

REF A11A01738

CONT.

IVD CE Rx Only

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ABX Pentra Sodium-E

- Pentra C200

Ion selective electrode intended for the quantitative determination of sodium in serum, plasma and urine on ISE module (Pentra C200).

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 determined 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:

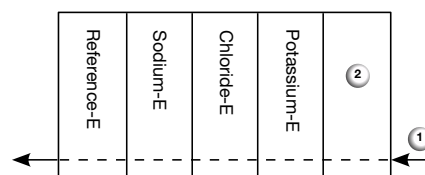
- direct (non diluted serum and plasma)
- indirect (diluted urine)

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.

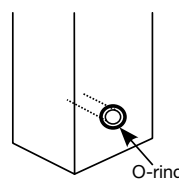
Handling

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** (A11A01719) (not included)
1 x 100 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: Pentra C200 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** (A11A01719) (not included)
1 x 100 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.
- Do not use hemolyzed samples. Hemolyzed samples may cause falsely erroneous results.
- 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.
- 24H urine without preservative or 24H urine with Boric acid as preservative may be used.
- 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

Because of potential interference effect, we do not recommend the use of serum samples containing: probenecid, ammonium nitrate or ammonium bromide (see § Interferences).

Reference Range

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

Serum/ plasma (4):

Adults 135.5 - 145.4 mmol/L

^aModification: new control.

ABX Pentra Sodium-E

Urine (5):

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. 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 Pentra C200

Serum, plasma

Sample Volume

93 µL/test 1, 2 or 3 electrolytes

Low Limit of the Assay

Based on our low limit and our linearity studies, the low limit of the assay measuring range has been established at 90 mmol/L.

Accuracy and Precision

Repeatability (within-run precision)

Repeatability according to the recommendations found in the Valtec protocol (6) with samples tested 20 times:

- 2 controls
- 6 specimens (low / medium / high levels)

	Mean value mmol/L	CV %
Control specimen 1	137.57	0.13
Control specimen 2	152.62	0.16
Specimen 1	105.42	0.57
Specimen 2	144.86	0.19
Specimen 3	176.78	0.15
Specimen 4	117.10	0.18
Specimen 5	143.51	0.13
Specimen 6	176.68	0.14

Reproducibility (total precision)

Reproducibility according to the recommendations found in the CLSI (NCCLS), EP5-A2 protocol (7) with samples tested in duplicate for 20 days (2 series per day):

- 2 controls
- 3 specimens (low / medium / high levels)

	Mean value mmol/L	CV %
Control specimen 1	130.02	2.22
Control specimen 2	148.49	0.88
Specimen 1	107.85	0.80
Specimen 2	138.93	0.62
Specimen 3	151.11	0.78

Linearity and Measuring Range

The assay confirmed a measuring range from 90 mmol/L to 190 mmol/L.

The linearity has been assessed on the measuring range according to the recommendations found in the CLSI (NCCLS), EP6-A protocol (8) and in the Valtec protocol (6).

Correlation

N patient samples are correlated with the ABX Pentra 400 for serum/plasma taken as reference according to the recommendations found in the CLSI (NCCLS), EP9-A2 protocol (9) and in the Valtec protocol (6). Values ranged:
For serum: from 103.40 to 166.50 mmol/L.
For plasma: from 93.40 to 165.90 mmol/L.

All the performance data listed below have been obtained on the Pentra C200 analyser using the following factors:

Serum/Plasma: $y = 1.00 x + 0$ (mmol/L)

x = Pentra C200 raw values.

These factors have been obtained by comparing with other commercially available analysers.

ABX Pentra Sodium-E

The equation for the allometric line obtained on serum (N=129) using Deming regression procedure (10) is:
 $Y = 0.96 x + 6.42$ (mmol/L) with a correlation coefficient $r^2 = 0.982$.

The equation for the allometric line obtained on plasma (N=132) using Deming regression procedure (10) is:
 $Y = 1.05 x - 5.32$ (mmol/L) with a correlation coefficient $r^2 = 0.998$.

Interferences (11, 12)

Haemoglobin:	No significant influence is observed up to 2 g/L.
Lipemia:	No significant influence is observed up to an Intralipid® concentration (representative of lipemia) of 37 mmol/L.
Triglycerides:	No significant influence is observed up to an Intralipid® concentration (representative of lipemia) of 11.5 mmol/L.
Total Bilirubin:	No significant influence is observed up to 340 µmol/L.
Urea:	No significant influence is observed up to 43 mmol/L.
Total Proteins:	No significant influence is observed up to 120 g/L.
Acetylsalicylic acid:	No significant influence is observed up to 3.62 mmol/L (0.65 g/L).
L Glutathione reduced:	No significant influence is observed up to 3 mmol/L (0.922 g/L).
Methyl Dopa:	No significant influence is observed up to 71 µmol/L (16.9 mg/L).
Cesium Chloride:	No significant influence is observed up to 0.09 mmol/L (1.5 mg/dL).
Lithium:	No significant influence is observed up to 3.2 mmol/L (1.18 g/L).
Bicarbonate:	No significant influence is observed up to 50 mmol/L (5 g/L).
Probenecid:	No significant influence is observed up to 2100 µmol/L.
Ammonium Nitrate:	No significant influence is observed up to 40 mmol/L.
Ammonium Bromide:	No significant influence is observed up to 37.5 mmol/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 (13, 14).

Calibration Stability

A two point calibration must be performed every day.

The calibration is stable for 8 hours. If the system is used more than 8 hours a day, a new calibration must be performed.

Urine

Sample Volume

27 µL/test 1, 2 or 3 electrolytes

Low Limit of the Assay

Based on our low limit and our linearity studies, the low limit of the assay measuring range has been established at 60 mmol/L.

Accuracy and Precision

Repeatability (within-run precision)

Repeatability according to the recommendations found in the Valtec protocol (6) with samples tested 20 times:

- 2 controls
- 3 specimens (low / medium / high levels)

	Mean value mmol/L	CV %
Control specimen 1	105.66	2.15
Control specimen 2	185.15	1.25
Specimen 1	81.34	2.38
Specimen 2	119.60	1.45
Specimen 3	238.57	0.78

Reproducibility (total precision)

Reproducibility according to the recommendations found in the CLSI (NCCLS), EP5-A2 protocol (7) with samples tested in duplicate for 20 days (2 series per day):

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

	Mean value mmol/L	CV %
Control specimen 1	91.52	4.21
Control specimen 2	184.23	2.82
Specimen 1	140.31	4.78
Specimen 2	165.43	3.07

Linearity and Measuring Range

The assay confirmed a measuring range from 60 mmol/L to 280 mmol/L.

ABX Pentra Sodium-E

The linearity has been assessed on the measuring range according to the recommendations found in the CLSI (NCCLS), EP6-A protocol (8) and in the Valtec protocol (6).

Correlation

N patient samples are correlated with the ABX Pentra 400 for urine taken as reference according to the recommendations found in the CLSI (NCCLS), EP9-A2 protocol (9) and in the Valtec protocol (6). Values ranged: from 67.64 to 273.61 mmol/L.

All the performance data listed below have been obtained on the Pentra C200 analyser using the following factors:

$$y = 1.12 x + 15 \text{ (mmol/L)}$$

x = Pentra C200 raw values.

These factors have been obtained by comparing with other commercially available analysers.

The equation for the allometric line obtained on urine (N=101) using Deming regression procedure (10) is:

$$Y = 1.01 x - 2.20 \text{ with a correlation coefficient } r^2 = 0.989.$$

Interferences

Haemoglobin: No significant influence is observed up to 10 g/L.

Total Bilirubin: No significant influence is observed up to 150 µmol/L.

Total Proteins: No significant influence is observed up to 2 g/L.

Urea: No significant influence is observed up to 600 mmol/L.

Ascorbic Acid: No significant influence is observed up to 3.40 mmol/L.

Boric Acid: No significant influence is observed up to 140 mmol/L (8.67 g/L).

Other limitations are given by Young as a list of drugs and preanalytical variables known to affect this methodology (13, 14).

Calibration Stability

A two point calibration must be performed every day.

The calibration is stable for 8 hours. If the system is used more than 8 hours a day, a new calibration must be performed.

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.

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13. Young DS. Effects of Drugs on Clinical Laboratory Tests. 4th Edition, Washington, DC, AACC Press (1997) **3**: 143-163.
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