Clinical Chemistry

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# ABX Pentra CRP CP

REF A11A01611
REAGENT 1 25 mL
REAGENT 2 23.5 mL

IVD CE 2797

HORIBA ABX SAS
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- Pentra C200

## 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**

2.xx

### Intended Use [a] [b] [c]

**ABX Pentra CRP CP** reagent is intended for the quantitative *in vitro* diagnostic determination of the C-reactive protein in human serum and plasma based on an immunoturbidimetric assay.
Clinical laboratories use.
CRP is one of the strongest acute phase reactants and aids in non-specific host defence against infectious agents, rising after myocardial infarction, stress, trauma, infection, inflammation, surgery or neoplastic proliferation.
This reagent is used to detect and measure C-reactive protein to assess the inflammatory status of the body.
Assessing physiologic and pathologic variations of C-reactive protein concentration in human serum and plasma is useful for screening or follow-up of inflammatory or infectious status.

### Clinical Interest (1) [d]

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 Tillett 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.

**Normal application (1.0 - 160 mg/L):**

C-reactive protein levels in serum can rise dramatically after myocardial infarction, stress, trauma, infection, inflammation, surgery, or neoplastic proliferation. The increase occurs within 24 to 48 hours, and the level may be 2000 times normal. Because the increase is non-specific, however, it cannot be interpreted without a complete clinical history, and even then only by comparison with previous values.

### 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

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

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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 C200 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.
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 |

## 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)

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 CRP Cal** (A11A01616)
- Controls:
  **ABX Pentra N MultiControl** (1300054414)
  **ABX Pentra P MultiControl** (1300054415)
- NaCl solution: 9 g/L
- Standard laboratory equipment.

## Specimen

This device intended testing population is general population.

- 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.

**Stability** (2)**:**

- At 20-25°C: 15 days
- At 4-8°C: 2 months
- At -20°C: 3 years

## Reference Range (3, 4)

Because values could vary according to the age, the diet, the sex and the geographic repartition, each laboratory

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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.

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 2-10°C.

**Stability after opening:**
Refer to the paragraph "Performance on Pentra C200".

## 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 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 (5).
- 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.
- 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.
- 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.
- 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).

## Performance on Pentra C200

### Lot to Lot Variability [g]

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 have been obtained on the Pentra C200 analyzer.

**Number of tests:** approximately 177 tests

### On Board Reagent Stability

Once opened, the reagent cassette placed in the refrigerated Pentra C200 compartment is stable for 40 days.

**Sample volume:** 3.4 µL/test

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[e]Modification: modification of waste management.
[f]Modification: general precautions modification.
[g]Modification: lot to lot variability specification added.

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### Detection Limit

The detection limit is determined according to CLSI (NCCLS), EP17-A2 protocol (6) and equals 0.07 mg/L.

### Limit of Quantitation

The limit of quantitation is determined according to CLSI (NCCLS), EP17-A2 protocol (6) and equals 0.20 mg/L.

### 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)

| | Mean value mg/L | CV % |
|---|---|---|
| Control specimen 1 | 6.01 | 1.86 |
| Control specimen 2 | 23.88 | 1.04 |
| Specimen 1 | 15.75 | 1.18 |
| Specimen 2 | 51 | 1.38 |
| Specimen 3 | 93 | 2.64 |

***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 mg/L | CV % |
|---|---|---|
| Control specimen 1 | 7.32 | 2.6 |
| Control specimen 2 | 24.35 | 1.5 |
| Specimen 1 | 16.18 | 1.4 |
| Specimen 2 | 53.86 | 3.1 |
| Specimen 3 | 98.85 | 4.3 |

### Measuring Range

The assay confirmed a measuring range from 0.2 mg/L to 160 mg/L.
The measuring range is extended up to 1600 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), EP06-Ed2 protocol (9).

### 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), EP09-A3 protocol (10).
Values ranged from 0.32 mg/L to 144.56 mg/L.
The equation for the allometric line obtained using Passing-Bablok regression procedure (11) is:
$Y = 0.9927 X + 0.07227$ (mg/L)
with a correlation coefficient $r^2 = 0.997$.

### Interferences

| | |
|---|---|
| Haemoglobin: | No significant influence is observed up to 400 µmol/L (690 mg/dL). |
| Triglycerides: | No significant influence is observed up to a triglyceride concentration of 4.91 mmol/L (429.63 mg/dL). |
| Total Bilirubin: | No significant influence is observed up to 300 µmol/L (17.6 mg/dL). |
| Direct Bilirubin: | No significant influence is observed up to 500 µmol/L (29.3 mg/dL). |
| Rheumatoid Factor: | No significant influence is observed up to 303 mg/L. |

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

### Prozone Effect

No antigen excess has been detected up to a concentration of 288 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 30 days.
*Note: A recalibration is recommended when reagent lots change, and when quality control results fall outside the range established.*

## Reference


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