Clinical Chemistry

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CONT.

IVD CE Rx Only

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ABX Pentra Potassium-E

- Pentra C200

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

Intended Use

ABX Pentra Potassium-E is intended for the quantitative determination of Potassium by potentiometry using ion selective electrode with associated reference solution, calibrators and controls. Measurements of Potassium 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.
Potassium is the main intracellular cation. It plays a key role in neuromuscular activity.
The decrease of potassium level is sometimes due to a decrease in potassium food supply or an excessive loss of potassium by the organism due to prolonged vomiting or diarrhea or an increase in the renal excretion.
An excessive loss of liquid or a shock, severe burns, diabetic acidocetose or potassium retention by kidneys are the main causes of potassium increase.
The increase of urine potassium level is sometimes due to a start of starvation, a primary or secondary aldosteronism or primary renal diseases (renal tubular syndroms, during the phase of recovery from a severe tubular necrosis, a metabolic acidose or alkalose). We observe as well hyperkaliury with administration of adrenocorticotropic hormones, hydrocortisone and cortisone.
Potassium level decreases with chronic potassic deficiency and renal diseases with urine flow decrease.
The measurement of urine potassium is useful for renal explorations and to study hydroelectric and acid-base balance.

Method

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

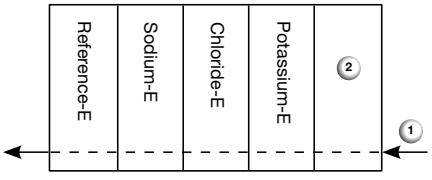
- direct (non diluted serum and plasma)
- indirect (diluted urine)

Characteristics

- **ABX Pentra Potassium-E** is packaged individually.
- **ABX Pentra Potassium-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

QUAL-QA-WORI-5541 Rev.1

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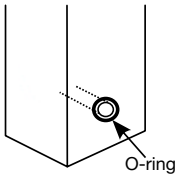
3. Make sure that O-rings are placed in the position shown in the drawing below. For the installation of each electrode, take care that the O-ring on the next electrode does not come off.



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

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.
- When using serum as sample, infiltration of potassium from blood cell elements, especially platelets may cause more grave problems than using blood plasma.
- Samples should be separated from the cells promptly after collection. If a sample is stored in a refrigerator without serum separation, a large amount of potassium is infiltrated from red blood cells.
- 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
Potassium in serum/plasma:	14 days	14 days	stable
Potassium in urine:	14 days	N/A	N/A

[a]Modification: new control.

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

Reference Range

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

Serum (4):

Adults 3.7 - 5.6 mmol/L

Plasma (4):

Adults 3.4 - 5.0 mmol/L

Urine (5):

Adults 25 - 125 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, Potassium electrode can be used for 6 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

Sample Volume

Serum/Plasma: 93 µL/test 1, 2 or 3 electrolytes
Urine: 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:

2 mmol/L for serum and plasma.

25 mmol/L for urine.

Accuracy and Precision

Repeatability (within-run precision)

2 serum control levels, 3 serum specimens and 3 plasma specimens were tested in a single run, 20 times per run, according to the recommendations found in the Valtec protocol (6).

	Mean value mmol/L	CV %
Control specimen 1	3.58	0.25
Control specimen 2	6.29	0.35
Serum specimen 1	3.56	0.85
Serum specimen 2	4.17	0.55
Serum specimen 3	5.15	0.85
Plasma specimen 1	2.37	0.57
Plasma specimen 2	3.96	0.70
Plasma specimen 3	7.16	0.75

2 urine control levels and 3 urine specimens were tested in a single run, 20 times per run, according to the recommendations found in the Valtec protocol (6).

	Mean value mmol/L	CV %
Control specimen 1	28.69	0.92
Control specimen 2	62.57	0.82
Urine specimen 1	23.26	1.13
Urine specimen 2	91.17	0.93
Urine specimen 3	192.14	0.42

Reproducibility (total precision)

2 serum controls and 3 serum specimens were tested in duplicate for 20 days according to the recommendations found in the CLSI (NCCLS), EP5-A2 protocol (7).

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	Mean value mmol/L	CV %
Control specimen 1	3.56	0.87
Control specimen 2	6.43	1.07
Serum specimen 1	4.02	0.86
Serum specimen 2	4.65	0.73
Serum specimen 3	4.79	0.85

2 urine controls and 3 urine specimens were tested in duplicate for 20 days according to the recommendations found in the CLSI (NCCLS), EP5-A2 protocol (7).

	Mean value mmol/L	CV %
Control specimen 1	28.75	1.72
Control specimen 2	62.84	1.64
Urine specimen 1	31.15	1.54
Urine specimen 2	106.05	1.67
Urine specimen 3	61.37	2.87

Linearity and Measuring Range

The measuring range of the assay is:
For serum and plasma: from 2 to 9.5 mmol/L.
For urine: from 25 to 250 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 and 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:
For serum: from 2.52 to 8.32 mmol/L.
For plasma: from 2.24 to 9.47 mmol/L.
For urine: from 25.3 to 236.6 mmol/L.

All the performance data listed below have been obtained on the Pentra C200 analyser using the following factors:
Serum/Plasma: y = 1 x + 0 (mmol/L)
Urine: y = 1 x + 2 (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 serum (N=122) using Deming regression procedure (10) is:
Y = 1.01 x - 0.06 (mmol/L) with a correlation coefficient r^2 = 0.998.

The equation for the allometric line obtained on plasma (N=125) using Deming regression procedure (10) is:
Y = 1.01 x - 0.09 (mmol/L) with a correlation coefficient r^2 = 0.998.

The equation for the allometric line obtained on urine (N=129) using Deming regression procedure (10) is:
Y = 0.99 x + 2.55 (mmol/L) with a correlation coefficient r^2 = 0.995.

Interferences (11, 12)

Interferences in serum/plasma

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 1650 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.

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Interferences in urine

Haemoglobin:	No significant influence is observed up to 10 g/L.
Total Bilirubin:	No significant influence is observed up to 150 µmol/L.
Urea:	No significant influence is observed up to 600 mmol/L.
Total Proteins:	No significant influence is observed up to 2 g/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

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11. 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.
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