Clinical Chemistry

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REAGENT 90 mL

IVD CE 2797

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FRANCE

ABX Pentra Glucose PAP CP

- **Pentra C200**

Diagnostic reagent for quantitative *in vitro* determination of Glucose by peroxydase method (PAP) in serum, plasma and urine by colorimetry.

Application Release

Serum, plasma: GluP

01.xx

Urine: GluP (not for use in the USA)

01.xx

Intended Use [a] [b] [c]

ABX Pentra Glucose PAP CP reagent is intended for the quantitative *in vitro* diagnostic determination of glucose in human serum, plasma and urine using glucose oxidase 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, and of pancreatic islet cell carcinoma.
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 determination of glucose using the following reactions (Trinder method):

$$\text{Glucose} + O_2 \xrightarrow{\text{Glucose oxidase}} \text{Gluconic acid} + H_2O_2$$

$$2H_2O_2 + \text{Phenol} + 4\text{AAP} \xrightarrow{\text{Peroxidase}} \text{Quinoneimine} + 4H_2O$$

(4AAP = 4-aminoantipyrine)

Reagents

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

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

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Reagent:	
Phosphate buffer, pH 7.40	13.8 mmol/L
Phenol	10 mmol/L
4-aminoantipyrine	0.3 mmol/L
Glucose oxidase	≥ 10000 U/L
Peroxidase	≥ 700 U/L
Sodium azide	< 0.1%

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

Handling

1. Remove the cap 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 (not for use in the USA)** (1300023946) (not included)
  6 x 5 mL
- **Yumizen C Urine Level 2 Control (not for use in the USA)** (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: Pentra C200
- Calibrator: **ABX Pentra Multical** (A11A01652)
- Controls:
  ABX Pentra N MultiControl (1300054414)
  ABX Pentra P MultiControl (1300054415)
  Yumizen C Urine Level 1 Control (not for use in the USA) (1300023946)
  Yumizen C Urine Level 2 Control (not for use in the USA) (1300023947)
- Standard laboratory equipment.

Specimen (2, 3)

This device intended testing population is general population.

Specimen types

- Serum.
- Plasma in lithium heparin.
- Urine (not for use in the USA).

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 (4):

- At 25°C: 8 hours
- At 4°C: 72 hours

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 (not for use in the USA):

For 24-hours collection urine, 5 mL of glacial acetic acid may be added to the container before starting the

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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 (5)**:**

0.74 - 1.06 g/L

74 - 106 mg/dL

4.10 - 5.90 mmol/L

Urine (6, 7)**:**

< 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 Pentra C200".

Waste Management [d]

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

General Precautions [e]

- 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.
- **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 (8).
- 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).

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

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Performance on Pentra C200

Lot to Lot Variability [f]

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: < 8%.

Serum, plasma

The performance data listed below have been obtained on the Pentra C200 analyzer.

Number of tests: approximately 268 tests

On Board Reagent Stability

Once opened, the reagent cassette placed in the refrigerated Pentra C200 compartment is stable for 94 days.

Sample volume: 4 µL/test

Detection Limit

The detection limit is determined according to CLSI (NCCLS), EP17-A protocol (9) and equals 0.04 mmol/L (0.77 mg/dL).

Limit of Quantitation

The limit of quantitation is determined according to CLSI (NCCLS), EP17-A protocol (9) and equals 0.24 mmol/L (4.3 mg/dL).

Accuracy and Precision

Repeatability (within-run precision)

Repeatability according to the recommendations found in the Valtec protocol (10) 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	5.47	98.38	0.72
Control specimen 2	14.28	257.09	0.68
Specimen 1	2.10	37.73	1.50
Specimen 2	5.55	99.93	0.76
Specimen 3	17.04	306.68	0.85

Reproducibility (total precision)

Reproducibility according to the recommendations found in the CLSI (NCCLS), EP5-A2 protocol (11) with samples tested in duplicate for 20 days (2 series per day):

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

	Mean value mmol/L	Mean value mg/dL	CV %
Control specimen 1	5.5	99.8	2.44
Control specimen 2	14.5	261.3	1.61
Specimen 1	2.0	36.4	2.89
Specimen 2	5.4	97.4	2.33
Specimen 3	16.9	303.8	1.57

Measuring Range

The assay confirmed a measuring range from 0.24 mmol/L (4.3 mg/dL) to 24.00 mmol/L (432.0 mg/dL).
The measuring range is extended up to 72.00 mmol/L (1296.0 mg/dL) with the automatic post-dilution.
The reagent linearity has been assessed up to 24.00 mmol/L (432.0 mg/dL) according to the recommendations found in the CLSI (NCCLS), EP06-Ed2 protocol (12).

Correlation

Patient samples: Serum
Number of patient samples: 108
Specimens are correlated with a commercial reagent taken as reference according to the recommendations found in the CLSI (NCCLS), EP09c protocol (13).
Values ranged from 0.61 mmol/L (10.98 mg/dL) to 23.33 mmol/L (419.94 mg/dL).
The equation for the allometric line obtained using Passing-Bablok regression procedure (14) is:
Y = 0.9819 X - 0.01636 (mmol/L)
Y = 0.9819 X - 0.2944 (mg/dL)
with a correlation coefficient r^2 = 0.997.

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

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Interferences

Haemoglobin:	No significant influence is observed up to 350 µmol/L (603 mg/dL).
Triglycerides:	No significant influence is observed up to a triglyceride concentration of 4.75 mmol/L (415.6 mg/dL).
Total Bilirubin:	No significant influence is observed up to 104 µmol/L (6.1 mg/dL).
Direct Bilirubin:	No significant influence is observed up to 160 µmol/L (9.4 mg/dL).
N-Acetylcysteine (NAC):	Patients treated with N-Acetylcysteine (NAC) for Paracetamol overdose may generate a false low result.
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 (15, 16).

Calibration Stability

The reagent is calibrated on Day 0. The calibration stability is checked by testing 2 control specimens.
The calibration stability is 50 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 (not for use in the USA)

The performance data listed below have been obtained on the Pentra C200 analyzer.

Number of tests: approximately 268 tests

On Board Reagent Stability

Once opened, the reagent cassette placed in the refrigerated Pentra C200 compartment is stable for 94 days.

Sample volume: 3 µL/test

Detection Limit

The detection limit is determined according to CLSI (NCCLS), EP17-A protocol (9) and equals 0.05 mmol/L (0.94 mg/dL).

Limit of Quantitation

The limit of quantitation is determined according to CLSI (NCCLS), EP17-A protocol (9) and equals 0.21 mmol/L (3.78 mg/dL).

Accuracy and Precision

Repeatability (within-run precision)

Repeatability according to the recommendations found in the Valtec protocol (10) 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	1.74	31.31	4.12
Control specimen 2	17.23	310.16	1.62
Specimen 1	1.51	27.16	2.08
Specimen 2	8.30	149.42	1.44
Specimen 3	28.37	510.74	1.39

Reproducibility (total precision)

Reproducibility according to the recommendations found in the CLSI (NCCLS), EP5-A2 protocol (11) with samples tested in duplicate for 20 days (2 series per day):

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

	Mean value mmol/L	Mean value mg/dL	CV %
Control specimen 1	1.8	31.6	2.70
Control specimen 2	17.2	310.0	1.94
Specimen 1	1.5	27.7	3.43
Specimen 2	8.4	150.7	2.41
Specimen 3	28.3	509.0	2.21

Measuring Range

The assay confirmed a measuring range from 0.21 mmol/L (3.8 mg/dL) to 30.00 mmol/L (540.0 mg/dL).
The measuring range is extended up to 90.00 mmol/L (1620.0 mg/dL) with the automatic post-dilution.
The reagent linearity has been assessed up to 30.00 mmol/L (540.0 mg/dL) according to the recommendations found in the CLSI (NCCLS), EP06-Ed2 protocol (12).

Correlation

Patient samples: urine
Number of patient samples: 92

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Specimens are correlated with a commercial reagent taken as reference according to the recommendations found in the CLSI (NCCLS), EP09c protocol (13).
Values ranged from 0.23 mmol/L (4.14 mg/dL) to 25.99 mmol/L (467.82 mg/dL).
The equation for the allometric line obtained using Passing-Bablok regression procedure (14) is:
Y = 0.9482 X + 0.08576 (mmol/L)
Y = 0.9482 X + 1.544 (mg/dL)
with a correlation coefficient r^2 = 0.997.

Interferences

Haemoglobin:	No significant influence is observed up to 350 µmol/L (603 mg/dL).
Direct Bilirubin:	No significant influence is observed up to 350 µmol/L (20.5 mg/dL).
Ascorbic Acid:	No significant influence is observed up to 0.17 mmol/L (3 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 (15, 16).

Calibration Stability

The reagent is calibrated on Day 0. The calibration stability is checked by testing 2 control specimens.
The calibration stability is 49 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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