CE IVD

Cl Reagent Kit (Thiocyanate Colorimetric Method)

Instructions for Use

REF CC1023

PRODUCT NAME

Cl Reagent Kit (Thiocyanate Colorimetric Method)

PACKAGE SPECIFICATION

R:1x10 mL	R:1x15 mL	R:1x20 mL	R:1x25mL
R:1x50 mL	R:1x60 mL	R:1x65 mL	R:1x75 mL
R:1x1000 mL	R:1x2000 mL	R:2x25 mL	R:2x30 mL
R:2x35mL	R:2x40 mL	R:2x45 mL	R:2x50 mL
R:2x55 mL	R:2x60 mL	R:2x65 mL	R:2x75 mL
R:2x80 mL	R:2x100 mL	R:2x2000 mL	R:3x50 mL
R:3x65 mL	R:3 x75 mL	R:3x100 mL	R:4x20 mL
R:4x25 mL	R:4x30 mL	R:4x35 mL	R:4x40 mL
R:4x45 mL	R:4x50 mL	R:4x55 mL	R:4x60 mL
R:4x65 mL	R:4x75 mL	R:4x100 mL	R:4x1000 mL
R:5x20 mL	R:5x40 mL	R:5x60 mL	R:5x80 mL
R:5x120 mL	R:6x20 mL	R:6x30 mL	R:6x35 mL
R:6x40 mL	R:6x45 mL	R:6x50 mL	R:6x55mL
R:6x60 mL	R:6x65 mL	R:6x100 mL	R:7x60 mL
R:8x20 mL	R:8x25 mL	R:10x10 mL	R:10x20 mL
R:36x3.8 mL	R:36x4.3 mL	R:12x72T(12x25.8 mL)	

INTENDED USE

This test kit is intended for the *in vitro* quantitative determination of Chlorine in human serum and it is mainly used clinically for the auxiliary diagnosis of hyperchloremia or hypochloremia. For professional and laboratory use only.

TEST PRINCIPLE

The reaction used to measure chloride ions was as follows:

$2Cl^- + Hg(SCN)_2 \rightarrow HgCl_2 + 2SCN^-$

$3SCN^- + Fe^{3+} \rightarrow Fe(SCN)_3$

Iron thiocyanate has a maximum absorption at 480 nm, and its absorption intensity is directly proportional to the content of chloride ions in serum. By comparing with the calibrator with the same treatment, the content of chloride ions in the sample can be calculated.

MAIN COMPONENTS

Kit composition	Reagent components	Content
Reagent	Mercuric thiocyanate	2 mmol/L
	Ferric nitrate	30 mmol/L
	Nitric acid	40 mmol/L

The components in different batches of a multi-component kit are not interchangeable.

STORAGE AND SHELF LIFE

Unopened reagents should be stored at 2°C-8°C away from light, with a shelf life of 18 months. Opened reagents are stable for 42 days when stored at 2°C-8°C.
Please refer to the label on the reagent kit for the production date and expiration date.

APPLICABLE INSTRUMENTS

The kit is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7170, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise (China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000FR, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc, models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemical analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480.
If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

SAMPLE REQUIREMENTS

1. Sample Type: Fresh and non-hemolyzed serum.
2. Sample Collection: Approximately 3mL of venous blood is routinely collected and placed in a test tube. After sample collection, it is immediately sealed and sent for testing.
3. Serum Separation: After blood collection, separate the serum promptly to avoid hemolysis.
4. Sample Interference: Samples that interfere with the reaction's absorbance, including hemolyzed and lipemic samples, can affect the test results. In such cases, it is recommended to recollect the samples. Samples with hemoglobin ≤ 100 mg/dL, ascorbic acid ≤ 200 mg/dL, and bilirubin ≤ 20 mg/dL do not interfere with the measurement.
5. Perform the serum separation and testing promptly. Store at 4°C for no more than 48 hours.

TEST PROCEDURE

1. Test conditions: (System parameters of the applicable instruments are available upon request from our company.)

Primary/secondary wavelengths	480nm/700 nm	**Cuvette light diameter**	1 cm
Reagent	300 μL	**Sample**	3 μL
Reaction type	End-point method	**Calibration method**	Two-point calibration
Direction of reaction	Upward		

Operating procedures:

Sample	3 μL
Reagent	300 μL
Mix well, keep warm at 37°C for 5 min, zero the reagent with water as a blank, and record the absorbance value A.	

2. Calibration procedure: A calibrator from Getein is recommended, and a calibration serum from Randox can also be used.
3. Quality control procedure: A composite quality control serum from Getein is recommended, and a quality control serum from Randox can also be used. and its measured value should be within the range of its label claim.
4. Result calculation
   Chlorine Concentration (mmol/L) = Concentration of Chlorine Standard Reference Material (SRM) × $\triangle A_{test\ sample} / \triangle A_{SRM}$

REFERENCE RANGE

(97-108) mmol/L is normal.
The above reference range is only a guideline. Each laboratory should establish its own reference range.

INTERPRETATION OF TEST RESULTS

1. If the results exceed the linear range, the sample should be diluted 1:1 with pure water, and the test result should be multiplied by 2.
2. Professional personnel are responsible for reviewing the test results. Test results may be influenced by factors such as the age, gender, and weight of the individual being tested. Typically, if the results fall within the reference range, they are considered normal. If the results are within the borderline area, a retest for confirmation is recommended. If the results significantly exceed the reference range or remain abnormal after confirmation testing, it is considered an anomaly in the target content in the serum. If the test results appear to be inconsistent or contradictory with the clinical condition, a thorough analysis should be conducted to identify the reasons.

LIMITATIONS

There is no interference with measurement when hemoglobin is ≤ 100 mg/dL, ascorbic acid ≤ 200 mg/dL, and bilirubin ≤ 20 mg/dL.

PERFORMANCE CHARACTERISTICS

1. Appearance
   The reagent is light-yellow clear solution. There are possibly some undissolved small particulates that does not interfere the test result.
2. Reagent blank absorbance
   Reagent blank absorbance A_{480nm} ≤ 0.800.
3. Accuracy
   When test reference material, the relative deviation should be within ± 15.0%.
4. Linear Range
   4.1 Linear correlation coefficient (r) should be ≥ 0.990 in the range of [70, 150] mmol/L.
   4.2 Linear deviation:
   When test a sample with concentration of [70, 100] mmol/L, the deviation should be within ± 10 mmol/L.
   When test a sample with concentration of (100, 150] mmol/L, the deviation should be within ± 10%.
5. Analytical sensitivity
   When a sample has a concentration of 70 mmol/L, its absorbance should be ranged from 0.3 to 0.7.
6. Precision
   6.1 Repeatability (within-run precision)
   CV should not be larger than 4.0%.
   6.2 Between-run precision
   Between-run precision should not be greater than 6.0%.

PRECAUTIONS

1. General precautions
   1.1 This product is for *in vitro* diagnostic use only.
   1.2 For clinical diagnosis, please make a comprehensive judgment based on the measurements, clinical symptoms and other findings.
   1.3 Please use this product according to the IFU.
2. Precautions for operation
   2.1 Treat the specimens as dangerous materials that may cause infection with HIV, HBV, HCV, etc. Please use disposable gloves to avoid or reduce the associated risk for infection.
   2.2 If the reagents get into the eyes or mouth, or touch the skin, rinse them quickly and thoroughly with water, and receive medical
   treatment from a doctor when necessary.
   2.3 Avoid hemolysis as much as possible during operation.
3. Precautions for use
   3.1 Please store the reagents according to the storage method, and avoid freezing. Please do not use frozen reagents whose quality may change.
   3.2 Please do not use expired reagents whose test results may be inaccurate.
   3.3 Please avoid adding reagents halfway during a test.
   3.4 Please avoid direct sunlight during operation.
   3.5 Do not use the reagents with visible signs of turbidity.
4. Precautions for waste disposal
   Samples, waste liquids, etc. are potentially biologically hazardous. Operators should comply with the SOP for laboratory safety and dispose of waste liquids in accordance with local regulations for medical waste, infectious waste, industrial waste, etc.
5. Other precautions
   5.1 On a fully automatic biochemistry analyzer, the linearity range is related to the ratio of the amount of a sample to the amount of a reagent and the time of measurement.
   5.2 The amounts of the reagent and sample can be changed proportionally according to the requirements of different instruments.
   5.3 Please do not use the reagent bottles for other purposes.
   5.4 A result calculated with the k value is not as reliable as that obtained using the SRM (calibrator).
   5.5 Please do not mix reagents in different batches.

REFERENCE

1. N. Tietz. Textbook of Clinical Chemistry, p. 1841.W.B. Sauder4s Company, Philadephia. (1986).
2. S. Kimura, S. Iyama, Y. Yamaguchi, S. Hayashi, R.Fushimimi and N. Amino. Ann. Clin.
3. Biochem(1997),34:384-388.
4. CSMLS: Clinical Laboratory Information Guide.1997,4:10.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on Cl Reagent Kit (Thiocyanate Colorimetric Method) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used					
	Manufacturer		Use-by date	REF	Catalogue number
	Date of manufacture	LOT	Batch code		Temperature limit
IVD	*In vitro* diagnostic medical device		Keep away from sunlight		Biological risks
	Consult *instructions for use* or consult electronic *instructions for use*		Do not use if package is damaged and consult *instructions for use*	EU REP	Authorized representative
CE	CE mark		This way up		Do not re-use

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