2025/01/29
A93A01255FUS

REF A11A01739

CONT.

IVD CE Rx Only

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

ABX Pentra Chloride-E

- **Pentra C200**

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

Intended Use [a]

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

Clinical Interest (1, 2)

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.
Chloride is the main extracellular anion and its function is to regulate the extracellular liquid balance.
A decrease in food chloride supply, prolonged vomiting, a decrease in the renal reabsorption as well as some acidose and alkalose forms are the main causes of chloride decrease.
Chloride values increase with an excessive loss of liquid, renal insufficiency, some acidose forms, a high chloride supply in food or by parenteral supply and intoxication by salicylic products.
Measurement of chloride in urine helps the evaluation of acid-base balance studies. It permits to distinguish whether or not a case of metabolic alkalosis is chloride-responsive (salt-responsive).

Method

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

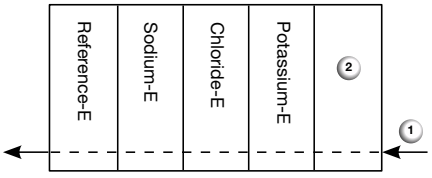
- direct (non diluted serum and plasma)
- indirect (diluted urine)

Characteristics

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

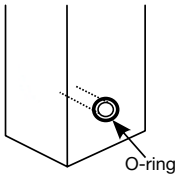


1: Sample
2: Air sensor

[a]Modification: new leaflet form.

ABX Pentra Chloride-E

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 [b]

For internal quality control, use:

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

- For urine application only:
  Not supplied by HORIBA Medical

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 [b c]

- Automated clinical chemistry analyzer: Pentra C200 equipped with ISE module option.
- Standard laboratory equipment.
- Electrodes: **ABX Pentra Reference-E** (A11A01741).
- Cleaning solution:
  ABX Pentra ISE Cleaner CP (A11A01971)
  1 x 90 mL
- Calibrator:
  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 MultiControl (1300054414)
  10 x 5 mL (lyophilisate)
  ABX Pentra P MultiControl (1300054415)
  10 x 5 mL (lyophilisate)

Specimen (3) [d e]

This device intended testing population is general population.

Specimen types

- 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.
- Lengthy collection of the blood sample causes a Chloride shift because of accumulation of CO_2 and Chloride being transferred to the red blood cells.
- Long-term exposure of sample to air causes metabolism of blood cells or exhalation of gas, which brings aberration in chloride density. Samples should be separated from the cells promptly after collection.
- Use centrifuged urine samples.
- 24H urine without preservative or 24H urine with Boric acid as preservative may be used.

[b]Modification: control removed.
[c]Modification: modification of materials required.
[d]Modification: modification of specimen stability.
[e]Modification: recommendation added.

ABX Pentra Chloride-E

- The serum or plasma separation must be done immediately or before 24 hours if the sample is stored in a closed tube (4).

Stability
Electrolyte stability in samples stored in airtight tubes (4) (after separation):
Serum, plasma

- At 15-25°C: 7 days
- At 4°C: 7 days
- At -20°C: 1 year

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 [f]

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

Serum, plasma **(5)**	
Adults	101-110 mmol/L

Urine **(6)**	
Adults	110 - 250 mmol/24h

If there is the slightest change in food diet, it is known that chloride results in urine are often incoherent and not interpretable. Chloride in urine/24h will be “high” or “low” but impossible to classify in a range, even very large.

Clinical sensitivity and specificity, positive predictive value and negative predictive value are not commonly reported for this analyte. This is largely attributed to the fact that this analyte is not sole indicator for the intended purpose and patient treatment decision making. To arrive at a diagnosis and a course of treatment, results from others routine clinical chemistry tests should be used in conjunction with other diagnostic information and the attending health-care professional's evaluation of the patient's condition.

Storage and Stability [g]

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, Chloride electrode can be used for 4 months or 2400 cycles.

Waste Management

Please refer to local legal requirements.

General Precautions [h]

- This electrode is for professional *in vitro* diagnostic use only.
  For laboratory use.
- 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.
- Do not use the product if there is visible evidence of biological, chemical or physical deterioration.
- Do not use the product if the recommended storage conditions, including temperature, are not followed.
- User must be trained by a HORIBA Medical representative before attempting to operate the device.
- It is the user's responsibility to verify that this document is applicable to the electrode used.
- For technical assistance, you can call +33 (0)4 67 14 15 16.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the country in which the user and/or the patient is established.

Performance on Pentra C200

Serum, plasma

Sample Volume

93 µL/test 1, 2 or 3 electrolytes

[f]Modification: information added.
[g]Modification: modification of storage and stability.
[h]Modification: general precautions modification.

ABX Pentra Chloride-E

Limit of Quantitation [i]

Based on our low limit and our linearity studies, the low limit of the assay measuring range has been established at: 70 mmol/L.

Accuracy and Precision

Repeatability (within-run precision)

Repeatability according to the recommendations found in the Valtec protocol (7) with samples tested 20 times:

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

	Mean value mmol/L	CV %
Control specimen 1	87.35	0.24
Control specimen 2	111.95	0.24
Specimen 1	79.54	0.88
Specimen 2	105.79	0.49
Specimen 3	138.61	0.72
Specimen 4	82.05	0.72
Specimen 5	106.92	0.61
Specimen 6	137.08	0.53

Reproducibility (total precision)

Reproducibility according to the recommendations found in the CLSI (NCCLS), EP5-A2 protocol (8) 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	85.88	1.20
Control specimen 2	113.36	1.55
Specimen 1	83.26	0.99
Specimen 2	104.72	0.96
Specimen 3	118.32	0.88

Measuring Range [j]

The assay confirmed a measuring range from 70 mmol/L to 170 mmol/L.

The linearity has been assessed on the measuring range according to the recommendations found in the CLSI (NCCLS), EP06-Ed2 protocol (9) and in the Valtec protocol (7).

Correlation [k]

N patient samples are correlated with the ABX Pentra 400 taken as reference according to the recommendations found in the CLSI (NCCLS), EP09c protocol (10) and in the Valtec protocol (7).

Patient samples: Serum
Number of patient samples: 169
Assay range: 72.3 - 167.5 mmol/L
Y = 0.961x + 3.81
With a correlation coefficient r^2 = 0.987

Patient samples: Plasma
Number of patient samples: 133
Assay range: 70.95 - 144.29 mmol/L
Y = 1.027x - 3.02
With a correlation coefficient r^2 = 0.997

Interferences [l] (11, 12, 13)

Haemoglobin:	No significant influence is observed up to 2 g/L.
Triglycerides:	No significant influence is observed up to a triglyceride concentration 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).
Probenecid:	No significant influence is observed up to 734 µmol/L.
Ammonium Nitrate:	No significant influence is observed up to 2.72 mmol/L.

[i]Modification: data added.
[j]Modification: modification of measuring range.
[k]Modification: modification of correlation.
[l]Modification: modification of interferences.

ABX Pentra Chloride-E

Ammonium Bromide:	No significant influence is observed up to 3.5 mmol/L.
Valproic Acid:	No significant influence is observed up to 351 µmol/L (5.06 mg/dL).
Salicylate:	0.6 mmol/L (16.45 mg/dL) salicylate concentration falsely increases the chloride concentration of around: 5%.
Calcium carbonate:	No significant influence is observed up to 50 mmol/L.

Other limitations are given by Young as a list of drugs and preanalytical variables known to affect this methodology (14, 15).

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

Limit of Quantitation [i]

Based on our low limit and our linearity studies, the low limit of the assay measuring range has been established at: 70 mmol/L.

Accuracy and Precision

Repeatability (within-run precision)

Repeatability according to the recommendations found in the Valtec protocol (7) with samples tested 20 times:

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

	Mean value mmol/L	CV %
Control specimen 1	98.64	2.74
Control specimen 2	176.08	1.71
Specimen 1	81.86	2.35
Specimen 2	148.30	2.13
Specimen 3	174.52	1.26

Reproducibility (total precision)

Reproducibility according to the recommendations found in the CLSI (NCCLS), EP5-A2 protocol (8) 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	98.27	4.59[a]
Control specimen 2	172.05	1.56
Specimen 1	116.68	4.02[a]
Specimen 2	169.16	3.12

[a]: *Total CV is higher than the claim but the calculated X^2 is lower than the critical upper 95% X^2 value (from table 1 of the CLSI EP5-A2). Then Total CV obtained is PASS.*

Measuring Range [j]

The assay confirmed a measuring range from 70 mmol/L to 280 mmol/L.

The linearity has been assessed on the measuring range according to the recommendations found in the CLSI (NCCLS), EP06-Ed2 protocol (9) and in the Valtec protocol (7).

Correlation [k]

N patient samples are correlated with the ABX Pentra 400 taken as reference according to the recommendations found in the CLSI (NCCLS), EP09c protocol (10) and in the Valtec protocol (7).

Number of patient samples: 116
Assay range: 61.62 - 267.3 mmol/L
Y = 1.047x - 6.37
With a correlation coefficient $r^2 = 0.99$

Interferences [l] (11, 12, 13)

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

[i]Modification: data added.
[j]Modification: modification of measuring range.
[k]Modification: modification of correlation.
[l]Modification: modification of interferences.

ABX Pentra Chloride-E

Ascorbic Acid: No significant influence is observed up to 3.4 mmol/L.
Boric Acid: No significant influence is observed up to 140 mmol/L.

Other limitations are given by Young as a list of drugs and preanalytical variables known to affect this methodology (14, 15).

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.
2. David S. Jacobs et al. Laboratory Test Handbook, Lexi-comp inc, 4th Edition (1996): 109.
3. Kanai I, Kanai M, Rinshokensaho-teiyo, revised, 30th edition, Kanehara-syuppan, Tokyo (1993): VIII709.
4. Young DS. Storage of specimen. In: Effects of Preanalytical Variables on Clinical Laboratory Tests. 1st ed.Washington: AACC Press (1993): 4-269 - 4-278.
5. Results of an internal study performed in accordance with CLSI C28-A3 (2008) 20 (13) guideline with serum and plasma normal samples.
6. TIETZ, Fundamentals of Clinical Chemistry, 5th Edition, (Carl A. Burtis, Edward R. Ashwood, USA), (2001) **970**.
7. Vassault A, Grafmeyer D, Naudin C et al. Protocole de validation de techniques (document B). Ann. Biol. Clin. (1986) **44**: 686-745.
8. Evaluation of Precision Performance of Quantitative Measurement Method. Approved Guideline, CLSI (NCCLS) document EP5-A2 (2004) **24** (25).
9. Evaluation of Linearity of Quantitative Measurement Procedures. 2nd Edition, CLSI (NCCLS) guideline EP06-Ed2 (2020) **40** (16).
10. Measurement Procedure Comparison and Bias Estimation Using Patient Samples. Approved Guideline, 3rd ed., CLSI (NCCLS) document EP09c (2018) **38** (12).
11. Interference Testing in Clinical Chemistry. Approved Guideline, 3rd ed., CLSI (NCCLS) guideline EP07 (2018) **38** (7).
12. 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.
13. Malinowska E, Meyerhoff M. Influence of Nonionic Surfactants on the Potentiometric Response of Ion-Selective polymeric Membrane Electrodes Designed for Blood Electrolyte Measurement.
14. Young DS. Effects of Drugs on Clinical Laboratory Tests. 4th Edition, Washington, DC, AACC Press (1997) **3**: 143-163.
15. Young DS. Effects of Preanalytical Variables on Clinical Laboratory Tests. 2nd Edition, Washington, DC, AACC Press (1997) **3**: 120-132.