Clinical Chemistry

2025/07/01
A93A01433EEN

REF A11A01933
REAGENT 1 30 mL
REAGENT 2 10 mL

IVD CE 2797

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

ABX Pentra Creatinine 120 CP

- **Pentra C400**
- **ABX Pentra 400**

Diagnostic reagent for quantitative *in vitro* determination of creatinine in serum, plasma and urine by colorimetry.

Application Release

Serum, plasma: [a] (not for use in the USA)
Pentra C400: CREA4
1.xx
ABX Pentra 400: CREA4
2.xx

Urine: [a]
Pentra C400: CREA_U4
1.xx
ABX Pentra 400: CREA_U4
2.xx

Intended Use [b] [c]

ABX Pentra Creatinine 120 CP reagent is a diagnostic reagent for quantitative *in vitro* determination of Creatinine in human serum, plasma and urine based on a kinetic method using alkaline picrate (Jaffé method).
Clinical laboratories use.
Creatinine measurements are used in the diagnosis and treatment of renal diseases, and as a calculation basis for measuring other urine analytes.
Assessing physiologic and pathologic variations of activity of creatinine in human serum, plasma and urine is useful for screening or follow-up of these diseases.

Clinical Interest

Creatinine measurements are used in the diagnosis and treatment of renal diseases and as a calculation basis for measuring other urine analytes.

Method

In 1886, Jaffe devoloped an assay for creatinine based upon the reaction between creatinine and sodium picrate (1). In 1904, Folin (2) used this reaction for the quantitative determination of creatinine in urine. Kinetic procedures based on the observed reaction rates various substances, including creatinine, with alkaline picrate have been proposed by Fabing (3) and Soldin (4). This improved Jaffe chemistry is a kinetic procedure which does not require deproteinization of the sample and is formulated to reduce the interference in serum proteins.

Creatinine + alkaline picrate ⟶ creatinine-picrate complex

At an alkaline pH, creatinine reacts with picrate to form Janovsky complex.
The rate of increase in absorbance at 510 nm due to the formation of creatinine-picrate complex is directly proportional to the creatinine concentration present in the sample.

Reagents

ABX Pentra Creatinine 120 CP is ready-to-use.

Reagent 1 (R1):	
Sodium hydroxide	0.25 mol/L
Surfactants	
Reagent 2 (R2):	
Picric acid	31.4 mmol/L

[a]Modification: application release modification.
[b]Modification: modification of CE mark.
[c]Modification: new leaflet form.

QUAL-QA-WORI-5541 Rev.3

ABX Pentra Creatinine 120 CP

ABX Pentra Creatinine 120 CP should be used according to this notice. The manufacturer cannot guarantee its performance if used otherwise.

Handling

1. Remove both caps of the cassette.
2. If present, remove foam by using a plastic pipette.
3. Position the protective cap (GBM0969) on the cassette.
4. Place the cassette into the ambient reagent compartment.

Calibrator

For calibration, use:
ABX Pentra Multical (A11A01652) (not included)
10 x 3 mL (lyophilisate)

Control

For internal quality control, use:

- **ABX Pentra N MultiControl** (1300054414) (not included)
  10 x 5 mL (lyophilisate)
- **ABX Pentra P MultiControl** (1300054415) (not included)
  10 x 5 mL (lyophilisate)
- **Yumizen C Urine Level 1 Control** (1300023946) (not included)
  6 x 5 mL
- **Yumizen C Urine Level 2 Control** (1300023947) (not included)
  6 x 5 mL

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

- Automated clinical chemistry analyzer: ABX Pentra 400 / Pentra C400
- Calibrator: **ABX Pentra Multical** (A11A01652)
- Controls:
  ABX Pentra N MultiControl (1300054414)
  ABX Pentra P MultiControl (1300054415)
  Yumizen C Urine Level 1 Control (1300023946)
  Yumizen C Urine Level 2 Control (1300023947)
- Standard laboratory equipment.

Specimen

This device intended testing population is general population.

Specimen types

- Fresh, clear serum.
- Plasma in lithium heparin or EDTA.
- Fresh centrifuged urine.

Anticoagulants other than those listed have not been tested by HORIBA and are therefore not recommended for use with this assay.

24h urine has to be collected without additive.

Stability

Serum, plasma **(5)**

- At 20-25°C: 7 days
- At 4-8°C: 7 days
- At -20°C: 3 months

Urine **(6)**

- At 20-25°C: 2 days
- At 4-8°C: 6 days
- At -20°C: 6 months

Reference Range

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

Serum, plasma (7)

Men	Women
8 - 13 mg/L	6 - 12 mg/L
0.8 - 1.3 mg/dL	0.6 - 1.2 mg/dL
71 - 115 µmol/L	53 - 106 µmol/L

ABX Pentra Creatinine 120 CP

***Urine* (24 hours)** (8)

Men	Women
14 - 26 mg/kg/day	11 - 20 mg/kg/day
124 - 230 µmol/kg/day	97 - 177 µmol/kg/day

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

Stability before opening:

Stable up to the expiry date on the label if stored at 18-26°C.

Stability after opening:

Refer to the paragraph "Performance on ABX Pentra 400 / Pentra C400".

Waste Management

Please refer to local legal requirements.

General Precautions

- This reagent is for professional *in vitro* diagnostic use only.
  For laboratory use.
- For prescription use only.
- This reagent is classified as hazardous in compliance with regulation (EC) N°.1272/2008.
- **Reagent 1 and 2 (R1 and R2):**
  Warning: This reagent is obtained from substances of animal origin. Consequently, it should be treated as potentially infectious and handled with the appropriate cautions in accordance with good laboratory practices (9).
- **Reagent 1 (R1):**
  Warning
  H290: May be corrosive to metals.
  H315: Causes skin irritation.
  H319: Cause serious eye irritation.
  P234: Keep only in original packaging.
  P264: Wash hands thoroughly after handling.
  P280: Wear protective gloves/protective clothing/eye protection/face protection.
  P302 + P352: IF ON SKIN: Wash with plenty of soap and water.
  P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  P321: Specific treatment (see [***] on this label).
  P332 + P313: If skin irritation occurs: Get medical advice/attention.
  P337 + P313: If eye irritation persists: Get medical advice/attention.
  P362 + P364: Take off contaminated clothing and wash it before reuse.
  P390: Absorb spillage to prevent material damage.
  P406: Store in corrosive resistant container with a resistant inner liner.
- Observe the standard laboratory precautions for use.
- The reagent cassettes are disposable and should be disposed of in accordance with the local legal requirements.
- Please refer to the SDS associated with the reagent.
- 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 representative before attempting to operate the device.
- It is the user's responsibility to verify that this document is applicable to the reagent 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.

ABX Pentra Creatinine 120 CP

Performance on ABX Pentra 400 / Pentra C400

Lot to Lot Variability [d]

The recovery of samples (serum and plasma) done during QC release of three consecutive lots of reagent shows that the lot to lot variability is within specification: < 5%.

Serum, plasma (not for use in the USA)

The performance data listed below are representative of performance on HORIBA Systems.

Number of tests: 120 tests

On Board Reagent Stability

Once opened, the reagent cassette placed in the ambient ABX Pentra 400 / Pentra C400 compartment is stable for 14 days.

Sample volume: 10.0 µL/test

Detection Limit

The detection limit is determined according to CLSI (NCCLS), EP17-A protocol (10) and equals 7.74 µmol/L (0.09 mg/dL).

Limit of Quantitation

The limit of quantitation is determined according to CLSI (NCCLS), EP17-A protocol (10) and equals 8.70 µmol/L (0.10 mg/dL).

Accuracy and Precision

Repeatability (within-run precision)

Repeatability according to the recommendations found in the Valtec protocol (11) with samples tested 20 times:

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

	Mean value µmol/L	Mean value mg/dL	CV %
Control specimen 1	92.71	1.05	2.36
Control specimen 2	335.24	3.79	0.51
Specimen 1	50.11	0.57	2.46
Specimen 2	141.59	1.60	0.86
Specimen 3	575.40	6.50	0.64

Reproducibility (total precision)

Reproducibility according to the recommendations found in the CLSI (NCCLS), EP5-A2 protocol (12) with samples tested in duplicate for 20 days (2 series per day):

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

	Mean value µmol/L	Mean value mg/dL	CV %
Control specimen 1	91.61	1.04	3.4
Control specimen 2	339.23	3.83	2.5
Specimen 1	46.31	0.52	5.2
Specimen 2	139.81	1.58	2.9
Specimen 3	584.50	6.60	2.2

Measuring Range

The assay confirmed a measuring range from 8.7 µmol/L (0.10 mg/dL) to 1600 µmol/L (18.08 mg/dL).
The measuring range is extended up to 4800 µmol/L (54.24 mg/dL) with the automatic post-dilution.
The reagent linearity has been assessed up to 1600 µmol/L (18.08 mg/dL) according to the recommendations found in the CLSI (NCCLS), EP6-A protocol (13).

Correlation

Patient samples: Serum
Number of patient samples: 143
Specimens are correlated with a commercial reagent taken as reference according to the recommendations found in the CLSI (NCCLS), EP09c protocol (14).
Values ranged from 14.56 µmol/L (0.16 mg/dL) to 1489.37 µmol/L (16.83 mg/dL).
The equation for the allometric line obtained using Passing-Bablok regression procedure (15) is:
Y = 0.9916 x – 5.68 (µmol/L)
Y = 0.9916 x – 0.064 (mg/dL)
with a correlation coefficient r^2 = 0.999.

[d]Modification: lot to lot variability specification added.

ABX Pentra Creatinine 120 CP

Interferences

Haemoglobin:	No significant influence is observed up to 290 µmol/L (500 mg/dL).
Triglycerides:	No significant influence is observed up to a triglyceride concentration of 6.66 mmol/L (582.75 mg/dL).
Total Bilirubin:	No significant influence is observed up to 75 µmol/L (4.4 mg/dL).
Direct Bilirubin:	No significant influence is observed up to 75 µmol/L (4.4 mg/dL).
Glucose:	No significant influence is observed up to 12.5 mmol/L (225 mg/dL).
Ascorbic Acid:	No significant influence is observed up to 340 µmol/L (5.99 mg/dL).
Ibuprofen:	No significant influence is observed up to 2.43 mmol/L (50.10 mg/dL).
Acetaminophen:	No significant influence is observed up to 1324 µmol/L (20 mg/dL).
Acetylsalicylic Acid:	No significant influence is observed up to 3.62 mmol/L (65.16 mg/dL).
Total Proteins:	There is an acceptable deviation in total protein from 36.0 g/L to 149.0 g/L.
Etamsylate:	No significant influence is observed up to 57 µmol/L (1.5 mg/dL).
Immunoglobulin M (IgM):	No significant influence is observed up to 4.02 g/L. Samples containing elevated levels of Immunoglobulin M (IgM) or samples from patients with Waldenstrom's Macroglobulinemia may produce unreliable results.
Eltrombopag:	No significant influence is observed up to 169.5 µmol/L (7.5 mg/dL).

Other limitations are given by Young as a list of drugs and preanalytical variables known to affect this methodology (16, 17).

Calibration Stability

The reagent is calibrated on Day 0. The calibration stability is checked by testing 2 control specimens.
The calibration stability is 1 day.
Note: A recalibration is recommended when reagent lots change, and when quality control results fall outside the range established.

Conversion Factor

µmol/L x 0.0113 = mg/dL

Urine

The performance data listed below are representative of performance on HORIBA Systems.

Number of tests: 120 tests

On Board Reagent Stability

Once opened, the reagent cassette placed in the ambient ABX Pentra 400 / Pentra C400 compartment is stable for 14 days.

Sample volume: 10.0 µL/test

Detection Limit

The detection limit is determined according to CLSI (NCCLS), EP17-A protocol (10) and equals 125 µmol/L (1.41 mg/dL).

Limit of Quantitation

The limit of quantitation is determined according to CLSI (NCCLS), EP17-A protocol (10) and equals 261 µmol/L (2.9 mg/dL).

Accuracy and Precision

Repeatability (within-run precision)

Repeatability according to the recommendations found in the Valtec protocol (11) with samples tested 20 times:

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

	Mean value µmol/L	Mean value mg/dL	CV %
Control specimen 1	5605	63.3	1.16
Control specimen 2	12396	140.1	0.99
Specimen 1	1122	12.7	1.55
Specimen 2	9252	104.6	0.84
Specimen 3	23025	260.2	0.93

Reproducibility (total precision)

Reproducibility according to the recommendations found in the CLSI (NCCLS), EP5-A2 protocol (12) with samples tested in duplicate for 20 days (2 series per day):

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

ABX Pentra Creatinine 120 CP

	Mean value µmol/L	Mean value mg/dL	CV %
Control specimen 1	5579.08	63.04	2.2
Control specimen 2	12149.12	137.29	2.1
Specimen 1	1116.18	12.61	2.0
Specimen 2	9328.88	105.42	1.9
Specimen 3	23148.04	261.57	2.1

Measuring Range

The assay confirmed a measuring range from 261 µmol/L (2.9 mg/dL) to 25000 µmol/L (282.5 mg/dL).
The measuring range is extended up to 75000 µmol/L (847.5 mg/dL) with the automatic post-dilution.
The reagent linearity has been assessed up to 25000 µmol/L (282.5 mg/dL) according to the recommendations found in the CLSI (NCCLS), EP6-A protocol (13).

Correlation

Patient samples: urine
Number of patient samples: 117
Specimens are correlated with a commercial reagent taken as reference according to the recommendations found in the CLSI (NCCLS), EP09c protocol (14).
Values ranged from 346.9 µmol/L (3.92 mg/dL) to 24178.2 µmol/L (273.21 mg/dL).
The equation for the allometric line obtained using Passing-Bablok regression procedure (15) is:
Y = 0.9988 x – 52.97 (µmol/L)
Y = 0.9988 x – 0.60 (mg/dL)
with a correlation coefficient r^2 = 0.998.

Interferences

Haemoglobin:	No significant influence is observed up to 210 µmol/L (362 mg/dL).
Direct Bilirubin:	No significant influence is observed up to 500 µmol/L (29.3 mg/dL).
Ascorbic Acid:	No significant influence is observed up to 340 µmol/L (5.99 mg/dL).
pH:	Acidification or alcalinisation do not interfere with this test.

Other limitations are given by Young as a list of drugs and preanalytical variables known to affect this methodology (16, 17).

Calibration Stability

The reagent is calibrated on Day 0. The calibration stability is checked by testing 2 control specimens.
The calibration stability is 1 day.

Note: A recalibration is recommended when reagent lots change, and when quality control results fall outside the range established.

Conversion Factor:

µmol/L x 0.0113 = mg/dL

Reference

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ABX Pentra Creatinine 120 CP

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