Clinical Chemistry

2020/03/20
A93A01320DUS

REF A11A01611
REAGENT 1 25 mL
REAGENT 2 23.5 mL

IVD CE

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FRANCE

ABX Pentra CRP CP

- **Pentra C400**

Diagnostic reagent for quantitative *in vitro* determination of C-Reactive Protein (CRP) in serum or plasma by latex-enhanced immunoturbidimetry.

Application Release

Serum, plasma: CRP

1.xx

Intended Use

ABX Pentra CRP CP reagent is intended for use for the quantitative *in vitro* diagnostic determination of the C-reactive protein in human serum and plasma based on an immunoturbidimetric assay. Measurement of C-reactive protein aids in evaluation of injury to body tissue.

Clinical Interest (1)

CRP (C-reactive protein) is an acute phase protein whose concentration is seen to increase as a result of the inflammatory process, most notably in response to pneumococcal (bacterial) infections, histolytic disease and a variety of disease states. Originally discovered by Tillet et al. in 1930 in patient sera with acute infection, CRP has now come to be used as a marker or general diagnostic indicator of infections and inflammation, in addition to serving as a monitor of patient response to therapy and surgery. Furthermore, regular measurements of CRP in infants can be a useful aid in the early diagnosis of infectious disease.
Indications obtained are general and not associated with specific diseases or risks for disease.

Method

ABX Pentra CRP CP (Licensed for USP6, 248, 597/ USP6, 828, 158 and equivalent patents in other countries) is a latex-enhanced immunoturbidimetric assay developed to accurately measure CRP levels in serum and plasma samples for conventional CRP ranges.
When an antigen-antibody reaction occurs between CRP in a sample and anti-CRP antibody which has been sensitized to latex particles, agglutination results. This agglutination is detected as an absorbance change, with the magnitude of the change being proportional to the quantity of CRP in the sample. The actual concentration is then determined by interpolation from a calibration curve prepared from calibrators of known concentration.

Reagents

ABX Pentra CRP CP is ready-to-use.

Reagent 1:

Buffer solution: Glycine buffer solution

Reagent 2:

Latex suspension: 0.20% w/v suspension of latex particles sensitized with anti-CRP antibodies (rabbit)

- After measurements are taken, reagent cassettes should remain in the Pentra C400 refrigerated tray.
- Care should be taken not to interchange the caps with others cassettes.
- Reagents with different lot numbers should not be interchanged or mixed.
- **ABX Pentra CRP 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.

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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 CRP Cal (A11A01616) (not included)
5 x 1 mL (5 levels)

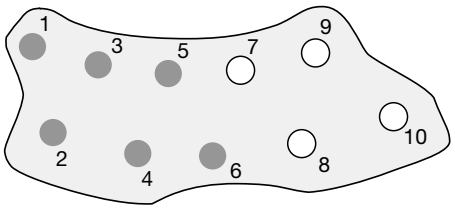
This calibrator is traceable against IRMM/ERM-DA472/IFCC.

Calibration of the CRP method is carried out by using:

- NaCl solution 9 g/L for Cal 0 (concentration 0 mg/L).
- **ABX Pentra CRP Cal**, which contains five CRP calibrator levels at different concentrations. Each vial is labelled from 1 to 5. The relation level/calibrator concentration is mentioned below:

Vials:	Cal 1	Cal 2	Cal 3	Cal 4	Cal 5
Concentration (mg/L):	2.5	10	40	80	160

Position of the calibrators on the calibrator sample rack:



Position 1: NaCl solution 9 g/L
Position 2: CAL 1 (2.5 mg/L)
Position 3: CAL 2 (10 mg/L)
Position 4: CAL 3 (40 mg/L)
Position 5: CAL 4 (80 mg/L)
Position 6: CAL 5 (160 mg/L)

Control [a]

For internal quality control, use:

- **ABX Pentra Immuno I Control L/H** (A11A01621) (not included)
  1 x 3 mL (lyophilisate) + 1 x 3 mL (lyophilisate)
  or
- **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 CRP Cal** (A11A01616)
- Controls:
  ABX Pentra Immuno I Control L/H (A11A01621)
  or
  ABX Pentra N MultiControl (1300054414)
  ABX Pentra P MultiControl (1300054415)
- NaCl solution: 9 g/L
- Cleaning solution: **ABX Pentra Clean-Chem CP** (A11A01755), 30 mL
- Standard laboratory equipment.

Specimen

- Serum.
- Plasma in lithium heparin.

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

[a]Modification: new control.

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Stability (2)**:**

- At 20-25°C: 15 days
- At 2-8°C: 2 months
- At -20°C: 3 years

Reference Range (3)

Because values could vary according to the age, the diet, the sex and the geographic repartition, each laboratory should establish its own reference ranges. The values given here are used as guidelines only.

CRP:
Adults (20-60 years) < 5 mg/L

Intra-individual variations of CRP are significant and should be taken into account when interpreting values.

Storage and Stability

Stability before opening:

Stable up to the expiry date on the label if stored at 2-10°C.

Stability after opening:

Refer to the paragraph "Performance on Pentra C400".

Waste Management

- Please refer to local legal requirements.
- This reagent contains less than 0.1% of sodium azide as a preservative. Sodium azide may react with lead and copper to form explosive metal azides.

General Precautions [b]

- This reagent is for professional *in vitro* diagnostic use only.
- For prescription use only.
- This reagent is classified as non-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 (4).
- Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration.
- 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.
- The assay is for conventional CRP use only.
- It is the user's responsibility to verify that this document is applicable to the reagent used.

Performance on Pentra C400

Serum, plasma

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

Number of tests: 200 tests
If the number of tests requested is low and the Pentra C400 user intends to utilise the cassette to the maximum on board stability, it is the recommendation of HORIBA Medical, 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 Pentra C400 compartment is stable for 64 days.

Sample volume: 4.0 µL/test

Minimum Interpretation Limit

The minimum interpretation limit (MIL) is evaluated using multiple determination of low concentration specimen and equals 1.00 mg/L.

Accuracy and Precision

Repeatability (within-run precision)

Repeatability according to the recommendations found in the Valtec protocol (5) with samples tested 20 times:

- 3 controls
- 5 specimens (very low / low / medium / high levels)

[b]Modification: general precautions modification.

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	Mean value mg/L	CV %
Control specimen 1	8.54	0.74
Control specimen 2	22.16	1.08
Control specimen 3	0.98	3.07
Specimen 1	0.86	4.15
Specimen 2	8.13	1.55
Specimen 3	18.66	0.92
Specimen 4	46.83	1.02
Specimen 5	126.11	2.25

Reproducibility (total precision)

Reproducibility according to the recommendations found in the CLSI (NCCLS), EP5-A protocol (6) with samples tested in duplicate for 20 days (2 series per day):

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

	Mean value mg/L	CV %
Control specimen 1	8.46	4.31
Control specimen 2	21.88	2.17
Control specimen 3	1.23	5.57
Specimen 1	62.25	2.32
Specimen 2	124.14	2.92
Specimen 3	0.86	7.04

Measuring Range

The assay confirmed a measuring range from 1.00 mg/L to 160 mg/L.
The measuring range is extended up to 800 mg/L with the automatic post-dilution.
The reagent linearity has been assessed up to 160 mg/L according to the recommendations found in the CLSI (NCCLS), EP6-A protocol (7).

Correlation

Patient samples: Serum
Number of patient samples: 190
Specimens are correlated with a commercial reagent taken as reference according to the recommendations found in the CLSI (NCCLS), EP9-A2 protocol (8).
Values ranged from < 1.00 mg/L to 158.30 mg/L.
The equation for the allometric line obtained using Passing-Bablok regression procedure (9) is:
Y = 1.03 X - 0.18 (mg/L)
with a correlation coefficient r^2 = 0.997.

Interferences

Haemoglobin: No significant influence is observed up to 280.8 µmol/L (485 mg/dL).
Triglycerides: No significant influence is observed up to an Intralipid® concentration (representative of lipemia) of 7 mmol/L (612.5 mg/dL).
Total Bilirubin: No significant influence is observed up to 289 µmol/L (16.9 mg/dL).
Direct Bilirubin: No significant influence is observed up to 321 µmol/L (18.8 mg/dL).
Other limitations are given by Young as a list of drugs and preanalytical variables known to affect this methodology (10, 11).

Prozone Effect

No antigen excess has been detected up to a concentration of 200 mg/L.

Calibration Stability

The reagent is calibrated on Day 0. The calibration stability is checked by testing 2 control specimens.
The calibration stability is 18 days.
Note: A recalibration is recommended when reagent lots change, and when quality control results fall outside the range established.

Reference

1. Tillet WS et al. Serological reactions in pneumonia with a nonprotein somatic fraction of pneumococcus. J. Exp. Med. (1930) **52**: 561.
2. Guder WG, Zawta B. The Quality of Diagnostics Samples. Samples: From the Patient to the Laboratory. 1st ed. Guder WG, Narayanan S, Zawta B. (WHILEY-VCH, Darmstadt, Germany), (2001): 24.
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4. Council Directive (2000/54/EC). Official Journal of the European Communities. No. L262 from October 17, 2000: 21-45.
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6. Evaluation of Precision Performance of Clinical Chemistry Devices. Approved Guideline, CLSI (NCCLS) document EP5-A (1999) **19** (2).

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7. Evaluation of the Linearity of Quantitative Analytical Methods. Approved Guideline, CLSI (NCCLS) document EP6-A (2003) **23** (16).
8. Method Comparison and Bias Estimation Using Patient Samples. Approved Guideline, 2nd ed., CLSI (NCCLS) document EP9-A2 (2002) **22** (19).
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11. Young DS. Effects of Preanalytical Variables on Clinical Laboratory Tests. 2nd Edition, Washington, DC, AACC Press (1997) **3**: 120-132.