clinically, serum creatine kinase levels increased in certain tissue damage or diseases, such as myocardial infarction, muscular dystrophy, acute cerebrovascular accident, etc.

Summary

Creatine kinase (CK), also known as creatine phosphokinase. The contents of creatine kinase in skeletal muscle, myocardium, and smooth muscle were more, followed by brain tissue, and the contents in gastrointestinal tract, lung and kidney were less. CK is an important kinase that is directly related to intracellular energy transport, muscle contraction, and ATP regeneration. When the striated muscle of the human body is damaged and necrotic, creatine kinase is released into the blood and abnormally elevated during detection. However, the increase of creatine kinase lacks specificity.

If it is combined with the increase of creatine kinase isoenzyme and troponin, it shall be judged that the myocardium is damaged. If abnormal elevation of myoglobin is also combined, it shall be judged that skeletal muscle injury occurs.

Principle

This kit uses rate method (improved based on the method recommended by IFCC) to determine the catalytic activity concentration of CK in samples. Creatine kinase (CK) catalyzes the conversion of phosphocreatine to creatine, while ADP is phosphorylated to ATP. Hexokinase (HK) catalyzes the reaction between ATP and glucose to generate glucose-6-phosphate. Glucose-6-phosphate dehydrogenase (G6PDH) catalyzes glucose-6-phosphate to generate 6-phosphogluconic acid, and simultaneously converts oxidative nicotinamide adenine dinucleotide phosphate ($NADP^+$) into reduced nicotinamide adenine dinucleotide phosphate (NADPH), causing the increase of the absorbance. The rate of increase is directly proportional to the catalytic activity concentration of CK in the sample. By continuously monitor the absorbance change rate, the catalytic activity concentration of CK in the sample can be calculated from the calibration curve generated by the calibrator treated in the same manner.

1. Phosphocreatine + ADP $\xrightarrow{CK}$ Creatine + ATP
2. ATP + Glucose $\xrightarrow{HK}$ Glucose-6-phosphate + ADP
3. Glucose-6-phosphate + $NADP^+$ $\xrightarrow{G6PDH}$ 6-phosphogluconic acid + NADPH + H^+

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	D-Glucose	20-30 mmol/L
	Nicotinamide adenine dinucleotide phosphate oxidized form ($NADP^+$)	1.5-2.0 g/L
	Hexokinase	4-8 kU/L
	Imidazole buffer	100 mmol/L
R2	Glucose-6-phosphate dehydrogenase (G6PDH)	12-16 kU/L
	Phosphocreatine	80-120 mmol/L
	Adenosine-5'-diphosphate (ADP) potassium salt	7-9 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 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 or plasma (heparin for anticoagulation) is suitable for samples, which shall be separated in time after collection to avoid hemolysis. Samples containing EDTA, citrate, and chloride should not be used. Samples are stable for 1 day 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 the blank absorbance > 0.400, 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**	1/25
Main Wavelength	340 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	546 nm	**Reaction Time**	10 min
Reaction Direction	+		

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2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	10
Calibrator (μL)	/	10	/
Purified Water (μL)	10	/	/
Reagent 1 (μL)	200	200	200
Mix well, incubate at 37 ℃ for 5 min			
Reagent 2 (μL)	50	50	50
Mix well, after adding R2 for 45 s, continuously monitor the absorbance change within 4 min and 15 s, 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 creatine kinase (CK) in the sample can be calculated on the working curve based on its absorbance change rate.

Reference Intervals

Male: 38~174 U/L Female: 26~140 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 CK 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 ≤ 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Vc	1.0 g/L
Hemoglobin	5 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 ≤ 0.400; the reagent blank absorbance change rate (Δ*A*/min) ≤ 0.002.
2. Analytical sensitivity: at the test catalytic activity concentration of 100 U/L, the reagent absorbance change rate (Δ*A*/min) > 0.002.
3. Accuracy: 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] Kitzenberg D, Colgan S, Glover L. Creatine kinase in ischemic and inflammatory disorders[J]. Clin Transl Med, 2016, 5:31.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
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	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 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
	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

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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Current Version: 02 Date of Issue: May, 2022

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
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Current Version: 02 Date of Issue: May, 2022

CE IVD

zybio

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
	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

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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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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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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.

Symbol Interpretation

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