Clinical Chemistry

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ABX Pentra RF CP

REF A11A01613
REAGENT 1 22 mL
REAGENT 2 9 mL

IVD CE

HORIBA ABX SAS
Parc Euromédecine - Rue du Caducée
B.P. 7290
34184 MONTPELLIER Cedex 4
FRANCE

- **Pentra C200**

Diagnostic reagent for quantitative *in vitro* determination of Rheumatoid Factor (RF) in serum or plasma by latex-enhanced immunoturbidimetric assay.

Application Release

Serum, plasma: RF (not for use in the USA)

02.xx

Intended Use (not for use in the USA)

The Rheumatoid Factor assay is used for the quantitation of rheumatoid factor in human serum. Measurement of rheumatoid factor may aid in the diagnosis of rheumatoid arthritis.

Clinical Interest (1)

Rheumatoid factor (RF) is an auto-antibody against human IgG commonly seen in sera at a high concentration in some conditions, particularly in patients with rheumatoid arthritis (RA).
The measurement of RF value is useful in evaluating the diagnosis, effects of therapy and prognosis of RA, systemic lupus erythematosus, chronic hepatopathy, etc.
ABX Pentra RF CP is a latex-enhanced immunoturbidimetric assay developed to accurately measure RF levels in serum samples.

Method (2)

When an antigen-antibody reaction occurs between RF in a sample and denatured human IgG 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 RF in the sample. The actual concentration is then determined by interpolation from a calibration curve prepared from calibrators of known concentration.

Reagents

ABX Pentra RF CP is ready-to-use.

Reagent 1:

Buffer solution: Glycine buffer solution

Reagent 2:

Latex suspension: 0.17% w/v suspension of latex particles sensitized with denatured human IgG

- 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 RF 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.

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Calibrator

For calibration, use:
ABX Pentra RF Cal (A11A01618) (not included)
5 x 1 mL
Calibration of the RF method is carried out by using:

- NaCl solution 9 g/L for Cal 0 (concentration 0 mg/L).
- **ABX Pentra RF Cal**, which contains five RF 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 (IU/mL):	10	20	40	80	120

Control

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)

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 RF Cal** (A11A01618)
- Control: **ABX Pentra Immuno I Control L/H** (A11A01621)
- NaCl solution: 9 g/L
- 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.

Stability (3)**:**

- At 20-25°C: 1 day
- At 4-8°C: 8 days
- At -20°C: 3 months

Reference Range (4)

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

Adults: < 30 IU/mL.

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

- 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 [a]

- 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 2 (R2):**
  Warning: Human source material. Treat as potentially infectious. Each plasma donor unit used in the preparation of this product has been tested by an FDA approved method and found negative for the presence of HBsAg, HCV and antibody to HIV1/2. Because no known test method can offer complete assurance that hepatitis B virus, Human Immunodeficiency Virus (HIV) or other infectious agents are absent, the reagent should be treated like patient specimens as potentially infectious and handled with appropriate cautions in accordance with good laboratory practices (5, 6).

[a]Modification: general precautions modification.

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- **Reagent 1 (R1):**
  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 (6).
- Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration.
- 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 MSDS associated with the reagent.
- Do not use the product if there is visible evidence of biological, chemical or physical deterioration.
- It is the user's responsibility to verify that this document is applicable to the reagent used.

Performance on Pentra C200

Serum, plasma

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

Number of tests: approximately 122 tests

On Board Reagent Stability

Once opened, the reagent cassette placed in the refrigerated Pentra C200 compartment is stable for 34 days.

Sample volume: 4 µL/test

Limit of Quantitation

The limit of quantitation is determined according to CLSI (NCCLS), EP17-A protocol (7) and equals 12.0 IU/mL.

Minimum Interpretation Limit

The minimum interpretation limit (MIL) is evaluated using multiple determination of low concentration specimen and equals 4.0 IU/mL.

Accuracy and Precision

Repeatability (within-run precision)

Repeatability according to the recommendations found in the Valtec protocol (8) with samples tested 20 times:

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

	Mean value IU/mL	CV %
Control specimen 1	19.61	1.60
Control specimen 2	36.82	0.68
Specimen 1	36.18	0.65
Specimen 2	47.93	0.96
Specimen 3	99.01	0.93

Reproducibility (total precision)

Reproductibility according to the recommendations found in the CLSI (NCCLS), EP5-A2 protocol (9) with samples tested in duplicate for 20 days (2 series per day):

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

	Mean value IU/mL	CV %
Control specimen 1	19.34	2.10
Control specimen 2	36.07	2.45
Specimen 1	29.60	2.40
Specimen 2	47.19	2.70
Specimen 3	95.56	2.14

Measuring Range

The assay confirmed a measuring range from 12.0 IU/mL to 120 IU/mL.
The measuring range is extended up to 1200 IU/mL with the automatic post-dilution.
The reagent linearity has been assessed up to 120 IU/mL according to the recommendations found in the CLSI (NCCLS), EP6-A protocol (10).

Correlation

Patient samples: Serum
Number of patient samples: 128
Specimens are correlated with a commercial reagent taken as reference according to the recommendations found in the CLSI (NCCLS), EP9-A2 protocol (11).
Values ranged from 4.50 IU/mL to 110.90 IU/mL.
The equation for the allometric line obtained using Passing-Bablock regression procedure (12) is:
Y = 0.93 X - 2.10 (IU/mL)
with a correlation coefficient r^2 = 0.997.

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 6.10 mmol/L (534 mg/dL).

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Total Bilirubin: No significant influence is observed up to 519 µmol/L (30 mg/dL).
Direct Bilirubin: No significant influence is observed up to 462 µmol/L (27 mg/dL).
*Other limitations are given by Young as a list of drugs and preanalytical variables known to affect this methodology (*13, 14*).*

Prozone Effect

No antigen excess has been detected up to a concentration of 340 IU/mL.

Calibration Stability

The reagent is calibrated on Day 0. The calibration stability is checked by testing 2 control specimens.
The calibration stability is 13 days.
Note: A recalibration is recommended when reagent lots change, and when quality control results fall outside the range established.

Reference

1. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: THBooks Verlagsgesellschaft. (1998): 810-13.
2. Winkles JW, Lunec J and Gray L. Automated enhanced latex agglutination assay for rheumatoid factors in serum, Clin. Chem. (1989) **35**: 303-307.
3. Use of anticoagulants in diagnostic laboratory investigations. WHO publication WHO/DIL/LAB/99.1 Rev. 2 (2002): 41.
4. Tietz NW, editor. Clinical Guide to Laboraroty Tests, 3rd ed. Philadelphia, PA: WB Saunders. (1995): 544-45.
5. Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR 1910. 1030). Federal Register July 1, 1998; **6**: 267-280.
6. Council Directive (2000/54/EC). Official Journal of the European Communities. No. L262 from October 17, 2000: 21-45.
7. Protocols for determination of limits of detection and limits of quantitation. Approved Guideline, CLSI (NCCLS) document EP17-A (2004) **24** (34).
8. Vassault A, Grafmeyer D, Naudin C et al. Protocole de validation de techniques (document B). Ann. Biol. Clin. (1986) **44**: 686-745.
9. Evaluation of Precision Performance of Quantitative Measurement Method. Approved Guideline, CLSI (NCCLS) document EP5-A2 (2004) **24** (25).
10. Evaluation of the Linearity of Quantitative Analytical Methods. Approved Guideline, CLSI (NCCLS) document EP6-A (2003) **23** (16).
11. Method Comparison and Bias Estimation Using Patient Samples. Approved Guideline, 2nd ed., CLSI (NCCLS) document EP9-A2 (2002) **22** (19).
12. Passing H, Bablock W. A new biometrical procedure for testing the equality of measurements from two different analytical methods. J. Clin. Chem. Clin. Biochem. (1983) **21**: 709-20.
13. Young DS. Effects of Drugs on Clinical Laboratory Tests. 4th Edition, Washington, DC, AACC Press (1997) **3**: 143-163.
14. Young DS. Effects of Preanalytical Variables on Clinical Laboratory Tests. 2nd Edition, Washington, DC, AACC Press (1997) **3**: 120-132.