Clinical Chemistry

2020/07/30
A93A01082IUS

REF A11A01738

CONT.

IVD CE

HORIBA ABX SAS
Parc Euromédecine
Rue du Caducée
BP 7290
34184 Montpellier Cedex 4
FRANCE

ABX Pentra Sodium-E

- **ABX Pentra 400**

Ion selective electrode intended for the quantitative determination of sodium in serum, plasma and urine on ISE module (ABX Pentra 400).

Intended Use

ABX Pentra Sodium-E is intended for the quantitative determination of Sodium by potentiometry using ion selective electrode with associated reference solution, calibrators and controls. Measurements of Sodium are used in diagnosis and treatment diseases involving electrolyte imbalance.

Clinical Interest (1)

Electrolytes take part in most of the metabolic functions of the organism. Sodium, potassium and chloride belong to the most important physiological ions and to the more often determinated electrolytes. They are basically brought by feeding, absorbed through the digestive tract and excreted by kidneys.
Sodium is the main extracellular cation and its function is to keep the liquid balance and the osmotic pressure.
The decrease of plasmatic or seric sodium level is sometimes due to prolonged vomiting or diarrhea, a decrease in the renal reabsorption or an excessive retention of liquid. An excessive loss of liquid, a high sodium supply and an increase in renal reabsorption are the main causes of sodium increase.
The excretion of urine sodium strongly relies on food contribution and hydration status. Urine sodium level is measured in order to evaluate renal function and to study the hydroelectrolytic and acidobasic balance.

Method

Quantitative determination of sodium with ISE module by potentiometry using ion selective electrode:

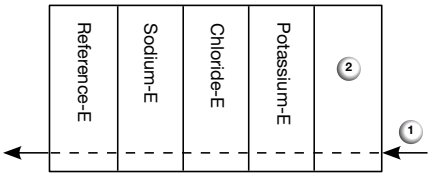
- direct (non diluted serum and plasma)
- indirect (diluted urine)

Characteristics

- **ABX Pentra Sodium-E** is packaged individually.
- **ABX Pentra Sodium-E** should be used according to this notice. The manufacturer cannot guarantee its performance if used otherwise.

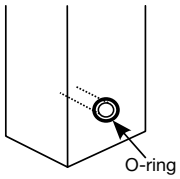
Handling

1. Before installing an electrode in the instrument, check there is an O-ring.
2. When installing the electrode, place the electrode in the correct position shown below.



1: Sample
2: Air sensor

3. Make sure that O-rings are placed in the position shown in the drawing below. For the installation of each electrode, take care that the O-ring on the next electrode does not come off.



4. Please refer to the User Manual for electrode installation and maintenance.

ABX Pentra Sodium-E

Calibrator

For calibration, use:
ABX Pentra Standard 1 (A11A01717) (not included)
1 x 280 mL
ABX Pentra Standard 2 (A11A01718) (not included)
1 x 100 mL
ABX Pentra Reference 280 mL (A11A01901) (not included)
1 x 280 mL

Control [a]

For internal quality control, use:

- For serum/plasma application only:
  ABX Pentra N Control / ABX Pentra N MultiControl (A11A01653 / 1300054414) (not included)
  10 x 5 mL (lyophilisate)
  ABX Pentra P Control / ABX Pentra P MultiControl (A11A01654 / 1300054415) (not included)
  10 x 5 mL (lyophilisate)

- For urine application only:
  in progress

Each control should be assayed daily and/or after a calibration.
The frequency of controls and the confidence intervals should correspond to laboratory guidelines and country-specific directives. You should follow federal, state and local guidelines for testing quality control materials. The results must be within the range of the defined confidence limits. Each laboratory should establish a procedure to follow if the results exceed these confidence limits.

Materials Required but not Provided [a]

- Automated clinical chemistry analyzer: ABX Pentra 400 equipped with ISE module option.
- Standard laboratory equipment.
- Electrode: **ABX Pentra Reference-E** (A11A01741).
- Calibrators:
  ABX Pentra Standard 1 (A11A01717) (not included)
  1 x 280 mL
  ABX Pentra Standard 2 (A11A01718) (not included)
  1 x 100 mL
  ABX Pentra Reference 280 mL (A11A01901) (not included)
  1 x 280 mL
- Controls:
  ABX Pentra N Control / ABX Pentra N MultiControl (A11A01653 / 1300054414)
  ABX Pentra P Control / ABX Pentra P MultiControl (A11A01654 / 1300054415)

Specimen (2)

- Serum.
- Plasma in lithium heparin.
- Urine.

- Anticoagulants other than those listed have not been tested by HORIBA Medical and are therefore not recommended for use with this assay.
- If heparinized plasma is used, check that collection tubes contain the correct volume of blood. If blood level in the tubes is insufficient, heparin concentration in samples may be elevated; sodium concentration, measured with ion selective electrodes, will be underestimated.
- Use centrifuged urine samples.
- The serum or plasma separation must be done immediately or before 24 hours if the sample is stored in a closed tube (3).

Electrolyte stability in samples stored in airtight tubes (3) (after separation):

	15-25°C	4°C	-20°C
Sodium in serum/plasma:	14 days	14 days	stable
Sodium in urine:	14 days	N/A	N/A

Reference Range

Each laboratory should establish its own reference ranges. The values given here are used as guidelines only.

Serum/ plasma (1):

Adults 136-145 mmol/L

Urine (1):

Adults 40 - 220 mmol/24h

Storage and Stability

The unopened electrodes may be installed up to the date mentioned on the packaging label if stored at 15-35°C.

[a]Modification: new control.

ABX Pentra Sodium-E

Once installed on the ISE module, Sodium electrode can be used for 12 months.

Waste Management

Please refer to local legal requirements.

General Precautions

- This electrode is for professional *in vitro* diagnostic use only.
- For prescription use only.
- This product is classified as non-hazardous in compliance with regulation (EC) N°.1272/2008.
- Observe the standard laboratory precautions for use.
- Operate the instrument according to User Manual under appropriate conditions.
- Wear rubber gloves during a replacement of electrodes.
- Please refer to the SDS associated with the electrode.
- Do not use the product if there is visible evidence of biological, chemical or physical deterioration.
- It is the user's responsibility to verify that this document is applicable to the electrode used.

Performance on ABX Pentra 400

Serum, plasma

Sample Volume

60 µL/test 1, 2 or 3 electrolytes

Accuracy and Precision [b]

Repeatability (within-run precision)

Repeatability according to the recommendations found in the Valtec protocol (4) with samples tested 20 times:

- 4 controls
- 4 specimens (medium / high levels)

	Mean value mmol/L	CV %
Control specimen 1	136.04	0.17
Control specimen 2	137.74	0.24
Control specimen 3	159.81	0.44
Control specimen 4	159.81	0.27

	Mean value mmol/L	CV %
Specimen 1	146.45	0.12
Specimen 2	151.21	0.09
Specimen 3	144.36	0.26
Specimen 4	143.95	0.23

Reproducibility (total precision)

Reproducibility according to the recommendations found in the CLSI (NCCLS), EP5-A protocol (5) with samples tested in duplicate for 20 days (2 series per day):

- 2 controls

	Mean value mmol/L	CV %
Control specimen 1	138.6	0.69
Control specimen 2	157.58	0.92

Linearity and Measuring Range

The assay confirmed a measuring range from 110 mmol/L to 200 mmol/L.

The linearity has been assessed on the measuring range according to the recommendations found in the CLSI (NCCLS), EP6-A protocol (6).

Correlation

All the performance data listed below have been obtained on the ABX Pentra 400 analyser using the following factors:
Serum/Plasma: y = 1.1 x - 4 (mmol/L)
x = ABX Pentra 400 raw values.
These factors have been obtained by comparing with MIRA Plus analyser (direct method).

N patient samples are correlated with the Mira Plus taken as reference according to the recommendations found in the CLSI (NCCLS), EP9-A2 protocol (7).

The equation for the allometric line obtained on serum (N=100) using Passing-Bablock regression procedure (8) is:
Y = 0.98 X + 2.64 with a correlation coefficient r^2 = 1.

The equation for the allometric line obtained on plasma (N=100) using Passing-Bablock regression procedure (8) is:
Y = 0.97 X + 4.77 with a correlation coefficient r^2 = 1.

[b]Modification: modification of performances.

ABX Pentra Sodium-E

Interferences [c] (9, 10)

Haemoglobin:	No significant influence is observed up to 1 g/L.
Triglycerides:	No significant influence.
Total Bilirubin:	No significant influence.
Direct Bilirubin:	No significant influence.
Probenecid:	No significant influence is observed up to 2100 µmol/L.
Valproic Acid:	No significant influence is observed up to 303.6 µg/mL.

Other limitations are given by Young as a list of drugs and preanalytical variables known to affect this methodology (11, 12).

Calibration Stability

A one point calibration is made automatically every 15 minutes.
A two point calibration is made automatically every 120 minutes.

Urine

Sample Volume

20 µL/test 1, 2 or 3 electrolytes

Accuracy and Precision [b]

Repeatability (within-run precision)

Repeatability according to the recommendations found in the Valtec protocol (4) with samples tested 20 times:

- 2 specimens (low / high levels)

	Mean value mmol/L	CV %
Specimen 1	95.61	1.09
Specimen 2	163.17	0.79

Linearity and Measuring Range

The assay confirmed a measuring range from 80 mmol/L to 300 mmol/L.

Correlation

All the performance data listed below have been obtained on the ABX Pentra 400 analyser using the following factors:

y = 1.18 x - 18 (mmol/L)
x = ABX Pentra 400 raw values.
These factors have been obtained by comparing with MIRA Plus analyser (direct method).

N patient samples are correlated with the Mira Plus taken as reference according to the recommendations found in the CLSI (NCCLS), EP9-A2 protocol (7).

The equation for the allometric line obtained on urine (N=103) using Passing-Bablock regression procedure (8) is:
Y = 1.00 X + 1.00 with a correlation coefficient r^2 = 0.99.

Calibration Stability

A one point calibration is made automatically every 15 minutes.
A two point calibration is made automatically every 120 minutes.

Reference

1. Scott MG, LeGrys VA, Klutts JS. Electrolytes and Blood Gases. In: Burtis CA, Ashwood ER, Bruns DE, eds. Tietz Textbook of Clinical Chemistry and Molecular Diagnosis. 4th ed. St Louis, Missouri: Elsevier Saunders (2006): 983-990.
2. Kanai I, Kanai M, Rinshokensaho-teiyo, revised, 30th edition, Kanehara-syuppan, Tokyo (1993): VIII709.
3. Young DS. Storage of specimen. In: Effects of Preanalytical Variables on Clinical Laboratory Tests. 1st ed.Washington: AACC Press (1993): 4-269 - 4-278.
4. Vassault A, Grafmeyer D, Naudin C et al. Protocole de validation de techniques (document B). Ann. Biol. Clin. (1986) **44**: 686-745.
5. Evaluation of Precision Performance of Clinical Chemistry Devices. Approved Guideline, CLSI (NCCLS) document EP5-A (1999) **19** (2).
6. Evaluation of the Linearity of Quantitative Analytical Methods. Approved Guideline, CLSI (NCCLS) document EP6-A (2003) **23** (16).
7. Method Comparison and Bias Estimation Using Patient Samples. Approved Guideline, 2nd ed., CLSI (NCCLS) document EP9-A2 (2002) **22** (19).
8. Passing H, Bablok W. A new biometrical procedure for testing the equality of measurements from two different analytical methods. J. Clin. Chem. Clin. Biochem. (1983) **21**: 709-20.

[c]Modification: modification of interferences.
[b]Modification: modification of performances.

ABX Pentra Sodium-E

9. Vlatko Rumenjak, Stjepan Milardovic, Ivan Kryhak. The study of some possible measurement errors in clinical blood electrolyte potentiometric (ISE) analyzers. Clinica Chimica Acta (2003) **335**: 75-81.
10. Malinowska E, Meyerhoff M. Influence of Nonionic Surfactants on the Potentiometric Response of Ion-Selective polymeric Membrane Electrodes Designed for Blood Electrolyte Measurement.
11. Young DS. Effects of Drugs on Clinical Laboratory Tests. 4th Edition, Washington, DC, AACC Press (1997) **3**: 143-163.
12. Young DS. Effects of Preanalytical Variables on Clinical Laboratory Tests. 2nd Edition, Washington, DC, AACC Press (1997) **3**: 120-132.