Hematology

2023/11/23
A95A00246DAEN

# ABX CRP Rea

REF 0501015
REAGENT 1 10 mL
REAGENT 2 10 mL
REAGENT 3 20 mL

IVD CE

- Pentra MS CRP

**HORIBA ABX SAS**
Parc Euromédecine
Rue du Caducée
BP 7290
34184 Montpellier Cedex 4
FRANCE

## Hematology Devices (for *in vitro* diagnostic use)

### Intended Use [a] [b]

**ABX CRP Rea** is constituted of 3 reagents (**R1**, **R2**, **R3**) intended for *in vitro* diagnostic use on HORIBA Medical blood cell counters with CRP measurement.

- **R1** is an hemolysis solution.
- **R2** is a buffered solution.
- **R3** contains latex beads coated with anti-human C-reactive protein anti-bodies.

### Warnings and Precautions [c]

- **ABX CRP Rea** is for professional *in vitro* diagnostic use only.
  For laboratory use.
- It is the user's responsability to verify that this document is applicable to the product use.
- 
- **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 (1).
- Users are advised to wear approved protective clothing when handling chemical products: lab coat, gloves, and eye protection.
- Observe the standard laboratory precautions for use and follow national or local health and safety guidelines.
- In the event of a malaise following skin contact, ingestion, or inhalation, consult a doctor.
- User must be trained by a HORIBA Medical representative before attempting to operate the device.
- Please refer to the Safety Data Sheet (SDS) associated with **ABX CRP Rea**.
- 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.
- This reagent is destined for use with HORIBA Medical blood cell counters specified above. HORIBA Medical cannot guarantee the correct functionning of this reagent with instruments other than those specified above, or with instruments not manufactured by HORIBA Medical.
- The reagent containers are disposable and should be disposed of in accordance with the local legal requirements.
- For technical assistance, you can call +33 (0)4 67 14 15 16.

### 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.

### Microbiological State

Not applicable.

[a]Modification: new reagent leaflet form.
[b]Modification: instrument removed.
[c]Modification: recommendation added.

QUAL-QA-WORI-5544 Rev.2

# ABX CRP Rea

## Description and Composition

**Description:**

**R1**: Limpid and colourless to light yellowish aqueous solution.
**R2**: Limpid and colourless to light yellowish aqueous solution.
**R3**: Creamy white aqueous solution.

**Composition:**

| **R1** | |
|---|---|
| Preservative | < 0.1% |
| Surfactant | < 2% |

| **R2** | |
|---|---|
| Buffer | < 12% |
| Preservative | < 0.1% |
| Surfactant | < 0.1% |

| **R3** | |
|---|---|
| Rabbit polyclonal antibodies | < 0.5% |
| Preservative | < 0.1% |
| Buffer | < 10% |

## Storage and Stability

- **Storage condition (before opening):** 2-10°C (35-50°F).
  Do not freeze.
- **Open stability:** 2 months maximum at 2-10°C (35-50°F) after opening and within the expiration limit.
- **Expiration date:** refer to "expiration date" reagent packaging label.

## Materials Required but not Provided [d]

- Automated hematology analyzer.
- Calibrator: **ABX CRP Std (0501016)**.
- Control: **ABX Minotrol 16 / ABX Minotrol CRP**.
- Standard laboratory equipment.

## Specimen [e]

**Sample collection:**

All blood samples should be collected using proper technique! Consider all specimens, reagents, calibrators, controls, etc. that contain human specimen extracts as potentially infectious and follow biosafety practices (2, 3). When collecting blood specimens, venous blood is recommended, but arterial blood may also be used in extreme cases. Blood collection must be placed in vacuum or atmospheric collection tubes (4, 5). The sample collection tube has to be filled to the exact quantity of blood indicated on the tube itself to avoid variations in the results.

**Recommended anti-coagulant:**

The recommended anticoagulant is $K_3$-EDTA with the proper proportion of blood to anticoagulant as specified by the tube manufacturer. $K_2$-EDTA is an acceptable alternative, as long as the sample collection is made in normal conditions. Otherwise, blood clots may be possible.

**Blood sample stability:**

The specimens were collected from the routine laboratory workload and stored at room temperature (25°C) and 4°C. Sample stability was assessed over a period of 72 hours. The results indicate a sample stability claim of 72 hours with storage at either room temperature or 4°C for C reactive protein determinations.

**Microsampling:**

Instrument sampling mode enables the user to work with microsamples for pediatrics and geriatrics (refer to the instrument user manual for the minimum blood sample volume). These microsamples can only be used in the following conditions:

- The tube must always be held in vertical position.
- Blood mixing must be obtained by slight tapping on the tube. Do not rotate the tube for mixing, otherwise the blood will be spread on the tube side, and the minimum required level will be lost.

**Mixing:**

Blood samples must be gently and thoroughly mixed just before sampling. This ensures a homogeneous mixture for measurement.

[d]Modification: correction.
[e]Modification: information added.

# ABX CRP Rea

## Procedure

These reagents are ready to use.
If one or more CRP reagents need to be replaced, you must replace all three reagents.
**Warning:** do not discard the new **ABX CRP Rea** packaging. The labeling on the front of the package contains the CRP reagent sensitivity factors. Those factors are to be entered into the calibration menu, when replacing CRP reagents.

1. Open the CRP reagent door, located on the right-hand side of the instrument.
2. If necessary, remove the empty **ABX CRP Rea** from the reagent compartment.
3. Remove the CRP reagent kit (R1, R2 and R3) from refrigeration.
4. Close the door. Verify that the CRP reagent door is completely closed into it's locking device.
5. Refer to the instrument user manual to enter the new sensitivity factors.

CRP concentration is determined by a polynomial calibration curve. A calibration curve is specifically defined for each batch. Reagent factor must be used to adjust the calibration curve for each batch of reagent to ensure the accuracy of the result.
Follow instructions displayed on your instrument software.
Refer to the instrument user manual for detailed analysis and control procedures.

## Methodology

The assay involves immuno-turbidimetry (6).
**ABX CRP Rea, R1**: During the first stage, blood cells are lysed by reagent R1.
**ABX CRP Rea, R2**: Addition of R2 inhibits interference.
**ABX CRP Rea, R3**: Stage 3 involves the addition of reagent R3, which contains anti-CRP antibodies bound to latex beads. Absorbance is measured at 850 nm, and the absorbance is proportional to the CRP concentration of the sample.

## Performance Characteristics and Limitations of the Method

Refer to the user manual for the performance characteristics of the instrument and the limitations of the analyses on instrument parameters.

## Calculation and Interpretation of Analytical Results

Refer to the instrument user manual for calculation and interpretation of analytical results.

## Changes in the Procedure and in the Performance

### Packaging spoiling

In case of protective packaging spoiling, do not use **ABX CRP Rea** if the damages might have an effect on the product performance.

### Signs of deterioration

In the event of any signs of physical or chemical deterioration (turbidity, change in colour etc.) **ABX CRP Rea** should be replaced.

### Temperature limits

Do not use **ABX CRP Rea** if it has been frozen or kept at excessive heat.
Before using **ABX CRP Rea**, make sure it has reached the operating temperature conditions as described in the instrument user manual.

## Internal Quality Control

HORIBA Medical control bloods must be used to periodically assess the integrity of the reagents and the instrument in the specified ranges.
HORIBA Medical offers an Online Interlaboratory Comparison Program (QCP) which provides internet access to:

- Submit Internal Quality Control results online.
- Monitor analytical performances and compare directly with hundreds of laboratories worldwide.
- Obtain real time peer group statistical reports from QCP

More informations are available at:
http://qcp.horiba-abx.com

## Traceability of Calibrators and Control Materials

Not applicable.

# ABX CRP Rea

## Reference Intervals

Lower than 5 mg/L

## Reference


1. Council Directive (2000/54/EC). Official Journal of the European Communities. No. L262 from October 17, 2000: 21-45.
2. Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR 1910. 1030). Federal Register July 1, 1998; **6**: 267-280.
3. Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline - Fourth Edition. CLSI (NCCLS), document M29-A4 (2014) **34** (18).
4. Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard - Sixth Edition. CLSI (NCCLS), document H3-A6 (2007) **27** (26).
5. Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard - Sixth Edition. CLSI (NCCLS), document H4-A6 (2008) **28** (25).
6. Tillett, W. S. et al.: Serological reactions in pneumonia with a nonprotein somatic fraction of pneumococcus. J. Exp. Med., 52, **561** (1930). 2.