

[Intended Use]

The i-Smart 30 PRO Cartridge E4 is a reagent for the i-Smart 30 PRO Electrolyte Analyzer intended to be used for the measurement of electrolyte concentrations (Na⁺, K⁺, Cl⁻, Ca²⁺) in whole blood samples, serum, plasma or urine by the use of electrochemical potential (ion-selective electrode) and conductivity measurement methods.

The i-Smart 30 PRO Cartridge E4 is intended for *in vitro* diagnostic use and for professional use only.

[How to Use]

For more details, please refer to the i-Smart 30 PRO Electrolyte Analyzer's operator's manual.

1. Specimen collection and handling

[Whole Blood]

- Use heparinized whole blood sample.
- Whole blood samples should be analyzed within 15 minutes. If a storage is required for a brief period, the sample should be stored under ice baths in a tightly capped container up to 30 minutes. The cooled sample needs to be allowed to return to room temperature prior to analysis.

[Serum]

- After a complete clot formation, transfer the separated serum (clear liquid) to a clean container.
- The sample should be refrigerated in a tightly capped container and allowed to return to room temperature prior to analysis.

[Plasma]

- Clear plasma should be obtained by centrifuging to remove formed elements from the heparin treated whole blood. Transfer the separated plasma to a clean container.
- Store tightly capped specimen containers in the refrigerator. Allow them to return to room temperature prior to analysis. In case formed elements such as fibrin occur, remove them by centrifuging.

[Urine]

- Urine samples can be analyzed without dilution. Pure urine samples should be used.
- When the urine sample cannot be analyzed right after the collection, the sample must be kept under refrigeration. The sample must be brought back to a room temperature for the analysis.

2. Preanalytical Preparation

- 1) Preparation of the analyzer
 - i-Smart 30 PRO Electrolyte Analyzer (medical device electrochemical potential ion-selective electrode analyzer)
- 2) Reagent
 - Remove the cartridge from the packaging.
 - Remove the cartridge cover.
 - Install the cartridge to the analyzer.
 - Wait until the cartridge warm up cycle is finished.

3. Analyzing Procedure

- 1) Check the Ready status of the analyzer.
- 2) Lift the sampler cover. Position the sampler probe into the sample.
- 3) Ensure the tip of the probe is fully immersed in the sample. Then press the "Aspirate" or "START ASPIRATION" button.
- 4) When the aspiration is completed, remove the sample container from the probe.
- 5) When prompted by the analyzer, close the sampler cover. The analysis will start.

4. Result Report

Measurement values of analyzed specimens will be calculated automatically upon completion when the measurement has been performed normally.

<Reference Ranges>

The following tables of reference ranges for healthy adults are provided for information. Each facility may define their own limits that are applicable for their institutions.

| Parameter | Unit | Blood Reference Range | Urine Reference Range |
|------------------|--------|-----------------------|-----------------------|
| Na ⁺ | mmol/L | 136 ~ 145 | 40 ~ 220 |
| K ⁺ | mmol/L | 3.5 ~ 5.1 | 25.0 ~ 125.0 |
| Cl ⁻ | mmol/L | 98 ~ 107 | 110 ~ 250 |
| Ca ²⁺ | mmol/L | 1.15 ~ 1.33 | - |

Reference:

TIETZ, Fundamentals of Clinical Chemistry. 6th ed. 2008

5. Quality Control

- 1) Perform Quality Control in accordance with local regulations or guidelines.
- 2) The i-Smart Electrolyte Quality Control is recommended for performing quality control.

[Safety Instructions]

- For *in vitro* diagnostic use and for professional use only.
- Use only with the i-Smart 30 PRO Electrolyte Analyzer. It is not designed to be used with any other analyzers.
- Comply with general guidelines required by clinics and laboratories.
- Dispose of potential biohazard materials in accordance with required biohazard control procedures or regulations.
- Blood specimens, collection devices and cartridges exposed to blood product samples must be handled as biohazards.
- Wear personal protective equipment (safety glasses, gloves, and lab coats) to avoid direct contact with biohazards. Keep them away from your mouth, eye, mucosa, superficial cuts or wounds.
- Wash your hands after handling specimen, analyzer or cartridges.
- Cartridges must be installed immediately after opening.
- Do not use expired cartridges.
- Do not reuse used cartridges.
- Avoid strong impact on cartridges.
- Do not attempt to disassemble, repair or modify cartridges.

[Composition]

1. Cal 1 Solution (410 mL)
 - Aqueous solution containing biological buffers, salts, preservative and surfactant
 - Na⁺: 145 mmol/L, K⁺: 4.3 mmol/L, Cl⁻: 124 mmol/L, Ca²⁺: 1.10 mmol/L
2. Cal 2 Solution (55mL)
 - Aqueous solution containing biological buffers, salts, preservative and surfactant
 - Na⁺: 101 mmol/L, K⁺: 7.4 mmol/L, Cl⁻: 84 mmol/L, Ca²⁺: 0.30 mmol/L
3. Reference Solution (40mL)
 - Glycerol: 1000 g/L
 - Surfactant: 15 g/L
 - Ammonium chloride: 1000 mmol/L

[Storage Condition and Lifespan]

| Cartridge Package | Required Storage Condition | Use Until |
|-------------------|----------------------------|----------------------------------|
| Unopened | 10 ~ 30 °C | 12 months from manufactured date |
| Opened | Installed | 4 weeks from installation |

* Expiration date: Printed on the packaging

[Performance]

For Whole blood/Serum/Plasma

| Parameter | Measuring Range | Resolution |
|------------------|--------------------|-------------|
| Na ⁺ | 20 ~ 250 mmol/L | 1 mmol/L |
| K ⁺ | 0.5 ~ 20.0 mmol/L | 0.1 mmol/L |
| Cl ⁻ | 20 ~ 250 mmol/L | 1 mmol/L |
| Ca ²⁺ | 0.25 ~ 5.00 mmol/L | 0.01 mmol/L |

For Urine

| Parameter | Measuring Range | Resolution |
|-----------------|--------------------|------------|
| Na ⁺ | 10 ~ 400 mmol/L | 1 mmol/L |
| K ⁺ | 1.0 ~ 120.0 mmol/L | 0.1 mmol/L |
| Cl ⁻ | 10 ~ 400 mmol/L | 1 mmol/L |

[Packaging Unit] Printed on the packaging



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