CE IVD

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Instructions for Use of Clinical Chemistry Multi-Analyte Calibrator

Package Specification

REF	Specification
01.09.0D.00.CA.02	1 Level × 5 mL × 10
012212047	1 Level × 5 mL × 6
01.09.0D.00.CA.04	1 Level × 5 mL × 1

Intended Use

This product is matched for the calibration of 31 biochemical items of Zybio Inc. (albumin, alkaline phosphatase, alanine aminotransferase, aspartate aminotransferase, calcium, cholinesterase, total cholesterol, creatine kinase, carbon dioxide, creatinine, direct bilirubin, ferrum, γ-glutamyl transferase, glutamate dehydrogenase, glucose, lactate, leucine amino peptidase, lactate dehydrogenase, lipase, magnesium, inorganic phosphorus, total bile acid, total bilirubin, triglyceride, total protein, uric acid, urea, zinc, α-amylase, α-hydroxybutyrate dehydrogenase and β-hydroxybutyrate).

Principle

A detection system is calibrated through the measurement on the calibrators with known concentration, so as to establish the metrological traceability of the measurement results for our system.

Reagents Components and Concentration

Human serum matrix.

It contains 31 biochemical items: Albumin (ALB), alkaline phosphatase (ALP), alanine aminotransferase (ALT), aspartate aminotransferase (AST), calcium (Ca), cholinesterase (ChE), total cholesterol (CHOL), creatine kinase (CK), carbon dioxide (CO_2), creatinine (CREA), direct bilirubin (DBIL), ferrum/iron (Fe), γ-glutamyl transferase (GGT), glutamate dehydrogenase (GLDH), glucose (GLU), lactate (LAC), leucine amino peptidase (LAP), lactate dehydrogenase (LDH), lipase (LPS), magnesium (Mg), inorganic phosphorus (P), total bile acid (TBA), total bilirubin (TBIL), triglyceride (TG), total protein (TP), uric acid (UA), urea (UREA), zinc (Zn), α-amylase (α-AMY), α-hydroxybutyrate dehydrogenase (α-HBDH) and β-hydroxybutyrate (β-HB).

Note: The traceability information is shown in the attached form, and the labeled value is shown in the target value list.

Storage and Validity

1. The product should be stored at 2 - 8 °C and kept away from direct light. The unopened product is valid for 24 months.
2. The re-dissolved components are stable for 2 days at 2 - 8 °C and 28 days at (-15) - (- 25) °C. (Freeze/thaw only once).
3. Alkaline phosphatase levels will increase during the stabilization time. It is recommended to stabilize at 15 - 25 °C for 1 hour after re-dissolution before detection. It is necessary to timely screw the bottle cap for preservation when CO_2 is not used after re-dissolution. And also it is necessary to kept away from direct light when direct bilirubin and total bilirubin are re-dissolved and subsequent preservation.
4. The production date and expiration date are available on package label.

System Information

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

Warnings and Precautions

1. For calibration during in vitro diagnostic clinical chemistry analysis. Do not be used for other purposes.
2. If the results are inconsistent with the specified values, the experiment should be stopped, and retested after the possible causes were analyzed.
3. This product can only be frozen and thawed once after re-constitution, avoiding repeatedly frozen and thawed.
4. Please use this product according to the specified method. The use of non-specified method and purpose cannot ensure the accuracy of the results.
5. If the product is contaminated with bacteria, the stability of many components will be reduced. If there are obvious signs that the product has been contaminated with microorganism, do not use it.
6. It is necessary to follow the routine precautions for the laboratory operation when using this product.
7. If the product accidentally enters the eyes, mouth or sticks to the skin, immediately wash thoroughly with water and go to the hospital if necessary.
8. The opened product shall be stored sealed according to the specified method. Do not use after the expiration date.
9. This product shall be stored according to the specified method and kept away from direct light.
10. Warning: This product contains human-derived or animal-derived ingredients. At present, there is no way to completely ensure that it is free of infectious substances, and there is also the possibility of contamination during use; this product and samples should be regarded as potential sources of infection, operators should take protective measures and follow the laboratory safe operation regulations; all wastes should be disposed of in accordance with local regulatory requirements.

Test Process

1. Take out the calibrator, carefully open the cap to avoid loss of contents, and accurately reconstitute with purified water marked on the label.
2. Carefully tighten the cap and place it at room temperature, out of direct light for 30 minutes. During reconstitution, gently rotate the vial several times to ensure complete dissolution of the contents. Do not shake the vial vigorously to avoid foam.
3. After the completion of reconstitution, please immediately operate according to the instructions for use (ALP should be stable for 1 hour before detection), add the calibrator according to the instructions for use of reagent, and calibrate in the linear calibration mode.
4. If it cannot be used immediately or after use, please timely put it back to the specified storage conditions.

Performance Characteristics

1. Appearance: yellowish lyophilized powder, and yellowish or yellow liquid after re-dissolution.
2. Moisture content: ≤ 5%.
3. Trueness: the trueness of the measurement value shall meet | En | ≤ 1.
4. Homogeneity:

4.1 within-vial homogeneity: within-vial $CV \leq 10\%$.

4.2 Between-vial homogeneity: between-vial $CV \leq 15\%$.

Materials Required (but not provided)

Chemistry analyzer, reagents, control, general lab equipment and consumable.

Symbol Interpretation

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

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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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CE IVD

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

(E-pNP-G7 Method)

Package Specification

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

Intended Use

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

Summary

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

Principle

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

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

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

Reagents Components and Concentration

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

The components in different batches are non-interchangeable.

Storage and Validity

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

System Information

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

Specimen Information

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

Warnings and Precautions

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

Test Process

1. Parameters

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

2. Operation

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

3. Calibration

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

4. Quality Control

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

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

5. Calculation

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

Reference Intervals

Serum: < 140 U/L

Urine: < 640 U/L

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

Explanation of Results

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

Limitations

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

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

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

Performance Characteristics

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

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

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

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

Materials Required (but not provided)

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

Symbol Interpretation

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

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Current Version: 02 Date of Issue: May, 2022

CE IVD

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

Package Specification

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

Intended Use

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

Summary

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

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

Principle

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

Reagents Components and Concentration

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

The components in different batches are non-interchangeable.

Storage and Validity

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

System Information

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

Specimen Information

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

Warnings and Precautions

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

Test Process

1. Parameters

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

2. Operation

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

3. Calibration

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

4. Quality Control

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

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

5. Calculation

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

Reference Intervals

35.0~55.0 g/L

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

Explanation of Results

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

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

Limitations

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

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

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

Performance Characteristics

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

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

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

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

Materials Required (but not provided)

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

References

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

Symbol Interpretation

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

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EC REP Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Current Version: 02 Date of Issue: May, 2022

CE IVD

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Instructions 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

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Instructions for Use of Aspartate Aminotransferase (AST) Kit (Enzymatic Method)

Package Specification

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

Intended Use

In vitro test for the quantitative determination of aspartate aminotransferase activity in human samples (serum or plasma). Clinically, it is mainly used as an aid to diagnosis of viral hepatitis, obstructive jaundice, and myocardial infarction.

Summary

The enzyme aspartate aminotransferase (AST) is widely distributed in tissue, principally hepatic, cardiac, muscle, and kidney. Elevated serum levels are found in diseases involving these tissues. Hepatobiliary diseases, such as cirrhosis, metastatic carcinoma, and viral hepatitis also increase serum AST levels. Following myocardial infarction, serum AST is elevated and reaches a peak two days after onset. In patients undergoing renal dialysis or those with vitamin B6 deficiency, serum AST may be decreased. The apparent reduction in AST may be related to decreased pyridoxal phosphate, the prosthetic group for AST, resulting in an increase in the ratio of apoenzyme to holoenzyme. Two isoenzymes of AST have been detected, cytoplasmic and mitochondrial. Only the cytoplasmic isoenzyme occurs in normal serum, while the mitochondrial, together with the cytoplasmic isoenzyme, has been detected in the serum of patients with coronary and hepatobiliary disease.

Principle

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

1. Aspartic Acid + α-Ketoglutaric Acid $\xrightarrow{AST}$ Oxaloacetic Acid + L-Glutamic Acid

2. Oxaloacetic Acid + NADH + H^+ $\xrightarrow{MDH}$ L-Lactic Acid + NAD^+ + H_2O

Oxidation of NADH to NAD^+ causes a decrease in absorbance at 340 nm, which is directly proportional to the AST activity in the sample.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	Trometamol (Tris) buffer	62 mmol/L
	Nicotinamide adenine dinucleotide (NADH)	0.4 mmol/L
R2	Trometamol (Tris) buffer	439 mmol/L
	α-Ketoglutaric Acid	37.1 mmol/L
	L-Aspartic Acid	>800 mmol/L
	Malate Dehydrogenase (MDH)	>2.5 kU/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 12 months.

2. Once opened, the reagents are stable for 4 weeks at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.

3. The production date and expiration date are available on package insert.

System Information

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

Specimen Information

Non-hemolytic serum or plasma is suitable for samples, which are stable for 3 days at 2 - 8 ℃. Avoid repeated freezing and thawing.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.

2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.

3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.

4. When reagent becomes turbid or the blank absorbance < 1.000, the reagent is failed and should be discarded.

5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.

6. The same sample tested with reagents from different manufacturers may lead to different measured values.

7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	Rate Method	Sample/Reagent	6/125
Main Wavelength	340 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	405 nm	**Reaction Time**	10 min
Reaction Direction	-		

2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	12
Calibrator (μL)	/	12	/
Purified Water (μL)	12	/	/
Reagent 1 (μL)	200	200	200
Mix well, incubate at 37 ℃ for 5 min			
Reagent 2 (μL)	50	50	50
Mix well, after 2 min, measure the average absorbance change rate 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
	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

Instructions for Use of Creatine Kinase MB Isoenzyme (CK-MB) Kit (Immunoinhibition Method)

Package Specification

REF	Reagent	Systems
01.09.04.04.EC.01	R1 30 mL × 3 R2 7.5 mL × 3 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1	Zybio EXC200/220
01.09.04.04.EC.02	R1 48 mL × 2 R2 12 mL × 2 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of the catalytic activity concentration of creatine kinase MB isoenzyme in human samples (serum or plasma). Clinically, it is mainly used as an aid to diagnosis of myocardial infarction, myopathy, and other diseases.

Summary

Creatine kinase isoenzyme is an enzyme component, which has four types: muscle type, brain type, hybrid type and mitochondrial type. It is one of the myocardial enzymes and mainly responds to the condition of myocardial cell damage. Increased CK-MB is mainly seen in acute myocardial infarction. After the onset of chest pain, the increase in serum creatine kinase isoenzymes preceded the increase in total activity, peaked at 24 hours, fluctuated parallel to total activity within 36 hours, and disappeared by 48 hours. Those who peaked at 8 to 12 hours had a better prognosis than those who peaked at 24 hours. If constant fluctuation of CK-MB is detected, it indicates the recurrence of myocardial infarction.

Principle

This kit uses immunoinhibition method to determine the catalytic activity concentration of CK-MB in samples. In the presence of antibodies against the CK-M subunit, the total CK-MM activity and 50% of the CK-MB activity in the sample were inhibited, while the activity of the B subunit in CK-MB and CK-BB was unaffected.

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

The production of NADPH causes an increase in absorbance, which is directly proportional to the activity of CK-B in the sample. CK-MB activity was twice the measured CK-B activity (Generally, serum levels of CK-BB are insignificant).

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	D-Glucose	20-30 mmol/L
	Nicotinamide adenine dinucleotide phosphate oxidized form ($NADP^+$)	1.5-2.0 g/L
	Hexokinase	4-8 kU/L
	Imidazole buffer	100 mmol/L
	CK-M antibody	0.1-0.2%
R2	Glucose-6-phosphate dehydrogenase (G6PDH)	12-16 kU/L
	Phosphocreatine	80-120 mmol/L
	Adenosine 5'-diphosphate (ADP) monopotassium salt	7-9 mmol/L
Calibrator	Bovine Serum Creatine kinase MB isoenzyme	Refer to the label for marked value
Control	Bovine Serum Creatine kinase MB isoenzyme	Refer to the label for marked value

The components in different batches are non-interchangeable.

The measurement system can be traceable to enterprise standard.

The target value of control has batch specificity.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from 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. To ensure accuracy, calibrator and control are stable for 3 days at 2 - 8 °C and 7 days at - 20 °C after reconstitution. Avoid repeated freezing and thawing.
4. The production date and expiration date are available on package insert.

System Information

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

Specimen Information

Serum or plasma (heparin for anticoagulation) is suitable for samples, which shall be separated in time after collection to avoid hemolysis. Samples are stable for 1 day at 2 - 8 ℃ and for 30 days at - 20 ℃. Avoid repeated freezing and thawing.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When reagent becomes turbid or the blank absorbance > 0.400, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. Dedicated calibrator is recommended for use to ensure the accuracy of test values.
7. The same sample tested with reagents from different manufacturers may lead to different measured values.
8. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	Rate Method	**Sample / Reagent**	1/25
Main Wavelength	340 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	546 nm	**Reaction Time**	10 min
Reaction Direction	+		

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2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	10
Calibrator (μL)	/	10	/
Purified Water (μL)	10	/	/
Reagent 1 (μL)	200	200	200
Mix well, incubate at 37 ℃ for 5 min			
Reagent 2 (μL)	50	50	50
Mix well, incubate at 37 ℃ for 3 min, then measure the absorbance change within 2 min, and calculate the absorbance change rate Δ*A*/ min.			

3. Calibration

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

Calibrator reconstitution: Reconstitution with the amount of purified water labeled on the bottle accurately absorbed, leave for 30 minutes, and mix well before use.

4. Quality Control

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

Control reconstitution: Reconstitution with the amount of purified water labeled on the bottle accurately absorbed, leave for 30 minutes, and mix well before use.

5. Calculation

Linear calibration was used to draw the working curve. The catalytic activity concentration of creatine kinase MB isoenzyme (CK-MB) in the sample can be calculated on the working curve based on its absorbance change rate.

Reference Intervals

≤ 24 U/L

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

Explanation of Results

If the catalytic activity concentration exceeds 500 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 shall be 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 range or if it is still beyond the reference range after confirmation, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

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

Substances	Concentrations
Hemoglobin	5 g/L
Bilirubin	342 μmol/L
Triglyceride	10 mmol/L

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

Performance Characteristics

1. The reagent blank absorbance ≤ 0.400, the reagent blank absorbance change rate (Δ*A*/min) ≤ 0.002.
2. Analytical sensitivity: at the test catalytic activity concentration of 100 U/L, the reagent absorbance change rate (Δ*A*/min) ≥ 0.0080.
3. Accuracy: the relative deviation ≤ 10%.
4. Precision: within-run *CV* ≤ 6%; between-run relative range ≤ 10%.
5. Linear range:

[2, 500] U/L, the correlation coefficient (*r*) ≥ 0.990.

[2, 50) U/L, the absolute deviation ≤ 2.5 U/L;

[50, 500] U/L, the relative deviation ≤ 5%.

6. Calibrator accuracy: relative deviation ≤ 10%.
7. Calibrator homogeneity: between-vial *CV* ≤ 10%.
8. Control accuracy: test value is within the allowable range of the marked value.
9. Control homogeneity: between-vial *CV* ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, General lab equipment and consumable.

References

[1] Bendz R, Ström S. Diagnostic significance of serum CK-MB elevations following surgical damage to skeletal muscles[J]. Scand J Thorac Cardiovasc Surg, 1981, 15:199-204.

[2] Wang H, Liu S, Xing Y, et al. The limitation of MB isoenzyme of creatine kinase mass in assess myocardial injury with muscular disease[J]. Chinese Critical Care Medicine, 2011, 23:723-726.

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

Zybio Inc.

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CE IVD

zybio

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 C-Reactive Protein (CRP) Kit

(Latex Enhanced Immunoturbidimetric Method)

Package Specification

REF	Reagent	Systems
01.09.07.03.EC.01	R1 30 mL × 3 R2 10 mL × 3 Calibrator 6 Levels × 0.6 mL × 1	Zybio EXC200/220
01.09.07.03.EC.02	R1 45 mL × 2 R2 15 mL × 2 Calibrator 6 Levels × 0.6 mL × 1	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of C-reactive protein concentration in human samples (serum).

Summary

C-reactive protein is mainly synthesized by hepatocytes and contains 5 polypeptide chain subunits, which are non-covalently combined into disc-shaped multimers with a molecular weight of 115,000 - 140,000. C-reactive protein is a typical acute phase protein, mainly as a non-specific inflammatory indicator, which can be used to evaluate infection, tissue damage and inflammatory diseases, and provide information for the diagnosis, treatment and monitoring of inflammatory diseases. Measuring changes in the concentration of CRP provides useful diagnostic information about how acute and how serious a disease is. It also allows judgement about the disease genesis. Persistence of a high serum CRP concentration is usually a grave prognostic sign which generally indicates the presence of an uncontrolled infection.

Principle

The C-reactive protein in the sample binds to the mouse anti-human C-reactive protein antibody bound on the surface of the latex particles, resulting in an antigen-antibody reaction, which causes the latex particles to agglutinate to form an antigen-antibody complex, resulting in a certain degree of turbidity. The turbidity level reflects the content of C-reactive protein in the sample, and the content of C-reactive protein in the sample can be calculated by comparing with the calibrator of the same treatment.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	Citric Acid Buffer	100 - 200 mmol/L
R2	Mouse Anti-Human C-Reactive Protein Monoclonal Antibody Latex Solution	0.1% - 0.5%
Calibrator	Recombinant C-Reactive Protein	Refer to the label for marked value
	Phosphate Buffer	10 - 30 mmol/L

The components in different batches are non-interchangeable.
The calibrator can be traceable to ERM-DA474/ IFCC.

Storage and Validity

1. The reagents should be stored at 2 - 8 °C and kept away from freezing. The unopened reagents are valid for 12 months.
2. Once opened, the reagents are stable for 1 month at 2 - 8 °C. For reagents not in use, the cap should be tightened to avoid contamination.
3. To ensure accuracy, calibrator is stable for 7 days after opened and stored at 2 - 8 °C.
4. The production date and expiration date are available on package insert.

System Information

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

Specimen Information

1. Serum is suitable for samples, which shall be separated in time after collection to avoid hemolysis.
2. Samples are stable for 7 days at 2 - 8 °C and 30 days at - 20 °C. Avoid repeated freezing and thawing.
3. Samples should be transported and stored at low temperature, and samples stored at low temperature should be equilibrated to room temperature before use.
4. Blood collection tubes from different manufacturers may lead to different results due to different raw materials and additives. This product is not tested on all possible applications of blood collection tube types and manufacturers, and each laboratory is required to make its own judgment on the suitability of the blood collection tube and serum separation product used.

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 > 2.000, 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. Dedicated calibrators are recommended for use. When other calibrator products are used, it is possible to affect the measured value.
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**	3/400
Main Wavelength	600 nm	**Reaction Temperature**	37 °C
Sub Wavelength	None	**Reaction Time**	10 min
Reaction Direction	+		

2. **Operation**

Addition	**Blank**	**Calibration**	**Detection**
Sample (μL)	/	/	3
Calibrator (μL)	/	3	/
Purified Water/ Saline (μL)	3	/	/
Reagent 1 (μL)	300	300	300
Mix well, incubate at 37 °C for 5 min, and add R2.			
Reagent 2 (μL)	100	100	100
Mix well, and measure absorbance A_1, then incubate at 37 °C for 5 min, and measure absorbance A_2, calculate $\Delta A = A_2 - A_1$.			

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3. Calibration

Use Zybio matched 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

Multi-point nonlinear calibration was used to draw the working curve. The concentration of C-reactive protein in the sample can be calculated on the working curve based on its absorbance change value.

Reference Intervals

< 10.0 mg/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

1. If the C-reactive protein content of a sample exceeds 270.0 mg/L, perform the assay using the reduced mode of the analyzer, or after diluting the sample with saline, multiply the reported result by the dilution factor and the maximum dilutable factor is 8.
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 the testing of reagents using different methodologies should not be directly compared with each other to avoid causing wrong 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 within ± 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Hemoglobin	4.6 g/L
Chyle	0.3%
Bilirubin	342.0 μmol/L

2. Hook effect: No hook effect was observed for sample concentrations up to 270.0 mg/L.
3. 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 ≤ 2.000.
2. Limit of detection ≤ 2.0 mg/L.
3. Analytical sensitivity: at the test concentration of 40.0 mg/L, the reagent absorbance change (ΔA) shall within 0.05 - 0.50.
4. Accuracy: relative deviation ≤ 10%.
5. Precision: within-run *CV* ≤ 8%, between-run relative range ≤ 10%.
6. Linear Range:
[3.0, 270.0] mg/L, the correlation coefficient (r) ≥ 0.990.
[3.0, 20.0) mg/L, the absolute deviation ≤ 2.0 mg/L;
[20.0, 270.0] mg/L, the relative deviation ≤ 10%.
7. Calibrator accuracy: relative deviation ≤ 10%.
8. Calibrator homogeneity: within-vial *CV* ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, control, general lab equipment and consumable.

References

[1] Young B, Gleeson M, Cripps AW. C-reactive protein: A critical review. Pathology 1991; 23:118-124.
[2] Mackenzie I, Woodhouse J. C-reactive protein concentrations during bacteremia: a comparison between patients with and without liver dysfunction. Intensive Care Medicine 2006; 32:1344-1351.

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

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

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CE IVD

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Instructions for Use of 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

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	Temperature Limit		Date of Manufacture
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CE IVD

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Instructions for Use of Lactate Dehydrogenase (LDH) Kit (Rate Method)

Package Specification

REF	Reagent	Systems
01.09.04.06.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	Zybio EXC200/220
01.09.04.06.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 lactate dehydrogenase activity in human samples (serum). Clinically, it is mainly used as an aid to diagnosis of myocardial infarction and hepatopathy.

Summary

Lactate dehydrogenase is a kind of NAD-dependent kinase, which has three subunits, LDHA, LDHB and LDHC, and can constitute six tetrameric isoenzymes. Animal lactate dehydrogenase is a tetramer composed of 4 subunits, 5 LDH isozymes (LDH1-5) composed of common A and B subunits, and only one LDH isozyme (LDH-C4) composed of C subunit. Lactate dehydrogenase is a metalloprotein containing zinc ions, with a molecular weight of 135-140 kD. It is one of the important enzymes for anaerobic glycolysis and gluconeogenesis of sugars. It can catalyze the reduction and oxidation reaction between propionic acid and L-lactic acid, and can also catalyze the related α-keto acid. LDH is widely present in human tissues, with the highest content in the kidney, followed by the myocardium and bony muscle. LDH in red blood cells is about 100 times higher than in normal serum.

Lactate dehydrogenase is a key enzyme in microorganisms that catalyzes the production of benzolactic acid (also known as 2-hydroxy-3-phenylpropionic acid) from phenylpyruvate. Lactate dehydrogenase is a crucial oxidoreductase in the glycolytic pathway in organisms, which can reversibly catalyze the oxidation of lactate to pyruvate, and this catalytic reaction is the end product of anaerobic glycolysis. Lactate dehydrogenase is mainly found in animal tissues such as heart muscle, liver, kidney, skeletal muscle, or lung. Lactate dehydrogenase measurements are commonly used in the diagnosis of myocardial infarction, liver disease, and certain malignancies.

Principle

L-Lactic acid + NAD^+ $\xrightarrow{LDH}$ Pyruvic acid + NADH + H^+

The activity of lactate dehydrogenase (LDH) in the sample can be detected by measuring the increase rate of the absorbance at 340 nm.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	Lactate	>6 mmol/L
	Trometamol (Tris) buffer	100 mmol/L
R2	Nicotinamide adenine dinucleotide (NAD^+)	>12 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 is suitable for samples, which are stable for 3 days at 2 - 8 ℃ and for 30 days at - 20 ℃. Avoid hemolysis and 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 > 0.500, 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	Rate Method	**Sample/Reagent**	1/50
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)	/	/	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 average absorbance change rate ΔA/min within 3 min.			

3. Calibration

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

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4. Quality Control

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

5. Calculation

Linear calibration was used to draw the working curve. The concentration of lactate dehydrogenase (LDH) in the sample can be calculated on the working curve based on its absorbance change rate.

Reference Intervals

105~245 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 LDH in the sample exceeds 800 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 ≤ 0.500; the reagent blank absorbance change rate (Δ*A*/min) ≤ 0.002 *A*/min.

2. Analytical sensitivity: at the test concentration of 200 U/L, the reagent absorbance change rate (Δ*A*/min) ≥ 0.005.

3. Accuracy: relative deviation ≤ 10%.

4. Precision: within-run *CV* ≤ 5%, between-run relative range ≤ 10%.

5. Linear Range:

[25, 800] U/L, the correlation coefficient (*r*) ≥ 0.990.

[25, 100] U/L, the absolute deviation ≤ 10 U/L;

(100, 800] 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] Eigentler T, Figl A, Krex D, et al. Number of metastases, serum lactate dehydrogenase level, and type of treatment are prognostic factors in patients with brain metastases of malignant melanoma[J]. Cancer, 2011, 117:1697-1703.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
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Instructions for Use of Inorganic Phosphorus (P) Kit (Direct UV Method)

Package Specification

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

Intended Use

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

Summary

About 88% of the phosphorus contained in the body is localized in bone in the form of calcium phosphate as the apatite Ca^{2+} $[Ca_3 (PO_4)_2]_3^{2-}$. The remainder is involved in intermediary carbohydrate metabolism and in physiologically important substances such as phospholipids, nucleic acids, and ATP. Phosphorus occurs in blood in the form of inorganic phosphate and in organically bound Phosphoric Acid. The small amount of extracellular organic phosphorus is found almost exclusively in the form of phospholipids.

The ratio of phosphate to calcium in the blood is approximately 6:10. An increase in the level of phosphorus causes a decrease in the calcium level. The mechanism is influenced by interactions between parathormone and Vitamin D. Hypoparathyroidism, Vitamin D intoxication and renal failure with decreased glomerular phosphate filtration give rise to hyperphosphatemia. Hypo-phosphatemia occurs in rickets, hyperparathyroidism and Fanconi's syndrome.

Principle

Phosphorus (inorganic) in the sample reacts with molybdate to generate a phosphomolybdic acid complex, resulting in an increase in the absorbance at 340 nm, and the change of the absorbance is directly proportional to the phosphorus (inorganic) concentration of the sample. The concentration of phosphorus (inorganic) in the sample can be calculated based on the calibration curve obtained with the calibrator treated in the same manner.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R	Ammonium Molybdate	0.4 mmol/L
	Sulfuric Acid	215 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 is suitable for samples, which shall be separated in time after collection to avoid hemolysis. Samples are stable for 5 days at 2 - 8 ℃ and 3 weeks 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 > 0.80, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. The same sample tested with reagents from different manufacturers may lead to different measured values.
7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	End-Point Method	Sample/Reagent	1/50
Main Wavelength	340 nm	Reaction Temperature	37 ℃
Sub Wavelength	700 nm	Reaction Time	8 min
Reaction Direction	+		

2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	5
Calibrator (μL)	/	5	/
Purified Water (μL)	5	/	/
Reagent (μL)	250	250	250
Mix well, incubate at 37 ℃ for 8 min, 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.

5. Calculation

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

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Reference Intervals

0.90~1.60 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 P in the sample exceeds 3.00 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 < 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 ≤ 0.80.
2. Analytical sensitivity: at the test concentration of 1.5 mmol/L, the reagent absorbance change (ΔA) ≥ 0.20.
3. Accuracy: relative deviation ≤ 10%.
4. Precision: within-run CV ≤ 5%, between-run relative range ≤ 8%.
5. Linear Range:

[0.2, 3.0] mmol/L, the correlation coefficient (r) ≥ 0.990.

[0.2, 0.8) mmol/L, the absolute deviation ≤ 0.08 mmol/L;

[0.8, 3.0] 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] Peacock M. Phosphate Metabolism in Health and Disease[J]. Calcif Tissue Int, 2021, 108:3-15.

[2] Muñoz M, Balón M, Fernandez C. Direct determination of inorganic phosphorus in serum with a single reagent[J]. Clin Chem, 1983, 29:372-374.

[3] Rubino L, Catapano V, Guerra G. Determination of inorganic phosphorus in serum: Evaluation of three methods applied to the Technicon RA-1000 analyzer[J]. J Automat Chem, 1989, 11:164-167.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
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CE IVD

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Instructions for Use of Total Bilirubin (TBIL) Kit (Vanadate Oxidation Method)

Package Specification

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

Intended Use

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

Summary

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

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

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

Principle

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

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

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

Reagents Components and Concentration

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

The components in different batches are non-interchangeable.

Storage and Validity

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

System Information

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

Specimen Information

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

Warnings and Precautions

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

Test Process

1. Parameters

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

2. Operation

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

3. Calibration

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

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4. Quality Control

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

5. Calculation

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

Reference Intervals

3.4~20.5 μmol/L (0.2~1.2mg/dL)

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

Explanation of Results

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

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

Limitations

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

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

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

Performance Characteristics

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

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

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

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

Materials Required (but not provided)

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

References

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

Symbol Interpretation

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

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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

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CE IVD

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Instructions for Use of Uric Acid (UA) Kit (Uricase Method)

Package Specification

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

Intended Use

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

Summary

Uric acid is the final product of purine metabolism in the human organism. Uric acid measurements are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions, and of patients receiving cytotoxic drugs.

The oxidation of uric acid provides the basis for two approaches to the quantitative determination of this purine metabolite. One approach is the reduction of phosphotungstic acid in an alkaline solution to tungsten blue, which is measured photometrically. The method is, however, subject to interferences from drugs and reducing substances other than uric acid.

A second approach, described by Praetorius and Poulson, utilizes the enzyme uricase to oxidize uric acid; this method eliminates the interferences intrinsic to chemical oxidation. Uricase can be employed in methods that involve the UV measurement of the consumption of uric acid or in combination with other enzymes to provide a colorimetric assay.

Another method is the colorimetric method developed by Town et al. The sample is initially incubated with a reagent mixture containing ascorbate oxidase and a clearing system. In this test system it is important that any ascorbic acid present in the sample is eliminated in the preliminary reaction; this precludes any ascorbic acid interference with the subsequent POD indicator reaction. Upon addition of the starter reagent, oxidation of uric acid by uricase begins.

Principle

1. Uric acid + O_2 + H_2O $\xrightarrow{\text{Uricase}}$ Allantoin + CO_2 + H_2O_2

2. H_2O_2 + 4-AAP + TOOS $\xrightarrow{\text{Peroxidase}}$ Quinoneimine + H_2O

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	Sodium 3-(N-ethyl-3-methylanilino)-2-hydroxypropanesulfonate (TOOS)	1.11 mmol/L
	Ascorbate Oxidase	10 kU/L
R2	Trometamol (Tris) buffer	200 mmol/L
	Uricase	1.5 kU/L
	Peroxidase	5 kU/L
	4-Aminoantipyrine (4-AAP)	4 mmol/L

The components in different batches are non-interchangeable.

Storage and Validity

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

System Information

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

Specimen Information

Serum or plasma (heparin or EDTA anticoagulation) is suitable for samples, which are stable for 3 days at 2 - 8 ℃ and for 30 days at - 20 ℃. Avoid repeated freezing and thawing.

Warnings and Precautions

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

Test Process

1. Parameters

Method	End-Point Method	Sample/Reagent	1/50
Main Wavelength	546 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	700 nm	**Reaction Time**	10 min
Reaction Direction	+		

2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	5
Calibrator (μL)	/	5	/
Purified Water (μL)	5	/	/
Reagent 1 (μL)	200	200	200
Mix well, incubate at 37 ℃ for 5 min, and measure absorbance A_1			
Reagent 2 (μL)	50	50	50
Mix well, measure absorbance A_2 after 5 min, calculate $\Delta A = A_2 - A_1$.			

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3. Calibration

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

4. Quality Control

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

5. Calculation

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

Reference Intervals

Male: 202~416 μmol/L

Female: 140~380 μmol/L

This reference interval is determined based on 95% distribution interval obtained from 210 healthy males and 210 healthy females specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of UA in the sample exceeds 1190 μmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

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

Limitations

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

Substances	Concentrations
Vc	0.5 g/L
Hemoglobin	5 g/L
Chyle	0.30%
Bilirubin	342 μmol/L

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

Performance Characteristics

1. The reagent blank absorbance ≤ 0.200.

2. Analytical sensitivity: at the test concentration of 360 μmol/L, the reagent absorbance change (Δ*A*) ≥ 0.03.

3. Accuracy: relative deviation ≤ 10%.

4. Precision: within-run *CV* ≤ 4%, between-run relative range ≤ 6%.

5. Linear Range:

[100, 1190] μmol/L, the correlation coefficient (*r*) ≥ 0.990.

[100, 300] μmol/L, the absolute deviation ≤ 30 μmol/L;

(300, 1190] μmol/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

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

References

[1] Young D. Effects of drugs on clinical laboratory tests[J]. Ann Clin Biochem, 1997, 34:579-581.

Symbol Interpretation

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

Instructions for Use of Urea (UREA) Kit (Urease-GLDH Method)

Package Specification

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

Intended Use

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

Summary

Urea is the major end product of protein nitrogen metabolism. It is synthesized by the urea cycle in the liver from ammonia which is produced by amino acid deamination. Urea is excreted mostly by the kidneys but minimal amounts are also excreted in sweat and degraded in the intestines by bacterial action. Determination of blood urea nitrogen is the most widely used screening test for renal function. When used in conjunction with serum creatinine determinations it can aid in the differential diagnosis of the three types of azotemia: prerenal, renal and postrenal. Elevations in blood urea nitrogen concentration are seen in inadequate renal perfusion, shock, diminished blood volume (prerenal causes), chronic nephritis, nephrosclerosis, tubular necrosis, glomerular nephritis (renal causes) and urinary tract obstruction (postrenal causes). Transient elevations may also be seen during periods of high protein intake. Unpredictable levels occur with liver diseases.

Principle

1. $Urea + H_2O \xrightarrow{Urease} 2NH_3 + CO_2$

2. $NH_3 + \alpha\text{-Ketoglutaric Acid} + NADH + H^+ \xrightarrow{GLDH} Glutamic\ Acid + NAD^+ + H_2O$

Oxidation of NADH to NAD^+ causes a decrease in absorbance at 340 nm, which is directly proportional to the Urea concentration in the sample.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	Trometamol (Tris) buffer	100 mmol/L
	Nicotinamide adenine dinucleotide (NADH)	0.3 mmol/L
R2	α-Ketoglutaric Acid	10 mmol/L
	Urease	6.0 kU/L
	Glutamate dehydrogenase (GLDH)	2.0 kU/L

The components in different batches are non-interchangeable.

Storage and Validity

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

System Information

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

Specimen Information

Serum or plasma (heparin or EDTA anticoagulation) is suitable for samples, which are stable for 3 days at 2 - 8 ℃ and for 30 days at - 20 ℃. Avoid repeated freezing and thawing.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When reagent becomes turbid or the blank absorbance < 1.000, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. The same sample tested with reagents from different manufacturers may lead to different measured values.
7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	Rate Method	**Sample/Reagent**	1/100
Main Wavelength	340 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	405 nm	**Reaction Time**	10 min
Reaction Direction	-		

2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	3
Calibrator (μL)	/	3	/
Purified Water (μL)	3	/	/
Reagent 1 (μL)	240	240	240
Mix well, incubate at 37 ℃ for 5 min			
Reagent 2 (μL)	60	60	60
Mix well, after 1 min, measure the absorbance change within 2 min, and calculate the absorbance change rate ΔA/ min.			

3. Calibration

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

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4. Quality Control

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

5. Calculation

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

Reference Intervals

1.7~8.3 mmol/L (10~50 mg/dL)

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

Explanation of Results

If the concentration of UREA in the sample exceeds 40.0 mmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

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

Limitations

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

Substances	Concentrations
Vc	0.5 g/L
Hemoglobin	5 g/L
Chyle	0.30%
Bilirubin	342 μmol/L

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

Performance Characteristics

1. The reagent blank absorbance ≥ 1.000; the reagent blank absorbance change rate (ΔA/min) ≤ 0.04.
2. Analytical sensitivity: at the test concentration of 7.5 mmol/L, the reagent absorbance change rate (ΔA/min) ≥ 0.008.
3. Accuracy: relative deviation ≤ 10%.
4. Precision: within-run *CV* ≤ 5%, between-run relative range ≤ 6%.
5. Linear Range:

[0.5, 40.0] mmol/L, the correlation coefficient (*r*) ≥ 0.990.

[0.5, 5.0] mmol/L, the absolute deviation ≤ 0.5 mmol/L;

(5.0, 40.0] mmol/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

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

References

[1] Ai H, Chen K. Diagnostic Value of Blood Urea Nitrogen and Serum Creatinine in the Diagnosis of Early Diabetic Nephropathy[J]. Journal of Practical Medical Techniques, 2008, 15:431-433.

Symbol Interpretation

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

Sediment Control

Specifications

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

Intended purpose

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

Test principles

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

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

Materials provided

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

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

Materials required (but not provided)

Urine analyzer, general laboratory equipment.

Storage and stability

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

Applicable instruments

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

Assay procedure

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

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

Performance characteristics

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

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

Precautions

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

Sediment Control

Symbol interpretation

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

References

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

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

Cleanser

Product Name

Cleanser
Model: D12

Specifications

REF	Specifications
01.09.1F.01.13.23	200 mL/ Bottle

Intended purpose

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

Operating principle

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

Main components

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

Storage and stability

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

Applicable instruments

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

Usage

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

Performance characteristics

pH: 7.00 ± 2.00 at 25℃.

Warnings and precautions

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

Symbol interpretation

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

References

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

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Color Control

Specifications

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

Intended purpose

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

Test principles

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

Materials provided

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

Note: Products of different batches cannot be used together.

Materials required (but not provided)

Urine analyzer, general laboratory equipment.

Storage and stability

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

Applicable instruments

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

Assay procedure

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

Performance characteristics

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

Precautions

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

Symbol interpretation

Symbol	Title and Description	Symbol	Title and Description
IVD	In vitro diagnostic medical device		Date of manufacture
LOT	Batch code		Use-by date
	Consult instructions for use		Temperature limit
	Keep away from sunlight	REF	Catalogue number
CE	CE marking of conformity		Manufacturer
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Color Control

References

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

CE IVD

Conductivity Calibrator

Specifications

REF	Specifications
01.09.1F.01.17.03	3 levels×1×8 mL

Intended purpose

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

Test principles

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

Main components

Level 1: potassium chloride 0.5–2% w/w.
Level 2: potassium chloride 2–10% w/w.
Level 3: potassium chloride 5–20% w/w.

Materials provided

Common component	3 levels
Conductivity Calibrator	3 bottles
Instructions for use	1 pc

Note:

Indicated value	Uncertainty
See bottle label	See bottle label

Traceability: Traceable to GBW13124 standard.

Materials required (but not provided)

Urine analyzer, general laboratory equipment.

Storage and stability

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

Applicable instruments

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

Assay procedure

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

Performance characteristics

Accuracy: correctness of measuring value transfer $|En| \leqslant 1$.
Homogeneity:

No.	level 1	level 2	level 3
$CV_{within\text{-}bottle}$	CV⩽15%	CV⩽5%	
$CV_{between\text{-}bottle}$	CV⩽15%	CV⩽5%	

Precautions

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

Symbol interpretation

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

Conductivity Calibrator

EC REP	Authorized Representative in the European Community		

References

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

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Conductivity Control

Specifications

REF	Specifications
01.09.1F.01.07.03	Level 1: 1×8 mL
01.09.1F.01.07.04	Level 2: 1×8 mL
01.09.1F.01.07.02	2 Levels × 1 × 8 mL

Intended purpose

This product is used for the QC of conductivity module of Urine Sediment Analyzer and Urinalysis Hybrid System.

Test principles

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

Materials provided

Common component	Level 1	Level 2	2 levels
Conductivity control	1 bottle	1 bottle	2 bottles
Instructions for use	1 pc	1 pc	1 pc

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

Materials required (but not provided)

Urine Chemistry Analyzer, general laboratory equipment.

Storage and stability

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

Applicable instruments

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

Assay procedure

Refer to the instructions on this product and the instructions on compatible instruments.
1. The QC test shall be performed before the instrument restart or daily test, and controls with 2 levels shall be used for QC as much as possible.
2. Before use, leave the control under room temperature for 30 minutes.
3. To use it, gently invert it several times to homogenize it.
4. During the test of Urine Sediment Analyzer: put the instrument at QC status, pour the control into a dry and clean test tube, place the test tube at a test position in a compatible instrument for testing.
5. The test result shall be within the indicated value range. If it exceeds the range, the user shall check the detection system, such as the validity period of the control, performance and status of instrument, etc.

Performance characteristics

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

Precautions

1. This product is only applicable to the QC of conductivity module of urine sediment analyzer or urinalysis hybrid system. Please do not use it for other purposes.
2. Avoid contact with the skin and eye. If this product is splashed into the eye, flush it with running warm water for several minutes; seek medical attention immediately if pain or swelling occurs . In case of contact with skin, rinse the skin with soapy water, and completely rinse off the product with water.
3. Please use this product according to the use method specified in this the instructions book. For purposes other than the prescribed use method of and use purpose, the accuracy of the results cannot be guaranteed.
4. Routine precautions for laboratory operations must be followed when this product is used.
5. Discarded controls and utensil that have been in contact with the control shall be disposed of as medical waste or industrial waste in accordance with relevant waste regulations. All waste shall be treated as a potential infection source.
6. The control that was unsealed shall be sealed and stored according to the specified method; do not use expired products.
7. Please keep this product as instructed, and avoid direct sunlight during operation.

Symbol interpretation

Symbol	Title and Description	Symbol	Title and Description
IVD	In vitro diagnostic medical device		Date of manufacture
LOT	Batch code		Use-by date
	Consult instructions for use		Temperature limit
	Keep away from sunlight	REF	Catalogue number
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Conductivity Control

References

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

Product Name
Urinalysis Diluent

Specifications

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

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

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

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

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

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

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

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

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

Symbol interpretation

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

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


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Current Revision and Release Date: 03, 2022-11

zybio

CE IVD

Focusing Fluid

Specifications

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

Intended purpose

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

Test principles

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

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

Materials provided

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

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

Materials required (but not provided)

Urine analyzer, general laboratory equipment.

Storage and stability

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

Applicable instruments

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

Assay procedure

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

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

Performance characteristics

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

Precautions

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

Symbol interpretation

Symbol	Title and Description	Symbol	Title and Description

Focusing Fluid

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

References

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

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

SG Calibrator

Specifications

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

Intended purpose

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

Test principles

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

Materials provided

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

Note:

Indicated value	Uncertainty
See bottle label	See bottle label

Traceability: traceable to enterprise reference.

Materials required (but not provided)

Urine analyzer, general laboratory equipment.

Storage and stability

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

Applicable instruments

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

Assay procedure

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

Performance characteristics

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

Precautions

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

Symbol interpretation

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

References

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

SG Calibrator

2. Cong Yulong, Ma Junlong, et al. Modern Urinalytical Technology and Clinic Application, China Science and Technology Press, 1998.
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SG Control

Specifications

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

Intended purpose

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

Test principles

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

Materials provided

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

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

Materials required (but not provided)

Urine analyzer, general laboratory equipment.

Storage and stability

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

Applicable instruments

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

Assay procedure

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

Performance characteristics

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

Precautions

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

Symbol interpretation

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

SG Control

References

1. Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline—Third Edition，from NCCLS Document GP16-A, 2009.
2. Cong Yulong, Ma Junlong, et al. Modern Urinalytical Technology and Clinic Application, China Science and Technology Press, 1998.
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IFU Revision: 02 Release date: 2022-05-20

Sheath Fluid

Product name

Sheath Fluid

Package specifications

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

Intended purpose

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

Main components

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

Materials provided

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

Operating principle

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

Storage and stability

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

Applicable instruments

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

Usage

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

Performance characteristics

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

Warnings and precautions

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

Symbol Interpretation

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

Sheath Fluid

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

References

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

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Current Revision and Release Date: 03, 2022-11

Turbidity Calibrator

Specifications

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

Intended purpose

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

Test principles

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

Materials provided

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

Note:

Indicated value	Uncertainty
See bottle label	See bottle label

Traceability: traceable to GBW12001 standard.

Materials required (but not provided)

Urine analyzer, general laboratory equipment.

Storage and stability

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

Applicable instruments

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

Assay procedure

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

Performance characteristics

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

Precautions

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

Symbol interpretation

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

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Turbidity Control

Specifications

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

Intended purpose

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

Test principles

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

Materials provided

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

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

Materials required (but not provided)

Urine analyzer, general laboratory equipment.

Storage and stability

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

Applicable instruments

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

Assay procedure

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

Performance characteristics

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

Precautions

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

Symbol interpretation

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

Turbidity Control

References

1. Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline—Third Edition，from NCCLS Document GP16-A, 2009..
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IFU Revision: 02 Release date: 2022-05-20

zybio

CE IVD

UDC-Control

Specifications

REF	Specifications
01.09.1F.01.03.05	Negative: 8 mL×1;
01.09.1F.01.03.06	Positive: 8 mL×1;
01.09.1F.01.03.04	Negative: 8 mL×1; Positive: 8 mL×1

Intended purpose

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

Test principles

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

Materials provided

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

Note: Control target values are batch-specific.

Materials required (but not provided)

Urine analyzer, general laboratory equipment.

Precautions

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

Storage and stability

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

Applicable instruments

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

Assay procedure

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

Interpretation of test result

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

Performance characteristics

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

Limitations

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

UDC-Control

Symbol interpretation

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

References

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

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

Urinalysis Strip (Dry Chemistry Method)

Specifications

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

Intended purpose

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

Summary and explanation

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

Test principle

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

Materials provided

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

Materials required (but not provided)

Detection instrument, quality controls, general laboratory equipment.

Precautions

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

Urinalysis Strip (Dry Chemistry Method)

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

Storage and stability

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

Sample requirements

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

Applicable instruments

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

Assay procedure

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

Reference interval

Reference value of normal human urine for urinalysis strip:

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

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

Interpretation of test result

1.Magnitude setting of test result

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

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

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

Urinalysis Strip (Dry Chemistry Method)

concentration around 17 μmol/L.

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

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

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

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

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

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

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

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

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

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

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

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

Performance characteristics

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

Limitations

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

Urinalysis Strip (Dry Chemistry Method)

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

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

Technical assistance

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

Symbol interpretation

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

References

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

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

US-Calibrator

Specifications

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

Intended purpose

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

Test principles

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

Materials provided

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

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

Materials required (but not provided)

Urine analyzer, general laboratory equipment.

Storage and stability

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

Applicable instruments

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

Assay procedure

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

Performance characteristics

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

Precautions

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

Symbol interpretation

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

US-Calibrator

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

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2. Cong Yulong, Ma Junlong, et al. Modern Urinalytical Technology and Clinic Application, China Science and Technology Press, 1998.
3. Cong Yulong, Ma Junlong, et al. Practical Urinalytical Technology and Clinical Application, People's Health Publishing House, first edition, September, 2013.

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

Wash Solution

Product Name

Wash Solution
Model: D21

Specifications

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

Intended purpose

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

Operating Principle

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

Main Components

Sodium hypochlorite: 0.01%-0.5%.

Storage and stability

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

Applicable instruments

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

Usage

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

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

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

Performance characteristics

pH ⩾9.00 at 25°C.

Warnings and Precautions

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

Symbol interpretation

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

References

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

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