Instruction for Electrolyte Reagents (ISE, Pressure Method)

【Product Name】

Electrolyte Reagents

【Package Specification】

Packaging specifications are shown in Table 1 (Unit: mL) :

Table 1

Type	STD A	STD B	STD C	CO_2 STD	Buffer	REF
DS-Ⅰ（NO.1）	400	90	0	0	0	42033001
DS-Ⅰ（NO.2）	390	160	0	0	0	42034001
DS-Ⅰ（NO.3）	390	160	0	0	0	42035001
DS-Ⅰ(AB buffer)	390	80	0	0	80	42036001
DS-Ⅱ（NO.1）	400	90	0	0	0	42037001
DS-Ⅱ（NO.2）	390	160	0	0	0	42038001
DS-Ⅱ(NO.3)	390	160	0	0	0	42039001
DS-Ⅱ(AB buffer)	390	80	0	0	80	42040001
DS-Ⅲ（NO.3）	390	80	80	0	0	42041001
DS-Ⅳ（NO.3）	390	80	80	0	0	42042001
DS-Ⅴ	0	0	0	50	0	42043001
DS-C	0	0	400	0	0	42044001
GE-1	750	250	700	0	0	42047001
GE-2	750	250	0	0	0	42048001
GE-3	600	200	0	0	0	42049001
GE-4	600	200	600	0	0	42050001
GE-5	500	150	0	0	0	42051001
GE-6	500	150	500	0	0	42052001
GE-7	400	120	0	0	0	42053001
GE-8	400	120	400	0	0	42054001
GE-9	300	90	0	0	0	42055001
GE-10	300	90	300	0	0	42056001
DS-ISE	0	0	0	0	0	42045001
DS-Ref	0	0	0	0	0	42046001

【Intended Use】

It can be used with Electrolyte Analyzers by professionals, for the detection of potassium (K^+), sodium (Na^+), chloride (Cl^-), calcium (Ca^{2+}), magnesium (Mg^{2+}), lithium (Li^+), pH (pH value) and TCO_2 concentration in human serum. In addition, GE-1 and GE-2 also can concentration in human blood and urine.

【Test Principle】

ISE method: Use ISE (Ion Selective Electrode) technology to measure K^+, Na^+, Cl^-, Ca^{2+}, Li^+, Mg^{2+} and pH in the sample. Test Standard A and B respectively to obtain two electrode potentials of known concentrations, and establish a calibration curve in the instrument programmed by these two potentials. Measure the electrode potential of sample with unknown concentration and then calculate ion concentration (mmol/L) of unknown samples from the established calibration curve.

Pressure method: Compare the pressure value obtained by the reaction of Standard C and sample with that of Standard C and TCO_2 solution, to obtain TCO_2 content in the sample by calculation.

【Main Compositions】

Standard A: K^+ : 1.1%, Na^+ : 57.0%, Cl^- : 40.5%, Ca^{2+} : 0.5%, Li^+ : 0.4%, Mg^{2+} : 0.5%.

Standard B: K^+ : 4.0%, Na^+ : 57.5%, Cl^- : 36.5%, Ca^{2+} : 1.3%, Li^+ : 0.3%, Mg^{2+} : 0.4%.

Standard C (weak acid) and TCO_2 solution (carbonate).

Components of test kits with different batches cannot be interchanged for use

【Accessories Required But Not Provided】

None.

【Storage and Transportation】

Storage: Ambient temperature of 2-30 °C, avoid direct sunlight.

Validity period: 24 months (sealed), 1 month (after opening).

GE-1&GE-2: 24 months (sealed), 50 days (after opening).

Please refer to the labels for production date.

【Applicable Instruments】

Applicable instruments	Test item
GE200, GE300, GE310, GE330, GE340, GE350, GE360	K^+, Na^+, Cl^-, Ca^{2+}, Li^+, pH
GE320	K^+, Na^+, Cl^-, Ca^{2+}, Li^+, pH, TCO_2
GE500	K^+, Na^+, Cl^-, Ca^{2+}, Li^+, Mg^{2+}, pH,

【Sample Requirements】

The optimum sample is non-hemolyzed fresh serum. Samples should be analyzed within 5 hour at room temperature.

Whole blood: it is recommed to use no-additive evacuated or sodium heparin evacuated specimen collection tubes for whole blood or plasma samples, Whole blood samples should be analyzed within 60 minutes at room temperature and avoid hemolysis.

Urine sample: it is required to dilute the fresh urine samples with urine diluent at 1:10 before testing.

【Test Methods】

1. Open the electrolyte analyzer's reagent room, carefully put in the corresponding reagent, connect the tubes of Standard A & B or Reagent package, and then close the reagent room.
2. Turn on the power, the system enters the main menu, select "Calibrate", the instrument automatically aspirates Standard A & B and establishes the calibration curve. After calibration, click "Measure" to aspirate sample. After calculating the concentration, the instrument displays and prints it out. It is recommended to leave the analyzer on for 24 hours.
3. When using reagents at room temperature, it takes about 30-60 seconds to test one sample, if the sample is refrigerated, bring it to room temperature before analysis.
4. Use Standard A and Standard B to perform two-point calibration.
5. Test QC to do quality control before testing samples every day to ensure the reliability of test results. QC must not contain substances that interfere with ion selective electrodes and must be accurately diluted. Mean value of test results of the QC must be within the allowable range.
6. For more instrument operations, please see the operation manual of electrolyte analyzer.

【Reference Range】

Item	Serum or Blood	Urine
K^+	3.5-5.3 mmol/L	25-125 mmol/L
Na^+	135-148 mmol/L	130-260 mmol/L
Cl^-	98-107 mmol/L	170-255 mmol/L
Ca^{2+}	1.10-1.30 mmol/L	2.7-7.5 mmol/L
Li^+	0-0.7 mmol/L	N/A
Mg^{2+}	0.7-1.1 mmol/L	3.0-4.5 mmol/L
TCO_2	22-29 mmol/L	N/A
pH	7.35-7.45	N/A

【Interpretation of Test Results】

1. Results are for clinicians' reference only. To draw a clinical conclusion, please also consider the patient's clinical symptoms and other test results.
2. Select calibrators and controls manufactured by qualified companies (such as Randox) to do calibration and quality control.

【Limitations of Test Method】

1. Using plasma that contains EDTA, heparin, sodium citrate and oxalate will result in increased sodium concentration and decreased calcium concentration in test results.
2. Sodium azide, salicylic acid and other drugs can cause increase in the chlorine concentration in test results.
3. ISE method can be used to measure ionized calcium only, total calcium cannot be measured directly (as concluded by test summary and technical exchange meeting). Diagnosis and treatment cannot rely on this test result only, but need to take the clinical history and other laboratory test results into account.

【Performance Indicators】

1. Analytical sensitivity

Minimum detection limit of Standard C ≤ 1.41mmol/L

2. Linearity range

Linear regression coefficient of Standard A, B, C: r≥0.990

Linearity shall comply with requirements in Table 2.

3. Measurement range

Testing diluented urine range shall comply with requirements in Table 3.

4. Precision, Accuracy, Difference between batches

When testing control material, calibrator, certified reference serum with electrolyte reagents, the precision, accuracy, difference between batches of each item should be consistent with requirements in Table 2&3.

Table 2 Performance for serum and whole blood

Item	Linearity range	Accuracy (B)	Precision	Difference between batches
K^+	1.5-7.5mmol/L	≤2.0%or ≦0.15mmol/L	CV ≦1.5% o SD ≦0.0	≤0.5mmol/L
Na^+	100-180mmol/L	≤2.0%or ≦0.15mmol/L	CV ≦1.5% o SD ≦1.5m	≤10mmol/L
Cl^-	80-160mmol/L	≤2.0%or ≦0.15mmol/L	CV ≦1.5% o SD ≦1.5mmol/L	≤10mmol/L
iCa^{2+}	0.5-2.5mmol/L	≤2.5%or ≦0.12mmol/L	CV ≦1.5% o SD ≦0.0	≤0.3mmol/L
Li^+	0.5-2.5mmol/L	≤2.5%or ≦0.12mmol/L	CV ≦1.5% o SD ≦0.0	≤0.3mmol/L
Mg^{2+}	0.5-2.5mmol/L	≤2.5%or ≦0.12mmol/L	CV ≦1.5% o SD ≦0.0	≤0.3mmol/L
pH	6.8-7.6	≤2.0%	≤1.5%	≤0.15
CO_2	10-60mmol/L	≤2.0%	≤1.5%	≤3.0

Table 3 Performance for diluented urine

Item	Measurement range	Accuracy (B)	Precision (CV)	Difference between batches
K^+	1-500 mmol/L	≤10.0%	≤5.0%	≤10mmol/L
Na^+	25-1000 mmol/L	≤10.0%	≤5.0%	≤20mmol/L
Cl^-	25-500 mmol/L	≤10.0%	≤5.0%	≤20mmol/L
iCa^{2+}	0.5-40.0 mmol/L	≤10.0%	≤5.0%	≤1.5mmol/L
Mg^{2+}	0.5-40.0 mmol/L	≤10.0%	≤5.0%	≤1.5mmol/L

【Precautions】

1. The product should be used within its validity period, not mixed up with toxic, corrosive or contaminated goods. Stop using it if the package is damaged, or the solution is cloudy, moldy or precipitated.
2. Ensure that all electrodes are immersed in Standard A & B when perform the calibration.
3. Keep remaining reagents under seal for the pH and ions may change when exposed to the air.
4. Avoid skin contact. Wear gloves when operating.
5. If the reagent is carelessly spattered onto the skin, eyes, etc., flush with clean water immediately, and if mistakenly swallowed, seek medical advice.
6. Waste from clinical use of this product should be disposed of in accordance with the relevant provisions of medical wastes.
7. Do not mix different batches of reagents.
8. Do not use the solution when package is damaged.

【Icon Illustration】

【Training information】

Please refer to the training manual.

【Help information】

If you need help please contact after sales.

【Trouble shooting】

Please contact after sales.

【References】

1. Huang Ziqing. Introduction to the theory of electrolyte solution. Science press, 1983.08.
2. Adrian Schreiber. Charite Universitats medizin Berlin. Solving electrolyte disturbances with the Ehrlich reagent. HELIOS Klinikum Berlin, Franz Volhard Clinic, Berlin, Germany.
3. Nephrology Dialysis Transplantation (Impact Factor: 3.37). 07/2003, 18(6): 1217-9.
4. REN Biqiong, XU Guofeng, ZOU Guoying, ZHANG Yu, YU Qihua. Department of Clinical Laboratory, Hunan Province Second People's Hospital, Assessment of the effect of self-made electrolyte reagent in the electrolyte system of Dimension AR analyzer. Hunan Changsha 410007, China. Laboratory medicine 2006.06.
5. United States Patent 6387646. Inventors: Kimata, Shinsuke (Tsuruga, JP), Mizuguchi, Katsuhiko (Tsuruga, JP), Kawamura, Yoshihisa (Tsuruga, JP). Reagent compositions for measuring electrolyte. Publication Date. 05.14.2002.
6. National Guide to Clinical Laboratory Procedures (Third Edition). Department of Medical Administration in People's Republic of China. Ye Yingwu, etc., 2006.11.

【Manufacturer】

Genrui Biotech Inc.

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【Medical Device Manufacturing Enterprise Permit Number】

GuangDong SFDA(State Food and Drug Administration) authorized Medical Device Manufacturing Permit No. 20041046.

【Guarantee and Technical Support】

If invalid message repeats or need technical support, please contact Genrui Customer Service and Support Center.

【Instruction Approved and Revised Dates】

Approved date: November 6th 2015

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	Consult Instructions for use		Main component
LOT	Batch code	REF	Catalogue number
	Temperature limit		Humidity limit
	Date of manufacture		Use-by date
	Manufacturer	CE	CE Marking
EC REP	Authorized representative in the European Community	IVD	In vitro diagnostic medical device
	Keep away from sunlight		Keep dry
	Contains sufficient for <n>tests		Volume
	Biological risks		