EC cartridge VET

Cat. No.	Pack Name	Number of Tests
VET00002	EC cartridge VET	250

VETERINARY USE ONLY
VETERINARY TECHNICAL DEVICE

EN

INTENDED USE
Automatic analyser intended for *in vitro* quantitative determination of specific electrolytes in whole blood, serum, plasma of animals (see table below for full list). The instrument is able to determine the concentration of sodium (Na^+), potassium (K^+), ionized calcium (iCa^{2+}) and chloride (Cl^-). The results for tested electrolytes can be used for screening, monitoring and diagnosis of diseases associated with ionic imbalance as kidney disease, disorders of acid-base balance, nutritional disorders and digestive tract function. For professional use in clinical and veterinary laboratory only.

PRINCIPLE
The electrolyte sensors are potentiometric sensors which measure the potential difference between an ion--selective electrode (ISE) and a reference electrode immersed in a sample liquid. The electrochemical potential between the sample side and the solid contact of the ion-selective membrane is proportional to the concentration of the corresponding ion in the sample. These potentials are recorded, electronically amplified and calculated[1].

DESCRIPTION AND COMPOSITION
1) EC cartridge VET
Calibration solution 1:
Na^+ 150 mmol/L, K^+ 5 mmol/L, iCa^{2+} 1.25 mmol/L, Cl^- 103 mmol/L, buffer, preservative, wetting agent
Calibration solution 2:
Na^+ 105 mmol/L, K^+ 2 mmol/L, iCa^{2+} 2.34 mmol/L, Cl^- 71.1 mmol/L, buffer, preservative, wetting agent
Reference solution:
K^+ 1.2 mol/L, buffer, preservative, wetting agent
2) EC Biosensor: Cat. No. REG00064 (for ordering extra pieces)

PREPARATION
Insert EC Biosensor into the cartridge according to the EC 90 VET user manual.

MATERIAL REQUIRED BUT NOT PROVIDED WITH THE DEVICE
EC 90 VET analyser, Cat. No. VET00001
Erba Clean I. Cat. No. EHL00042
Control material: ERBA NORM 4 × 5, Cat. No. BLT00080
ERBA NORM 10 × 5, Cat. No. XSYS0123
ERBA PATH 4 × 5, Cat. No. BLT00081
ERBA PATH 10 × 5, Cat. No. XSYS0124

STABILITY AND STORAGE
Store at 2–30 °C. Note the expiration date on the labels.
On board stability: 90 days after opening. On-board stability of EC Biosensor is at least 45 days.

SPECIMEN COLLECTION AND HANDLING
Whole blood samples may be directly measured or further processed to create plasma and serum samples. Take care to prevent haemolysis in blood samples during handling and processing of specimens. Use only sample containers spray-coated with sodium heparin. Do not use EDTA or citrate as anticoagulants. This may result in incorrect measurement results.

QUALITY CONTROL
For quality control ERBA NORM and ERBA PATH are recommended. It is recommended to perform QC measurements according to your local laboratory guidelines. More information about quality control can be found in the EC 90 VET User manual.

METROLOGICAL TRACEABILITY
Traceability is ensured by testing laboratory standards according to standard EN ISO 17511:2021 against primary and secondary certified reference materials.

ASSAY PROCEDURE AND CALCULATION
1. In the analyser software, in the maintenance screen, click on CHANGE EC CARTRIDGE button. Follow instructions on the screen.
2. Unpack new cartridge, remove the cap and seal cap, insert EC Biosensor and place it in the analyser.
3. In the analyser software click the OK button. The software will detect new cartridge and perform priming automatically.
4. Calibration will be performed automatically.

The EC 90 analyser performs the evalution automatically according to Nernst equation[1]:

$$E_i = E_i^0 + \frac{R \cdot T}{Z_i \cdot F} \ln a_i$$

Where:
E_i Ion activity dependent potential
E_i^0 Standard potential
R universal gas constant
T absolute Temperature
Z_i valency of ion i
F Faraday constant
a_i activity of ion i

EXPECTED VALUES
The EC 90 VET has 13 different animals predefined – see the table below. For some of these animals, expected values are set according to the The Merck Veterinary Manual, 11th Edition2. Other animals (bird, rat, mouse, reptile, camel, other) have a *default expected values range*. However, all ranges can be adjusted – please see the User manual of the instrument:

	Na [mmol/L]	K [mmol/L]	iCa [mmol/L]	Cl [mmol/L]
cat	143–156	3.5–5.2	1.07–1.47	108–128
dog	142–152	3.9–5.1	1.18–1.37	110–124
rabbit	145–155	2.7–5	1.35–1.75	96–122
horse	137–148	2.8–5.1	1.25–1.65	99–109
cow	143–151	4.1–5.3	1.0–1.4	97–111
pig	135–150	4.4–5.1	0.89–1.45	94–106
sheep	135–145	3.5–5.1	1.44–1.6	98–107
goat	135–145	3.5–5.1	1.12–1.48	98–107
Default	135–145	3.5–5.1	1.15–1.3	98–107

ANALYTICAL PERFORMANCE

	Specified for	Measuring range [mmol/L]	Display range [mmol/L]	Precision within run	Precision between runs	Resolution [mmol/L]
Na^+	Whole blood Serum Plasma Aqueous	100–200	20–200	≤ 1 % CV	≤ 2 % CV	0.1
K^+	Whole blood Serum Plasma Aqueous	1–15	0.2–4	≤ 1 % CV	≤ 2.5 % CV	0.01
iCa^{2+}	Whole blood Serum Plasma Aqueous	0.1–2.5	0.1–6	≤ 0.02 SD in mmol/L	≤ 0.03 SD in mmol/L	0.01
Cl^-	Whole blood Serum Plasma Aqueous	50–170	25–200	≤ 1 % CV	≤ 2.5 % CV	0.1

INTERFERENCES
The following substances were found to significantly interfere with respective measurement parameters of the instrument.

Substance	Test concentration	Significant interference with				Test matrix
		c Na^+	*c* K^+	*c* iCa^{2+}	*c* Cl^-	
Magnesium (Mg^{2+})	> 2.2 mmol/L	–	–	✓	–	Plasma
Bromide (Br^-)	> 5.3 mmol/L	–	–	–	✓	Plasma
Iodide (I^-)	> 3.0 mmol/L	–	–		✓	Plasma
Thiocyanate (SCN^-)	> 3.9 mmol/L	–	–	–	✓	Plasma
pH	6.9–7.9 pH units	–	–	✓	–	Plasma
		–	–	✓	–	Whole Blood
Citrate	> 0.4 mmol/L	–	–	✓	–	Plasma
EDTA	> 0.5 mmol/L	–	–	✓	–	Plasma

WARNING AND PRECAUTIONS
For *in vitro* diagnostic use. To be handled by entitled and professionally educated person.

Hazards identification in accordance with Regulation (EC) No 1272/2008
Calibration solution 1 and 2:
EUH 208 Contains reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one. May produce an allergic reaction.
Reference solution:
The reagent is not classified as dangerous.

WASTE MANAGEMENT
Users should be exceedingly careful when working with this biological material and treat the waste as potential infectious material. Please refer to local legal requirements.

REFERENCES

1. Orna, Mary Virginia; Stock, John (1989). Electrochemistry, past and present. Columbus, OH: American Chemical Society. ISBN 978-0-8412-1572-6. OCL 19124885.
2. AIELLO, Susan E.; MOSES, Michael A.; ALLEN, Dana G.; CONSTABLE, Peter D.; DART, Andrew et al. (ed.). The Merck veterinary manual. Eleventh edition. Kenilworth, NJ: Merck & Co., 2016. ISBN 978-0-911-91061-2.

USED SYMBOLS
REF Catalogue number
LOT Lot number
Expiry date
Consult instructions for use
Biological risks
Manufacturer
Temperature limit
CONT Content
Contains sufficient for <n> tests

QUALITY SYSTEM CERTIFIED
ISO 13485

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