FUJIFILM

Use after reading this "Instructions for Use"

IVD

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Blood test for electrolytes (Na^+, K^+, Cl^-)

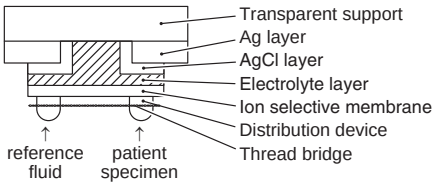
FUJI DRI-CHEM SLIDE Na-K-Cl

[Warnings and precautions]

1. Only the required number of slides should be taken out of the refrigerator and warmed up to room temperature before opening the individual packages.
2. Do not touch the thread bridge part.
3. A new slide must be used for each measurement. Do not reuse.
4. Handle all patient specimens, control serum and used tips carefully as biohazardous samples. Wear proper gloves, glasses and other protective gear for your safety.
5. Used slides are categorized as infectious waste. Make sure to dispose them in accordance with the Waste Disposal Law and other related regulations, which prescribe the proper method of disposal, such as incineration, melting, sterilization or disinfection.
6. The reference fluid may condense without a cap. Re-cap after each measurement.

[Composition of the slide]

1. Multi-layered structure



2. Ingredients per slide

• Common to Na, K, Cl	Silver	0.50 mg
	Silver chloride	0.26 mg
• Na	NaCl	0.52 mg
	Methyl monensin	0.31 mg
• K	NaCl	0.51 mg
	Valinomycin	0.14 mg
• Cl	Tri-alkyl ammonium chloride	0.95 mg

[Intended use]

Quantitative measurement of sodium, potassium and chloride ion concentration in whole blood, plasma or serum.
For *in vitro* diagnostic use only.

[Principle of the measurement]

50 µL of reference fluid and 50 µL of whole blood, plasma or serum is deposited on a FUJI DRI-CHEM SLIDE Na-K-Cl at the same time on the reference side and the sample side respectively. After depositing, the reference fluid and the specimen spread along the distribution device and also towards each other on the special thread bridge to form a stable ionic junction. A differential potential is generated between the two half-cells. The potential difference is proportional to the logarithm of each ion concentration ratio of the two fluids. The slide is incubated for a fixed time in the FUJI DRI-CHEM ANALYZER and the potentiometric difference between the reference and the specimen is measured. The potentiometric value is then converted into each of the electrolyte's concentration using a calibration curve preinstalled in the analyzer.

[Additional special equipment]

Analyzer: FUJI DRI-CHEM ANALYZER
Other implements: FUJI DRI-CHEM REFERENCE FLUID RE
: FUJI CLEAN TIPS or FUJI AUTO TIPS
: FUJI HEPARIN/PLAIN TUBE or Blood collection tube specified in the "INSTRUCTION MANUAL" for FUJI DRI-CHEM ANALYZER

[Specimen requirements]

1. Heparin can be used as anticoagulant. When using heparin, less than 10 units of heparin-Na or less than 50 units of heparin-Li should be used per 1 mL of whole blood. Do not use EDTA salt, sodium fluoride, citric acid, oxalic acid and monoiodoacetic acid.
2. Measure the specimen immediately after blood drawing. When specimens are to be left standing, take the following care.
   a) Keep the specimen at room temperature. Potassium concentration deviates higher when the blood sample is cooled in a refrigerator.
   b) It is recommended to measure the specimen within one hour.
   c) Swirl the specimen tube gently prior to the measurement.
3. Avoid using plasma or serum with precipitate such as fibrin.
4. Do not use hemolytic plasma or serum.
5. When measuring a specimen from a patient administered with medicines containing bromide or iodide, the effect of the halide should be taken into consideration.

[Procedure]

1. Set slides on FUJI DRI-CHEM ANALYZER.
2. Set a sample tube in the specified sample rack.
3. Set the reference fluid in the specified position.
4. Input a sequence No. and a sample ID if appropriate.
5. Press the "START" key to initiate testing.
   For further details of operation procedure, consult "INSTRUCTION MANUAL" for FUJI DRI-CHEM ANALYZER.

[Reference interval]

Blood

Na: 136–149 mmol/L
K: 3.8–5.0 mmol/L
Cl: 98–106 mmol/L

As the reference intervals depend on the population of the test, it is required that each laboratory set its own reference intervals. The clinical diagnosis must be made by the doctor in charge based on the measured results in the light of clinical symptoms and other test results.

[Performance characteristics]

1. Dynamic range

	Whole Blood, Plasma, Serum
Na	75–250 (mmol/L)
K	1.0–14.0 (mmol/L)
Cl	50–175 (mmol/L)

2. Accuracy

	Concentration range	Accuracy
Na	75–250 (mmol/L)	Within ±8 mmol/L
K	1.0–14.0 (mmol/L)	Within ±0.8 mmol/L
Cl	50–175 (mmol/L)	Within ±10 mmol/L

3. Precision

	Concentration range	Precision
Na	75–250 (mmol/L)	CV ≦ 5 %
K	1.0–4.0 (mmol/L) 4.0–14.0 (mmol/L)	SD ≦ 0.2 mmol/L CV ≦ 5 %
Cl	50–175 (mmol/L)	CV ≦ 5 %

4. Correlation

Correlation was evaluated between flame photometry (Na, K) or coulometry (Cl) methods and FUJI DRI-CHEM system. Flame photometry (Na, K) and coulometry (Cl) methods were run on each of the analyzer. This examination was carried out at the laboratory of FUJIFILM Corporation.

Na	n	Slope	Intercept	Correlation coefficient
Blood	55	0.957	7.56	0.997
Plasma/Serum	55	0.931	10.2	0.996

K	n	Slope	Intercept	Correlation coefficient
Blood	55	1.035	0.06	0.998
Plasma/Serum	55	1.045	-0.15	0.999

Cl	n	Slope	Intercept	Correlation coefficient
Blood	55	0.938	1.771	0.997
Plasma/Serum	55	0.992	-0.91	0.997

5. Known interfering substances

(1) Cationic surfactants as benzalkonium chloride and alcohols give plus bias.
(2) Br^- or I^- contained in a specimen may affect the Cl^- data.
Be aware of this when analyzing specimens from patients who are taking medicines containing Br^- or I^-.
(3) Specimen from a patient overdosed with aspirin, may show plus bias of the Cl^- data.

[Internal quality control]

The accuracy and precision of this product can be evaluated with FUJI DRI-CHEM CONTROL QE.

1. Measure FUJI DRI-CHEM CONTROL QE in the same way as patient specimens.
2. When the results obtained are outside the expected range shown in the sheet attached to FUJI DRI-CHEM CONTROL QE, investigate the cause.
   For additional information, consult "Instructions for Use" for FUJI DRI-CHEM CONTROL QE.

[Traceability of calibrators and control materials]

Na, K, Cl...HECTEF IP3-6
Note: This reference material is applied to the reference method of FUJIFILM Corporation and is not directly applicable to FUJI DRI-CHEM SLIDE.
HECTEF: Health Care Technology Foundation

[Storage and shelf life]

1. Storage: This product must be stored between 2–8 °C (35.6–46.4 °F) before use.
2. Expiry date is printed on the carton.
3. Use immediately after opening the individual package.

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