Clinical Chemistry

2025/09/26
A93A01304FUS

ABX Pentra Glucose HK CP

REF A11A01667
REAGENT 1 56 mL
REAGENT 2 14 mL

IVD CE 2797

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

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

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

Application Release

Serum, plasma: [a]

Pentra C400: GluK
1.xx
ABX Pentra 400: GluK
World wide except the USA: 4.xx
For the USA only: 2.xx

Urine: [a]

Pentra C400: GluHK-U
1.xx
ABX Pentra 400: GluHK-U
World wide except the USA: 2.xx
For the USA only: 2.xx

Intended Use [b c d]

ABX Pentra Glucose HK CP reagent is intended for the quantitative *in vitro* diagnostic determination of glucose in human serum, plasma and urine using glucose hexokinase method by colorimetry.
Clinical laboratories use.
Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia.
Assessing physiologic and pathologic variations of glucose concentration in human Serum/Plasma and urine is useful for screening or follow-up of these diseases.

Clinical Interest (1)

Glucose is the main source of energy for human body. Glucose of food origin is converted either in glycogen in order to be stocked in liver, or in triglycerides in order to be stocked in the adipose tissues. The level of blood glucose is regulated by the effect of different hormones for which two antagonist ones are insulin and glucagon. Under physiological conditions, glucose is not excreted in the urine.
The blood sugar dosage is used to diagnostic affections of the carbohydrate metabolism as diabetes, neonatal or idiopathic hypoglycaemia and pancreatic pathologies.
The main physiological troubles are linked with the appearance of hyperglycaemia (type I mellitus diabetes and type II mellitus diabetes).
The type I diabetes is insulin-dependent and appears principally before 30 years. The type II diabetes is non insulin-dependent, and appears often after 40 years. However, it could appear earlier among obese subjects. Other diabetes types come of secondary origin and appear following endocrinal or hepatic diseases.

Method (1)

Enzymatic method (Hexokinase).
Determination of glucose using the following reactions:

$$\text{D-glucose + ATP} \xrightarrow{\text{HK}} \text{Glucose-6-phosphate + ADP}$$

$$\text{Glucose-6-phosphate + NAD}^+ \xrightarrow{\text{G6P-DH}} \text{D-gluconate-6-phosphate + NADH + H}^+$$

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

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ABX Pentra Glucose HK CP

(HK = Hexokinase, G6P-DH = Glucose-6-phosphate dehydrogenase)

Reagents

ABX Pentra Glucose HK CP is ready-to-use.

Reagent 1 (R1):	
Pipes buffer, pH 7.60	100 mmol/L
NAD^+	3.8 mmol/L
ATP	2.2 mmol/L
Sodium azide	< 0.1%

Reagent 2 (R2):	
Hexokinase	≥ 8500 U/L
G6P-DH	≥ 8500 U/L
Magnesium sulfate	20 mmol/L
Sodium azide	< 0.1%

ABX Pentra Glucose HK 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. Place the cassette into the refrigerated 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 (2, 3)

This device intended testing population is general population.

Specimen types

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

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

Stability:

The stability of glucose in specimen depends on the storage temperature, bacterial contamination and glycolysis.

Serum, plasma:

In separated, non-haemolysed sterile serum (2):

- At 25°C: 8 hours
- At 4°C: 72 hours

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The plasma or serum specimen without preservative should be separated from cells or blood clot in the half hour following the taking.
In the uncentrifuged blood, at room temperature, the average decrease of glucose in serum is about 7% per hour (0.28 to 0.56 mmol/L or 5 to 10 mg/dL). This decrease results from glycolysis.

Urine:
For 24-hours collection urine, 5 mL of glacial acetic acid may be added to the container before starting the collection. Without preservatives, loss of glucose can be -40% after 24 hours at room temperature (3).

Reference Range

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

Serum, plasma (4)**:**

0.70 - 1.15 g/L

70 - 115 mg/dL

3.89 - 6.39 mmol/L

Urine (5, 6)**:**

< 0.84 mmol/L (< 15 mg/dL)

< 2.8 mmol/24 hours (0.5 g/24 hours)

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 2-8°C.

Stability after opening:
Refer to the paragraph "Performance on ABX Pentra 400 / Pentra C400".

Waste Management [e]

- Please refer to local legal requirements.
- This reagent contains less than 0.1% of sodium azide as a preservative.

General Precautions [f]

- This reagent is for professional *in vitro* diagnostic use only.
  For laboratory use.
- For prescription use only.
- This reagent is classified as non-hazardous in compliance with regulation (EC) N°.1272/2008.
- **Reagent 2 (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 (7).
- Do not pipette by mouth.
- Do not replenish the reagents.
- Do not swallow. Avoid contact with skin and mucous membranes.
- 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.
- The Summary of Safety and Performance (SSP) of the product is available in Eudamed (https://ec.europa.eu/tools/eudamed).

[e]Modification: modification of waste management.
[f]Modification: general precautions modification.

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Performance on ABX Pentra 400 / Pentra C400

Lot to Lot Variability

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: < 10%.

Serum, plasma

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

Number of tests: 200 tests

If the number of tests requested is low and the ABX Pentra 400 / Pentra C400 user intends to utilise the cassette to the maximum on board stability, it is the recommendation of HORIBA, to utilise the consumable part XEC232 (Kit membrane) to achieve the number of tests stated in this notice.

On Board Reagent Stability

Once opened, the reagent cassette placed in the refrigerated ABX Pentra 400 / Pentra C400 compartment is stable for 55 days.

Sample volume: 2 µL/test

Detection Limit

The detection limit is determined according to CLSI (NCCLS), EP17-A2 protocol (8) and equals 0.11 mmol/L (1.98 mg/dL).

Limit of Quantitation

The limit of quantitation is determined according to CLSI (NCCLS), EP17-A2 protocol (8) and equals 0.15 mmol/L (2.7 mg/dL).

Accuracy and Precision

Repeatability (within-run precision)

Repeatability according to the recommendations found in the Valtec protocol (9) with samples tested 20 times:

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

	Mean value mmol/L	Mean value mg/dL	CV %
Control specimen 1	5.38	96.90	0.66
Control specimen 2	13.99	251.90	0.81
Specimen 1	1.73	31.15	1.18
Specimen 2	5.24	94.35	0.52
Specimen 3	14.08	253.45	0.74

Reproducibility (total precision)

Reproducibility according to the recommendations found in the CLSI (NCCLS), EP5-A2 protocol (10) with samples tested in duplicate for 20 days (2 series per day):

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

	Mean value mmol/L	Mean value mg/dL	CV %
Control specimen 1	5.45	98.18	2.00
Control specimen 2	14.05	252.88	1.19
Specimen 1	5.55	99.86	2.03
Specimen 2	15.19	273.38	1.48

Measuring Range

The assay confirmed a measuring range from 0.15 mmol/L (2.70 mg/dL) to 50.00 mmol/L (900.0 mg/dL). The measuring range is extended up to 150.00 mmol/L (2700.0 mg/dL) with the automatic post-dilution.
The reagent linearity has been assessed up to 50.00 mmol/L (900.0 mg/dL) according to the recommendations found in the CLSI (NCCLS), EP06-Ed2 protocol (11).

Correlation

Patient samples: Serum
Number of patient samples: 103
Specimens are correlated with a commercial reagent taken as reference according to the recommendations found in the CLSI (NCCLS), EP09c protocol (12).
Values ranged from 1.12 mmol/L (20.16 mg/dL) to 19.55 mmol/L (351.90 mg/dL).
The equation for the allometric line obtained using Passing-Bablok regression procedure (13) is:
Y = 0.925 X + 0.1675 (mmol/L)
Y = 0.925 X + 3.015 (mg/dL)
with a correlation coefficient r^2 = 0.995.

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 6.43 mmol/L (562.63 mg/dL).
Total Bilirubin:	No significant influence is observed up to 616 µmol/L (36 mg/dL).
Direct Bilirubin:	No significant influence is observed up to 616 µmol/L (36 mg/dL).

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Etamsylate: No significant influence is observed up to 228 µmol/L (6.0 mg/dL).

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

Calibration Stability

The reagent is calibrated on Day 0. The calibration stability is checked by testing 2 control specimens.
The calibration stability is 14 days.
Note: A recalibration is recommended when reagent lots change, and when quality control results fall outside the range established.

Conversion Factor

mmol/L x 0.18 = g/L
mmol/L x 18 = mg/dL

Urine

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

Number of tests: 200 tests
If the number of tests requested is low and the ABX Pentra 400 / Pentra C400 user intends to utilise the cassette to the maximum on board stability, it is the recommendation of HORIBA, to utilise the consumable part XEC232 (Kit membrane) to achieve the number of tests stated in this notice.

On Board Reagent Stability

Once opened, the reagent cassette placed in the refrigerated ABX Pentra 400 / Pentra C400 compartment is stable for 55 days.

Sample volume: 3 µL/test

Detection Limit

The detection limit is determined according to CLSI (NCCLS), EP17-A protocol (16) and equals 0.16 mmol/L (2.9 mg/dL).

Limit of Quantitation

The limit of quantitation is determined according to CLSI (NCCLS), EP17-A protocol (16) and equals 0.22 mmol/L (3.96 mg/dL).

Accuracy and Precision

Repeatability (within-run precision)

Repeatability according to the recommendations found in the Valtec protocol (9) with samples tested 20 times:

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

	Mean value mmol/L	Mean value mg/dL	CV %
Control specimen 1	1.61	29.0	1.25
Control specimen 2	16.00	288.0	0.42
Specimen 1	1.04	18.8	2.56
Specimen 2	9.98	179.7	0.73
Specimen 3	29.65	533.7	0.76

Reproducibility (total precision)

Reproducibility according to the recommendations found in the CLSI (NCCLS), EP5-A2 protocol (10) with samples tested in duplicate for 20 days (2 series per day):

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

	Mean value mmol/L	Mean value mg/dL	CV %
Control specimen 1	1.64	29.4	3.57
Control specimen 2	16.17	291.1	2.62
Specimen 1	0.81	14.6	4.82
Specimen 2	5.81	104.5	1.21
Specimen 3	9.72	175.0	2.96
Specimen 4	27.57	496.2	2.74
Specimen 5	46.04	828.7	1.59

Measuring Range

The assay confirmed a measuring range from 0.22 mmol/L (3.96 mg/dL) to 50.00 mmol/L (900.0 mg/dL).
The measuring range is extended up to 150.00 mmol/L (2700.0 mg/dL) with the automatic post-dilution.
The reagent linearity has been assessed up to 50.00 mmol/L (900.0 mg/dL) according to the recommendations found in the CLSI (NCCLS), EP06-Ed2 protocol (11).

Correlation

Patient samples: urine
Number of patient samples: 104
Specimens are correlated with a commercial reagent taken as reference according to the recommendations found in the CLSI (NCCLS), EP09c protocol (12).
Values ranged from 0.30 mmol/L (5.40 mg/dL) to 49.94 mmol/L (898.92 mg/dL).
The equation for the allometric line obtained using Passing-Bablok regression procedure (13) is:
Y = 0.968 X + 0.03165 (mmol/L)

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Y = 0.968 X + 0.5693 (mg/dL)
with a correlation coefficient r^2 = 0.996.

Interferences

Haemoglobin:	No significant influence is observed up to 290 µmol/L (500 mg/dL).
Total Bilirubin:	No significant influence is observed up to 500 µmol/L (29.3 mg/dL).
Ascorbic Acid:	No significant influence is observed up to 350 µmol/L (6.16 mg/dL).
Specific gravity:	In the range of 1.005 to 1.035, no significant influence is observed.
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 (*14, 15*).*

Calibration Stability

The reagent is calibrated on Day 0. The calibration stability is checked by testing 2 control specimens.
The calibration stability is 21 days.
Note: A recalibration is recommended when reagent lots change, and when quality control results fall outside the range established.

Conversion Factor:

mmol/L x 0.18 = g/L
mmol/L x 18 = mg/dL

Reference

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