CE IVD

NA Reagent Kit (Enzymatic Method)

Instructions for Use

REF CC1064

PRODUCT NAME

NA Reagent Kit (Enzymatic Method)

PACKAGE SPECIFICATION

R1: 1×15 mL	R2: 1×5 mL	R1: 1×30 mL	R2: 1×10 mL
R1: 1×30 mL	R2: 1×12 mL	R1: 1×33 mL	R2: 1×13 mL
R1: 1×45 mL	R2: 1×15 mL	R1: 1×60 mL	R2: 1×20 mL
R1: 2×15 mL	R2: 1×10 mL	R1: 2×30 mL	R2: 1×20 mL
R1: 2×30 mL	R2: 2×10 mL	R1: 2×45 mL	R2: 2×15 mL
R1: 2×45 mL	R2: 2×20 mL	R1: 2×55 mL	R2: 2×20 mL
R1: 2×60 mL	R2: 1×40 mL	R1: 2×60 mL	R2: 1×45 mL
R1: 2×60 mL	R2: 2×20 mL	R1: 2×90 mL	R2: 1×60 mL
R1: 2×90 mL	R2: 2×30 mL	R1: 2×120 mL	R2: 2×40 mL
R1: 3×40 mL	R2: 3×15 mL	R1: 3×45 mL	R2: 3×15 mL
R1: 3×60 mL	R2: 1×60 mL	R1: 3×60 mL	R2: 3×20 mL
R1: 4×30 mL	R2: 2×20 mL	R1: 4×45 mL	R2: 2×30 mL
R1: 4×45 mL	R2: 4×15 mL	R1: 4×55 mL	R2: 4×20 mL
R1: 4×60 mL	R2: 2×40 mL	R1: 4×60 mL	R2: 2×45 mL
R1: 4×60 mL	R2: 4×20 mL	R1: 4×90 mL	R2: 2×60 mL
R1: 4×651 mL	R2: 4×230 mL	R1: 6×13.5 mL	R2: 6×4.3 mL
R1: 6×54 mL	R2: 6×20 mL	R1: 6×250 mL	R2: 6×97 mL
R1: 8×60 mL	R2: 8×20 mL	R1: 12×4.2 mL	R2: 6×2.9 mL
R1: 24×3.8 mL	R2: 12×2.6 mL	150 T (R1: 1×20 mL R2: 1×6 mL)	
2×100 T (R1: 2×15 mL R2: 2×5 mL)			
2×260 T (R1: 2×65 mL R2: 2×21 mL)			
2×260 T (R1: 2×70 mL R2: 2×21 mL)			
6×52 T (R1: 6×16.8 mL R2: 6×5.8 mL)			
12×52 T (R1: 12×16.8 mL R2: 12×5.8 mL)			

INTENDED USE

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

TEST PRINCIPLE

Sodium is detected through the enzymatic kinetic reaction of the substrate ONPG catalyzed by sodium-dependent β-galactosidase, and the absorbance value of its product, O-nitrophenol, at 405 nm is directly proportional to the concentration of sodium.

MAIN COMPONENTS

Kit composition	Reagent components	Content
Reagent 1	Trimethylolaminomethane	450 mmol/L, pH9.0
	β-galactosidase	0.8 U/mL
	18-Crown -6	5.4 mmol/L
Reagent 2	Trimethylolaminomethane	10 mmol/L, pH9.0
	O-Nitrophenol galactoside	5.5 mmol/L

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

STORAGE AND SHELF LIFE

The unopened reagents are stable for a shelf life of 18 months in the dark at 2-8°C. Opened reagents are stable for 30 days at 2-8°C.
Refer to the label on the reagent kit for the manufacturing date and the expiry 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 3 mL of blood is routinely collected from a vein and placed in a test tube. After sample collection, it is immediately sealed and sent for testing.
3. Serum should be separated in time after blood collection to avoid hemolysis.
4. Sample interference: Samples that interfere with the absorbance of the reaction, including hemolyzed and lipemic samples, may affect the test results. In the above cases, it is recommended to recollect the sample. Bilirubin ≤ 665.125 μmol/L, Hb ≤ 10 g/L, TG ≤ 13.183 mmol/L in the sample will not interfere with this test.
5. Serum samples should be tested promptly, and stored at 4°C for no more than 48 h.

TEST PROCEDURE

1. Dual reagents are used directly without preparation.
2. Test conditions: (Different load parameters can be requested based on different testing instruments)

Primary Wavelength	405 nm	**Sample**	6 μL
Secondary wavelengths	660 nm	**Reagent 1**	180 μL
Reaction temperature	37˚C	**Reagent 2**	60 μL
Cup light path	1 cm	**Method**	Two-point Rate Method
Calibration Method	Two-point calibration	**Direction**	Upward

3. Operating procedures:

Substances Added	Calibration Tube	Test Tube
Reagent 1	180 μL	180 μL
Calibrator	6 μL	-
Sample	-	6 μL
Mix well, incubate at 37°C for 5min		
Reagent 2	60 μL	60 μL
Mix well, incubate at 37°C for 1 min, and read the absorbance (A_1); then incubate for 2 min, and read the absorbance (A_2), calculate the change in absorbance ΔA/min.		

4. Calibration procedure: Use the calibrator that matches the reagent kit, and assign values by comparing it with the calibrator from Randox. Calibration should be performed every day.
5. Quality control procedure: Select quality control serum from reagent kit, and its measured value should be within the range of its label claim.
6. Result calculation
   Sample Concentration = (Sample△A/min) / (Calibration△A/min) × Calibration concentration

REFERENCE RANGE

136.0-146.0 mmol/L
The above reference range is only a guideline. Each laboratory should establish its own reference range.

RESULT INTERPRETATION

Professionals are responsible for the review and analysis of the test results. The test results, which are influenced by age, gender, diet, and region, are usually considered normal within the reference range. If they exceed the range, retesting should be done for confirmation. If the test results are inconsistent with or even contrary to the clinical situation, the cause should be analyzed and identified.

LIMITATIONS

There is no interference with measurement when bilirubin ≤ 665.125 μmol/L, Hb ≤ 10 g/L, TG ≤ 13.183 mmol/L.

PERFORMANCE CHARACTERISTICS

1. Appearance
   R1 is colorless and clear solution. R2 is light-yellow and clear solution. There are possibly undissolved particulates in the solution, which do not interfere the test result.
2. Reagent blank
   Reagent blank absorbance $A_{405\,nm} \leq 0.500$.
   Reagent blank absorbance change rate $|\triangle A_{405\,nm}|$ /min ≤ 0.500.
3. Accuracy
   The relative deviation should be within ±15.0%.
4. Linear Range
   Test serum samples with reagents within the linear range of [80,180] mmol/L;
   a) The linear correlation coefficient (r) should not be less than 0.9900;
   b) Within the range of [80,180] mmol/L, the linear deviation should not exceed ±10%.
5. Analytical sensitivity
   When a sample has a concentration of 160.0 mmol/L, its absorbance difference is between 0.0003-0.0031.
6. Precision
   6.1 Within-run precision
   Within-run precision should not be greater than 5.0%.
   6.2 Between-run precision
   Between-run precision should not be greater than 10.0%.

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 Hemolysis should be avoided as much as possible during the operation process.
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 When the sample is cloudy or too high to exceed the standard curve, it is determined by diluting with purified water and multiplying the result by the dilution factor
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 Fixed-value serum can be dispensed in small tubes, sealed and stored at 4°C. Fixed-value serum cannot be repeatedly frozen or thawed.
   5.5 A result calculated with the k value is not as reliable as that obtained using the SRM (calibrator).
   5.6 Please do not mix reagents in different batches.

REFERENCE

1.Berry, M. N. et al., (1988) Clin. Chem. 34,2295.
2.Tietz, N. W. (1983) Clinical guide to Laboratory Tests, p384 W.B. Saunders Co., Philadelphia.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on NA Reagent Kit (Enzymatic 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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