

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 (Ca²⁺), magnesium (Mg²⁺), lithium (Li⁺), pH (pH value) and TCO₂ 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⁻, Ca²⁺, Li⁺, Mg²⁺ 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 TCO₂ solution, to obtain TCO₂ content in the sample by calculation.

【Main Compositions】

Standard A: K⁺ : 1.1%, Na⁺ : 57.0%, Cl⁻ : 40.5%, Ca²⁺ : 0.5%, Li⁺ : 0.4%, Mg²⁺ : 0.5%.

Standard B: K⁺ : 4.0%, Na⁺ : 57.5%, Cl⁻ : 36.5%, Ca²⁺ : 1.3%, Li⁺ : 0.3%, Mg²⁺ : 0.4%.

Standard C (weak acid) and TCO₂ 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

85% at or below 20°C.

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】

- 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.
- 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.
- 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.
- Use Standard A and Standard B to perform two-point calibration.
- 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.
- 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】

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

【Limitations of Test Method】

- Using plasma that contains EDTA, heparin, sodium citrate and oxalate will result in increased sodium concentration and decreased calcium concentration in test results.
- Sodium azide, salicylic acid and other drugs can cause increase in the chlorine concentration in test results.
- 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】

- Analytical sensitivity

Minimum detection limit of Standard C $\leq 1.41\text{mmol/L}$

2. Linearity range

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

Linearity shall comply with requirements in Table 2.

3. Measurement range

Testing diluted 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 | $\leq 2.0\%$ or $\leq 0.15\text{mmol/L}$ | CV $\leq 1.5\%$ SD ≤ 0.0 | $\leq 0.5\text{mmol/L}$ |
| Na ⁺ | 100-180mmol/L | $\leq 2.0\%$ or $\leq 0.15\text{mmol/L}$ | CV $\leq 1.5\%$ SD $\leq 1.5\text{mmol/L}$ | $\leq 10\text{mmol/L}$ |
| Cl ⁻ | 80-160mmol/L | $\leq 2.0\%$ or $\leq 0.15\text{mmol/L}$ | CV $\leq 1.5\%$ SD $\leq 0.15\text{mmol/L}$ | $\leq 10\text{mmol/L}$ |
| iCa ²⁺ | 0.5-2.5mmol/L | $\leq 2.5\%$ or $\leq 0.12\text{mmol/L}$ | CV $\leq 1.5\%$ SD ≤ 0.0 | $\leq 0.3\text{mmol/L}$ |
| Li ⁺ | 0.5-2.5mmol/L | $\leq 2.5\%$ or $\leq 0.12\text{mmol/L}$ | CV $\leq 1.5\%$ SD ≤ 0.0 | $\leq 0.3\text{mmol/L}$ |
| Mg ²⁺ | 0.5-2.5mmol/L | $\leq 2.5\%$ or $\leq 0.12\text{mmol/L}$ | CV $\leq 1.5\%$ SD ≤ 0.0 | $\leq 0.3\text{mmol/L}$ |
| pH | 6.8-7.6 | $\leq 2.0\%$ | $\leq 1.5\%$ | ≤ 0.15 |
| CO ₂ | 10-60mmol/L | $\leq 2.0\%$ | $\leq 1.5\%$ | ≤ 3.0 |

Table 3 Performance for diluted urine

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

【Precautions】

- 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.
- Ensure that all electrodes are immersed in Standard A & B when perform the calibration.
- Keep remaining reagents under seal for the pH and ions may change when exposed to the air.
- Avoid skin contact. Wear gloves when operating.
- If the reagent is carelessly splattered onto the skin, eyes, etc., flush with clean water immediately, and if mistakenly swallowed, seek medical advice.
- Waste from clinical use of this product should be disposed of in accordance with the relevant provisions of medical wastes.
- Do not mix different batches of reagents.
- 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】

- Huang Ziqing. Introduction to the theory of electrolyte solution. Science press, 1983.08.
- Adrian Schreiber. Charite Universitats medizin Berlin. Solving electrolyte disturbances with the Ehrlich reagent. HELIOS Klinikum Berlin, Franz Volhard Clinic, Berlin, Germany.

- Nephrology Dialysis Transplantation (Impact Factor: 3.37). 07/2003, 18(6): 1217-9.
- 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.
- 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.
- National Guide to Clinical Laboratory Procedures (Third Edition). Department of Medical Administration in People's Republic of China. Ye Yingwu, etc., 2006.11.

【Manufacturer】

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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

Revised date: October 20th 2017



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