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.
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Current Version: 02 Date of Issue: May, 2022

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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	LOT CODE
	CONSULT INSTRUCTIONS FOR USE
	PRODUCTION DATE
	USE-BY DATE
	TEMPERATURE LIMIT
	MANUFACTURER

【Manufacturer Information】

Supplier/manufacturer: Zybio Inc.

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Instructions for Use of α-Amylase (α-AMY) Kit

(E-pNP-G7 Method)

Package Specification

REF	Reagent	Systems
01.09.0B.00.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	Zybio EXC200/220
01.09.0B.00.EC.02	R1 48 mL × 2 R2 12 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of the catalytic activity concentration of α-amylase (α-AMY) in human samples (serum, plasma or urine).

Summary

α-Amylase activity is one of the important diagnostic markers of acute pancreatitis. Serum amylase can be increased in diseases such as chronic pancreatitis, pancreatic cancer, acute appendicitis, ulcerative perforation, intestinal obstruction, mumps, and salivary gland suppuration. When renal function decreased, serum amylase increased and urine amylase decreased. Patients with various liver diseases will show a simultaneous decrease in serum and urine amylase.

Principle

This kit uses E-pNP-G7 method (IFCC recommended method) to determine the activity of α-amylase (α-AMY) in samples. α-AMY in the sample hydrolyzes 4, 6-ethylene-4-nitrophenyl-4-a-D-maltoheptaose (E-pNP-G7) to generate 4, 6-ethylene-maltopentaose (E-G5), 4, 6-ethylene-maltotetraose (E-G4), 4, 6-ethylene-maltotriose (E-G3), and 4-nitrophenyl-maltose (G2-NP), 4-nitrophenyl-maltotriose (G3-NP), 4-nitrophenyl-maltotetraose (G4-NP) and other fragments, and the three 4-nitrophenyl-maltopolysaccharides generated are hydrolyzed to glucose and 4-nitrophenol under the action of α-glucosidase, causing an increase in absorbance at a rate directly proportional to the activity of α-AMY in the sample. The activity of α-AMY in the sample can be calculated from the working curve by continuously monitoring and comparing with the calibrator treated in the same manner.

$$\text{E-pNP-G7} + H_2O \xrightarrow{\alpha\text{-AMY}} \text{E-G5} + \text{E-G4} + \text{E-G3} + \text{G2-NP} + \text{G3-NP} + \text{G4-NP}$$

$$\text{G2-NP} + \text{G3-NP} + \text{G4-NP} + H_2O \xrightarrow{\alpha\text{-Glucosidase}} \text{Glucose (G)} + \text{4-NP}$$

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	HEPES	50 mmol/L
	Glucosidase	5.5 - 6.5 KU/L
R2	HEPES	50 mmol/L
	Ethylene-pNP-G7	7.5 - 9.5 mmol/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 °C and kept away from freezing. The unopened reagents are valid for 18 months.
2. Once opened, the reagents are stable for 30 days at 2 - 8 °C. For reagents not in use, the cap should be tightened to avoid contamination.
3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Sample types are serum, plasma (heparin), or urine (random or timed). Serum and plasma are stable for 4 days at room temperature, 2 weeks at 2 - 8 °C, and 1 year at - 20 °C to avoid repeated freezing and thawing. Urine is stable for 7 days at 2 - 8 °C with pH adjusted to 7.0 prior to storage.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When the blank absorbance > 0.35, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. The same sample tested with reagents from different manufacturers may lead to different measured values.
7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	Rate Method	**Sample/Reagent**	1/50
Main Wavelength	405 nm	**Reaction Temperature**	37 °C
Sub Wavelength	505 nm	**Reaction Time**	10 min
Reaction Direction	+		

2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	5
Calibrator (μL)	/	5	/
Purified Water (μL)	5	/	/
Reagent 1 (μL)	200	200	200
Mix well, incubate at 37 °C for 5 min			
Reagent 2 (μL)	50	50	50
Mix well, incubate at 37 °C for 1 min, measure the average absorbance change rate ΔA/min within 2 min.			

3. Calibration

Use Randox multi-analyte calibrator or Zybio Clinical Chemistry Multi-analyte Calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it

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is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The catalytic activity concentration of α-Amylase (α-AMY) in the sample can be calculated on the working curve based on its absorbance change rate.

Reference Intervals

Serum: < 140 U/L

Urine: < 640 U/L

This reference interval is determined according to the 95% distribution area of 200 healthy human specimens without related diseases in each group, and is only for reference. It is recommended that each laboratory establish its own reference interval.

Explanation of Results

1. If the catalytic activity concentration of α-AMY in the sample exceeds 1000 U/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.
2. The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by re-measuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.
3. The results obtained from tests using reagents from different manufacturers or methodologies should not be directly compared to each other to avoid incorrect medical interpretation; it is recommended that the laboratory indicate the characteristics of the reagents used in the test report sent to the clinician.

Limitations

1. The deviation of test results caused by interferents is less than 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Vc	0.3 g/L
Hemoglobin	1.25 g/L
Bilirubin	342 μmol/L
Triglyceride	10 mmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 0.35; the reagent blank absorbance change rate (ΔA/min) ≤ 0.002.
2. Analytical sensitivity: at the test catalytic activity concentration of 140 U/L, the reagent absorbance change rate (ΔA/min) ≥ 0.01.
3. Accuracy: relative deviation ≤ 10%.
4. Precision: within-run *CV* ≤ 5%, between-run relative range ≤ 10%.
5. Linear Range:

[5, 1000] U/L, the correlation coefficient (r) ≥ 0.990.

[5, 50] U/L, the absolute deviation ≤ 5 U/L;

(50, 1000] U/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

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Current Version: 02 Date of Issue: May, 2022

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Instructions for Use of Albumin (ALB) Kit (Bromocresol Green Method)

Package Specification

REF	Reagent	Systems
01.09.00.04.EC.01	R 30 mL × 6	Zybio EXC200/220
01.09.00.04.EC.03	R 60 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of albumin (ALB) concentration in human samples (serum). Clinically, it is mainly used as an aid to evaluation of liver function as well as nutritional assessment.

Summary

Albumin is a carbohydrate-free protein, which constitutes 55 - 65% of total plasma protein. It maintains plasma oncotic pressure, and is also involved in the transport and storage of a wide variety of ligands and is a source of endogenous amino acids. Albumin binds and solubilizes various compounds, e g. bilirubin, calcium and long-chain fatty acids. Furthermore, albumin is capable of binding toxic heavy metal ions as well as numerous pharmaceuticals, which is the reason why lower albumin concentrations in blood have a significant effect on pharmacokinetics.

Hyperalbuminemia is of little diagnostic significance except in the case of dehydration. Hypoalbuminemia occurs during many illnesses and is caused by several factors: compromised synthesis due either to liver disease or as a consequence of reduced protein uptake; elevated catabolism due to tissue damage (severe burns) or inflammation; malabsorption of amino acids (Crohn's disease); proteinuria as a consequence of nephrotic syndrome; protein loss via the stool (neoplastic disease). In severe cases of hypoalbuminemia, the maximum albumin concentration of plasma is 2.5 g/dL (380 µmol/L). Due to the low osmotic pressure of the plasma, water permeates through blood capillaries into tissue (edema). The determination of albumin allows monitoring of a controlled patient dietary supplementation and serves also as an excellent test of liver function.

Principle

Albumin in serum binds to bromocresol green to form a blue-green complex at pH 4.2, which has an absorption peak at the wavelength of 630 nm, and the change in color intensity is directly proportional to the albumin concentration. The albumin concentration in the serum can be obtained by comparing with that in calibrator treated in the same manner.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R	Bromocresol Green	0.15 mmol/L
	Succinic Acid buffer	74.9 mmol/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 12 months.
2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Non-hemolytic serum is suitable for samples, which are stable at 2 - 8 ℃ for 14 days.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When reagent becomes turbid or the blank absorbance > 0.500, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. The same sample tested with reagents from different manufacturers may lead to different measured values.
7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	End-Point Method	**Sample/Reagent**	1/100
Main Wavelength	630 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	700 nm	**Reaction Time**	2 min
Reaction Direction	+		

2. Operation

Addition	Blank	Calibration	Detection
Sample (µL)	/	/	3
Calibrator (µL)	/	3	/
Purified Water (µL)	3	/	/
Reagent (µL)	300	300	300
Mix well, measure absorbance *A* after 2 min.			

3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality

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control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The concentration of albumin (ALB) in the sample can be calculated on the working curve based on its absorbance change value.

Reference Intervals

35.0~55.0 g/L

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of ALB in the sample exceeds 60.00 g/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is less than 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Vc	0.5 g/L
Chyle	0.30%
Bilirubin	342 μmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 0.500.
2. Analytical sensitivity: at the test concentration of 40.0 g/L, the reagent absorbance change (ΔA) ≥ 0.50.
3. Accuracy: relative deviation ≤ 6.0%.
4. Precision: within-run *CV* ≤ 2.0%, between-run relative range ≤ 5.0%.
5. Linear Range:

[10.0, 60.0] g/L, the correlation coefficient (r) ≥ 0.990.

[10.0, 20.0] g/L, the absolute deviation ≤ 4.0 g/L;

(20.0, 60.0] g/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Guo J, Xie J, Zhao H. Design of method comparison study and bias estimation for albumin assays[J]. Chin J Lab Med, 2000, 23:343-345.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

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Current Version: 02 Date of Issue: May, 2022

CE IVD

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 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.

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
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EC REP

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Current Version: 02 Date of Issue: May, 2022

CE IVD

zybio

Instructions for Use of Alanine Aminotransferase (ALT) Kit (Enzymatic Method)

Package Specification

REF	Reagent	Systems
01.09.00.05.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	Zybio EXC200/220
01.09.00.05.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 alanine aminotransferase activity in human samples (serum or plasma). Clinically, it is mainly used as an aid to diagnosis of hepatobiliary diseases.

Summary

The enzyme alanine aminotransferase (ALT) has been widely reported as present in a variety of tissues. The major source of ALT is the liver, which has led to the measurement of ALT activity for the diagnosis of hepatic diseases. Elevated serum ALT is found in hepatitis, cirrhosis, obstructive jaundice, carcinoma of the liver, and chronic alcohol abuse. ALT is only slightly elevated in patients who have an uncomplicated myocardial infarction. Although both serum aspartate aminotransferase (AST) and ALT become elevated whenever disease processes affect liver cell integrity, ALT is the more liver-specific enzyme. Moreover, elevations of ALT activity persist longer than elevations of AST activity. In patients with vitamin B6 deficiency, serum aminotransferase activity maybe decreased. The apparent reduction in aminotransferase activity may be related to decreased pyridoxal phosphate, the prosthetic group for aminotransferases, resulting in an increase in the ratio of apoenzyme to holoenzyme.

Principle

This kit uses the method recommended by the International Federation of Clinical Chemistry (IFCC):

1. Alanine + α -Ketoglutaric Acid $\xrightarrow{ALT}$ Pyruvic Acid + L-Glutamic Acid

2. Pyruvic Acid + NADH + H^+ $\xrightarrow{LDH}$ 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 ALT 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	512 mmol/L
	α -Ketoglutaric Acid	79.6 mmol/L
	L-Alanine	898 mmol/L
	Lactate Dehydrogenase (LDH)	≥8.5 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)	60	60	60
Mix well, after 2 min, accurately measure the 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 alanine aminotransferase (ALT) in the sample can be calculated on the working curve based on its absorbance change rate.

Reference Intervals

Male: 9~50 U/L

Female: 7~40 U/L

This reference interval is determined based on 95% distribution interval obtained from 200 healthy males and 200 healthy females specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of ALT 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
Hemoglobin	5 g/L
Chyle	0.30%
Bilirubin	300 μmol/L
Triglyceride	11.3 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 ≥ 1.000; the reagent blank absorbance change rate (Δ*A*/min) ≤ 0.004.

2. Analytical sensitivity: at the test concentration of 130 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:

[5, 1000] U/L, the correlation coefficient (*r*) ≥ 0.990.

[5, 40] U/L, the absolute deviation ≤ 4 U/L;

(40, 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] Prati D, Taioli E, Zanella A, et al. Updated definitions of healthy ranges for serum alanine aminotransferase levels[J]. Ann Intern Med, 2002, 137:1-10.

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: 03 Date of Issue: April, 2023

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 Δ*A*/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
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CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

Zybio Inc.

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Current Version: 02 Date of Issue: May, 2022

CE IVD

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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
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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

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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
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 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

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Current Version: 02 Date of Issue: May, 2022

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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
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Current Version: 02 Date of Issue: May, 2022

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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
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Current Version: 02 Date of Issue: May, 2022

CE IVD

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Instructions for Use of Magnesium (Mg) Kit (Xylidyl Blue Method)

Package Specification

REF	Reagent	Systems
01.09.0C.02.EC.01	R 30 mL × 6	Zybio EXC200/220
01.09.0C.02.EC.02	R 60 mL × 2	Hitachi 7180 Zybio EXC400/420
01.09.0C.02.EC.03	R 30 mL × 6 Calibrator 1 Level × 1.0 mL × 1	Zybio EXC200/220
01.09.0C.02.EC.04	R 60 mL × 2 Calibrator 1 Level × 1.0 mL × 1	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of magnesium concentration in human samples (serum or plasma). Clinically, it is mainly used as an aid to diagnosis of magnesium metabolism disorders.

Summary

Magnesium along with potassium is a major intracellular cation. Mg^{2+} is a cofactor of many enzyme systems. Thus, all ATP-dependent enzymatic reactions require Mg^{2+} as a cofactor in the ATP-magnesium complex. Approximately 69% of magnesium are stored in bone. The rest are part of the intermediary metabolism, about 70% being present in free form while the other 30% is bound to proteins (especially albumin), citrates, phosphate, and other complex formers. The Mg^{2+} serum level is kept constant within very narrow limits (0.65-1.05 mmol/L).

Regulation takes place mainly via the kidneys, especially via the ascending loop of Henle.

This assay is used as an aid to diagnosis of hypomagnesemia (magnesium deficiency) and hypermagnesemia (magnesium excess). Numerous studies have shown a correlation between magnesium deficiency and changes in calcium-, potassium- and phosphate-homeostasis which are associated with cardiac disorders such as ventricular arrhythmias that cannot be treated by conventional therapy, increased sensitivity to digoxin, coronary artery spasms, and sudden death. Additional concurrent symptoms include neuromuscular and neuropsychiatric disorders.

Hypermagnesemia is found in acute and chronic renal failure, magnesium excess, and magnesium release from the intracellular space.

The method described here is based on the reaction of magnesium with xylidyl blue in alkaline solution containing EGTA to mask the calcium in the sample.

Urine magnesium levels are determined in magnesium depletion tests.

Principle

This kit uses xylidyl blue method to determine the content of magnesium. In the alkaline solution, magnesium in the serum combine with xylidyl blue dye to generate a purple complex. The absorbance of this complex at 505 nm is directly proportional to the concentration of magnesium in the sample.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R	Sodium Hydroxide	77 mmol/L
	Xylidyl Blue	0.14 mmol/L
	Polyvinylpyrrolidone	0.03 mmol/L
Calibrator (Optional)	Magnesium Chloride	Refer to the label for marked value

The components in different batches are non-interchangeable.

The measurement system can be traceable to enterprise standard.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 12 months.
2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Serum or plasma is suitable for samples, which are stable for 1 week at 2 - 8 ℃ and for 1 month at - 20 ℃. Avoid repeated freezing and thawing.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When reagent becomes turbid or the blank absorbance > 0.800, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. It is recommended that medical institutions purchase the kit containing calibrator when using the kit for the first time.
7. The same sample tested with reagents from different manufacturers may lead to different measured values.
8. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	End-Point Method	**Sample/Reagent**	1/100
Main Wavelength	505 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	700 nm	**Reaction Time**	8 min
Reaction Direction	+		

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2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	3
Calibrator (μL)	/	3	/
Purified Water/Saline (μL)	3	/	/
Reagent (μL)	300	300	300
Mix well, incubate at 37 ℃ for 8 min, and measure absorbance *A*.			

3. Calibration

Use Zybio matched calibrator, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The concentration of magnesium (Mg) in the sample can be calculated on the working curve based on its absorbance change value.

Reference Intervals

0.8~1.0 mmol/L

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of Mg^{2+} in the sample exceeds 2.0 mmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is < 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Bilirubin	280 μmol/L
Ca^{2+}	3 mmol/L
K^{+}	8 mmol/L
Na^{+}	180 mmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 0.800.
2. Analytical sensitivity: at the test concentration of 1.00 mmol/L, the reagent absorbance change (Δ*A*) ≥ 0.05.
3. Accuracy: relative deviation ≤ 10%.
4. Precision: within-run *CV* ≤ 4%, between-run relative range ≤ 6%.
5. Linear Range:

[0.20, 2.0] mmol/L, the correlation coefficient (*r*) ≥ 0.990.

[0.20, 0.80) mmol/L, the absolute deviation ≤ 0.08 mmol/L;

[0.80, 2.0] mmol/L, the relative deviation ≤ 10%.

6. Calibrator accuracy: relative deviation ≤ 10%.
7. Calibrator homogeneity: within-vial *CV* ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Ehrhardt V, Paschen K, Vogt W, et al. Magnesium-Bestimmung im Serum und Urin mit einer verbesserten Xylidyl-Blau-Methode[C]. Workshop Kaiserslautern, 1989.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	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 Bilirubin (TBIL) Kit (Vanadate Oxidation Method)

Package Specification

REF	Reagent	Systems
01.09.00.21.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	Zybio EXC200/220
01.09.00.21.EC.03	R1 48 mL × 2 R2 12 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of total bilirubin concentration in human samples (serum or plasma). Clinically, it is mainly used as one of the evaluation indicators for bilirubin metabolism diseases.

Summary

Measurement of the levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, is used in the diagnosis and treatment of liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gall bladder blockage.

Bilirubin is formed in the reticuloendothelial system during the degradation of aged erythrocytes. The heme portion from hemoglobin and from other heme-containing proteins is removed, metabolized to bilirubin, and transported as a complex with serum albumin to the liver. In the liver, bilirubin is conjugated with glucuronic acid for solubilization and subsequent transport through the bile duct and elimination via the digestive tract.

Diseases or conditions which, through hemolytic processes, produce bilirubin faster than the liver can metabolize it, cause the levels of unconjugated (indirect) bilirubin to increase in the circulation. Liver immaturity and several other diseases in which the bilirubin conjugation mechanism is impaired cause similar elevations of circulating unconjugated bilirubin. Bile duct obstruction or damage to hepatocellular structure causes increases in the levels of both conjugated (direct) and unconjugated (indirect) bilirubin in the circulation.

Principle

The total bilirubin in the sample is oxidized to biliverdin, which causes a decrease in absorbance at 450 nm.

1. Bilirubin $\xrightarrow{\text{Vanadate}}$ Biliverdin

The concentration of total bilirubin in the sample shall be calculated by measuring the absorbance change at 450 nm and comparing with that in calibrator treated in the same manner.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	Citric Acid buffer	100 mmol/L
	Surfactant 1	0.2% (v/v)
R2	Citrate Buffer	18.36 mmol/L
	Sodium Metavanadate	6.56 mmol/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 12 months.
2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Serum or plasma (heparin anticoagulation) is suitable for samples, which are stable for 3 days at 2 - 8 ℃. Samples should be protected from direct light.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When reagent becomes turbid or the blank absorbance > 0.050, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. The same sample tested with reagents from different manufacturers may lead to different measured values.
7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	End-Point Method	**Sample/Reagent**	1/35
Main Wavelength	450 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	546 nm	**Reaction Time**	10 min
Reaction Direction	-		

2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	10
Calibrator (μL)	/	10	/
Purified Water (μL)	10	/	/
Reagent 1 (μL)	280	280	280
Mix well, incubate at 37 ℃ for 5 min, and measure absorbance A_1			
Reagent 2 (μL)	70	70	70
Mix well, measure absorbance A_2 after 5 min, calculate $\Delta A = A_2 - A_1$.			

3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

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4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The concentration of total bilirubin (TBIL) in the sample can be calculated on the working curve based on its absorbance change value.

Reference Intervals

3.4~20.5 μmol/L (0.2~1.2mg/dL)

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of TBIL in the sample exceeds 500 μmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is less than 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Vc	0.5 g/L
Hemoglobin	5 g/L
Chyle	0.30%

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 0.050.
2. Analytical sensitivity: at the test concentration of 30 μmol/L, the reagent absorbance change (ΔA) > 0.003.
3. Accuracy: relative deviation ≤ 10%.
4. Precision: within-run *CV* ≤ 4%, between-run relative range ≤ 10%.
5. Linear Range:

[3, 500] μmol/L, the correlation coefficient (r) ≥ 0.990.

[3, 20] μmol/L, the absolute deviation ≤ 2 μmol/L;

(20, 500] μmol/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Doumas B, Cheung P, Perry B. Candidate reference method for determination of total bilirubin in serum: development and validation[J]. Clin Chem, 1985, 31:1779-1789.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

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Current Version: 02 Date of Issue: May, 2022

CE IVD

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Instructions for Use of Triglyceride (TG) Kit (Enzymatic Method)

Package Specification

REF	Reagent	Systems
01.09.02.02.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	Zybio EXC200/220
01.09.02.02.EC.02	R1 48 mL × 2 R2 12 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of triglyceride concentration in human samples (serum). Clinically, it is mainly used for auxiliary diagnosis of hypertriglyceridemia.

Summary

Triglycerides are esters of the trihydric alcohol glycerol with 3 long-chain fatty acids. They are partly synthesized in the liver and partly ingested in food.

The determination of triglycerides is utilized in the diagnosis and treatment of patients having diabetes mellitus, nephrosis, liver obstruction, lipid metabolism disorders and numerous other endocrine diseases.

Using a lipoprotein lipase from microorganisms for the rapid and complete hydrolysis of triglycerides to glycerol followed by oxidation to dihydroxyacetone phosphate and hydrogen peroxide. The hydrogen peroxide produced then reacts with 4-aminophenazone and TOPS under the catalytic action of peroxidase to form a red dyestuff (Trinder endpoint reaction). The color intensity of the red dyestuff formed is directly proportional to the triglyceride concentration and can be measured photometrically.

Principle

1. Triglyceride + H_2O $\xrightarrow{\text{Lipase}}$ Glycerol + Fatty Acid
2. Glycerol + ATP $\xrightarrow{\text{Glycerol kinase}}$ Glycerin-3- Phosphoric Acid + ADP
3. Glycerol-3-Phosphoric Acid + O_2 $\xrightarrow{\text{GPO}}$ Dihydroxyacetone Phosphate + H_2O_2
4. $2H_2O_2$ + 4-AAP + TOPS $\xrightarrow{\text{Peroxidase}}$ Quinonimine + $4H_2O$

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	3-Morpholinepropanesulfonic acid buffer	200 mmol/L
	Lipoprotein Lipase (LPL)	2-3 kU/L
	3-(N-Ethyl-3-methylanilino) propanesulfonic acid sodium salt (TOPS)	7-11 mmol/L
R2	3-Morpholinepropanesulfonic acid buffer	200 mmol/L
	Peroxidase	4-6 kU/L
	Glycerophosphate Oxidase (GPO)	6.5-8.5 kU/L
	Glycerokinase	4-6 kU/L
	Adenosine 5'-triphosphate (ATP) disodium salt	1.8-2.8 mmol/L
	4-Aminoantipyrine (4-AAP)	1-2 mmol/L

The components in different batches are non-interchangeable.

The measurement system can be traceable to ERM-DA470k/IFCC.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 12 months.
2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Serum is suitable for samples, which shall be separated in time after collection to avoid hemolysis. Samples are stable for 3 days at 2 - 8 ℃ and 30 days at - 20 ℃. Avoid repeated freezing and thawing.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When reagent becomes turbid or the blank absorbance > 0.200, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. The same sample tested with reagents from different manufacturers may lead to different measured values.
7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	End-Point Method	**Sample/Reagent**	1/100
Main Wavelength	546 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	700 nm	**Reaction Time**	10 min
Reaction Direction	+		

2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	3
Calibrator (μL)	/	3	/
Purified Water (μL)	3	/	/
Reagent 1 (μL)	240	240	240
Mix well, incubate at 37 ℃ for 5 min, and measure absorbance A_1			
Reagent 2 (μL)	60	60	60
Mix well, measure absorbance A_2 after 5 min, calculate $\Delta A = A_2 - A_1$.			

3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

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4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The concentration of triglyceride (TG) in the sample can be calculated on the working curve based on its absorbance change value.

Reference Intervals

≤ 2.30 mmol/L

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of TG in the sample exceeds 10.00 mmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is less than 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Vc	0.5 g/L
Hemoglobin	5 g/L
Bilirubin	342 μmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 0.200.
2. Analytical sensitivity: at the test concentration of 1.0 mmol/L, the reagent absorbance change (ΔA) > 0.03.
3. Accuracy: relative deviation ≤ 10%.
4. Precision: within-run *CV* ≤ 5%, between-run relative range ≤ 8%.
5. Linear Range:

[0.50, 10.00] mmol/L, the correlation coefficient (*r*) ≥ 0.990.

[0.50, 2.00] mmol/L, the absolute deviation ≤ 0.20 mmol/L;

(2.00, 10.00] mmol/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Toth P. Triglyceride-rich lipoproteins as a causal factor for cardiovascular disease[J]. Vasc Health Risk Manag, 2016, 12: 171-183.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

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Current Version: 02 Date of Issue: May, 2022

CE IVD

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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

Zybio Inc.

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Current Version: 02 Date of Issue: May, 2022

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

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