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REAGENT 29.5 mL

IVD CE

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FRANCE

ABX Pentra Total Protein 100 CP

- **Pentra C400**

Diagnostic reagent for quantitative *in vitro* determination of Total Protein in serum or plasma by colorimetry.

Application Release

Serum, plasma: TP3

1.xx

Intended Use

ABX Pentra Total Protein 100 CP reagent is intended for the quantitative *in vitro* diagnostic determination of total protein in serum and plasma by colorimetry.
Measurements obtained by this device are used in the diagnosis and treatment of a variety of diseases involving the liver, kidney, or bone marrow as well as other metabolic or nutritional disorders.

Clinical Interest (1)

Total protein is useful for monitoring gross changes in proteins levels caused by various diseases states. It is usually performed in conjunction with other tests such as serum albumin, liver function tests or protein electrophoresis. An albumin/globulin ratio is often calculated to obtain additional information.
Increased levels are found in dehydratation, multiple myeloma and chronic liver diseases, while decreased levels are found in renal disease and terminal liver failure.

Method (2)

Biuret reaction.
The peptide bonds of protein react with the copper II ions in alkaline solution to form a blue-violet complex (the so-called biuret reaction), each copper ion complexing with 5 or 6 peptides bonds (2). Tartrate is added as a stabilizer whilst iodide is used to prevent auto-reduction of the alkaline copper complex. The colour formed is proportional to the protein concentration and is measured at 520-560 nm.

Reagents

ABX Pentra Total Protein 100 CP is ready-to-use.

Reagent:	
Copper sulfate	≤ 14 mmol/L
Sodium-potassium tartrate	≤ 36 mmol/L
Potassium iodide	≤ 36 mmol/L
Sodium hydroxide	≤ 240 mmol/L

ABX Pentra Total Protein 100 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. Position the protective cap (GBM0969) on the cassette.
4. Place the cassette into the refrigerated reagent compartment.

Calibrator

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

ABX Pentra Total Protein 100 CP

Control [a]

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)

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 C400
- Calibrator: **ABX Pentra Multical** (A11A01652)
- Controls:
  ABX Pentra N MultiControl (1300054414)
  ABX Pentra P MultiControl (1300054415)
- Standard laboratory equipment.

Specimen [b]

This device intended testing population is general population.

Specimen types

- Non-haemolysed serum.
- Non-haemolysed plasma in lithium heparin or EDTA.

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

Stability (3)

- At 20-25°C: up to 6 days
- At 4-8°C: up to 4 weeks
- At -20°C: up to 1 year

Reference Range [c]

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

Values for serum specimens (4):

Ambulatory patients:	64 - 83 g/L
	6.4 - 8.3 g/dL
Recumbent patients:	60 - 78 g/L
	6.0 - 7.8 g/dL

Serum and plasma can be used for total protein determination. Due to fibrinogen, the mean total protein concentration in plasma is higher than in serum, and specifically as shown below (5):

Blood origin	**Protein concentration increase from serum to plasma**
Blood donors:	+ 2.5 g/L
Nonhospitalized patients:	+ 3.6 g/L
Hospitalized patients:	+ 4.6 g/L
Hospitalized patients with CRP >50mg/dL:	+ 6.6 g/L

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. Store protected from light.

Stability after opening:

Refer to the paragraph "Performance on Pentra C400".

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[a]Modification: control removed.
[b]Modification: modification of "Specimen".
[c]Modification: information added.

ABX Pentra Total Protein 100 CP

Waste Management

Please refer to local legal requirements.

General Precautions [d]

- 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.
- **Warning**
  H290: May be corrosive to metals.
  H315: Causes skin irritation.
  H319: Cause serious eye irritation.
  H411: Toxic to aquatic life with long lasting effects.
  P273: Avoid release to the environment.
  P280: Wear protective gloves/protective clothing/eye protection/face protection.
  P390: Absorb spillage to prevent material damage.
  P406: Store in corrosive resistant container with a resistant inner liner.
  P501: Dispose of contents and container in accordance with all local, regional, national and international regulations.
  P302 + P352: IF ON SKIN: Wash with plenty of soap and water.
  P332 + P313: If skin irritation occurs: Get medical advice/attention.
  P337 + P313: If eye irritation persists: Get medical advice/attention.
  P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- 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 Medical 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.

Performance on Pentra C400

Lot to Lot Variability [e]

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

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

Number of tests: 100 tests

On Board Reagent Stability

Once opened, the reagent cassette placed in the refrigerated Pentra C400 compartment is stable for 17 days.

Sample volume: 5 µL/test

Detection Limit [f]

The detection limit is determined according to CLSI (NCCLS), EP17-A2 protocol (6) and equals 1.23 g/L (0.12 g/dL).

Limit of Quantitation

The limit of quantitation is determined according to CLSI (NCCLS), EP17-A2 protocol (6) and equals 6.5 g/L (0.65 g/dL).

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)

[d]Modification: general precautions modification.
[e]Modification: chapter added.
[f]Modification: data added.

ABX Pentra Total Protein 100 CP

	Mean value g/L	Mean value g/dL	CV %
Control specimen 1	62.86	6.29	0.37
Control specimen 2	47.92	4.79	0.23
Specimen 1	41.11	4.11	0.68
Specimen 2	66.34	6.63	0.64
Specimen 3	106.48	10.65	0.24

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 g/L	Mean value g/dL	CV %
Control specimen 1	63.48	6.35	1.0
Control specimen 2	48.73	4.87	1.2
Specimen 1	41.29	4.13	1.4
Specimen 2	66.36	6.64	1.5
Specimen 3	93.14	9.31	1.4

Measuring Range

The assay confirmed a measuring range from 6.5 g/L (0.65 g/dL) to 160 g/L (16.0 g/dL).
The reagent linearity has been assessed up to 160 g/L (16.0 g/dL) according to the recommendations found in the CLSI (NCCLS), EP06-Ed2 protocol (9).

Correlation [g]

Patient samples: Serum
Number of patient samples: 152
Specimens are correlated with a commercial reagent taken as reference according to the recommendations found in the CLSI (NCCLS), EP09c protocol (10).
Values ranged from 7.06 g/L (0.71 g/dL) to 158.43 g/L (15.84 g/dL).
The equation for the allometric line obtained using Passing-Bablok regression procedure (11) is:
Y = 0.9761 x + 0.673 (g/L)
Y = 0.9761 x + 0.0673 (g/dL)
with a correlation coefficient r^2 = 0.999.

Interferences [h]

Haemoglobin: No significant influence is observed up to 113 µmol/L (195 mg/dL).
Triglycerides: No significant influence is observed up to a triglyceride concentration of 3.79 mmol/L (331.52 mg/dL).
Total Bilirubin: No significant influence is observed up to 480 µmol/L (28.1 mg/dL).
Direct Bilirubin: No significant influence is observed up to 384 µmol/L (22.5 mg/dL).
Glucose: No significant influence is observed up to 55.6 mmol/L (10 g/L).
Ascorbic Acid: No significant influence is observed up to 340 µmol/L (5.98 mg/dL).

Other limitations are given by Young as a list of drugs and preanalytical variables known to affect this methodology (12, 13).

Calibration Stability

The reagent is calibrated on Day 0. The calibration stability is checked by testing 2 control specimens.
The calibration stability is 3 days.
Note: A recalibration is recommended when reagent lots change, and when quality control results fall outside the range established.

Conversion Factor

g/L x 0.1 = g/dL

Reference

1. Tietz NW. (Ed), Textbook of Clinical Chemistry, WB saunders (1986): 579.
2. Roberts WL, McMillin GA, Burtis CA, Bruns DE. Reference Information for the Clinical Laboratory. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 4th Ed., Burtis CA, Ashwood ER, Bruns DE (Elsevier Saunders eds. St Louis USA), (2006): 2293.
3. Ehret W, Heil W, Schmitt Y, Töpfer G, Wisser H, Zawta B et al. Use of anticoagulants in diagnostic laboratory investigations and stability of blood, plasma and serum samples. WHO publication WHO/DIL/LAB/99.1 Rev.2: 40 (2002).

[g]Modification: modification of correlation.
[h]Modification: modification of interferences.

ABX Pentra Total Protein 100 CP

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6. Evaluation of detection capability for clinical laboratory measurement procedures. Approved Guideline, 2nd ed., CLSI (NCCLS) document EP17-A2 (2012) **32** (8).
7. Vassault A, Grafmeyer D, Naudin C et al. Protocole de validation de techniques (document B). Ann. Biol. Clin. (1986) **44**: 686-745.
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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).
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13. Young DS. Effects of Preanalytical Variables on Clinical Laboratory Tests. 2nd Edition, Washington, DC, AACC Press (1997) **3**: 120-132.