Hematology

2013/02/12
A95A00246DEN

# ABX CRP Rea

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

IVD CE

- ABX Micros CRP200
- Pentra MS CRP

**HORIBA ABX SAS**
Parc Euromédecine - Rue du Caducée
B.P. 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.
- It is the user's responsability to verify that this document is applicable to the product use.
- **ABX CRP Rea** is classified as non-hazardous in compliance with regulations 67/548/EEC - 1999/45/EC.
- **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.
- Please refer to the Material Safety Data Sheet (MSDS) associated with **ABX CRP Rea**.
- 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.

### 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.

### 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% |

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

QUAL-QA-TEMP-0866 Rev.5

# ABX CRP Rea

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

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

## Storage and Shelf Life after First Opening

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

## Materials Required but not Provided

- Automated hematology analyzer.
- Calibrator: **ABX CRP Std (P/N: 0501016)**.
- Control: refer to the user manual for the specific control used with your instrument.
- Standard laboratory equipment.

## 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. Remove caps from reagents and place them immediatly into the **ABX Micros CRP 200** CRP reagent compartment.
5. Close the door. Verify that the CRP reagent door is completely closed into it's locking device.
6. Refer to the instrument user manual to enter the new sensitivity factors.

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 (2).
**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.

# ABX CRP Rea

**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.

## Reference Intervals

Not applicable.

## Reference

1. Council Directive (2000/54/EC). Official Journal of the European Communities. No. L262 from October 17, 2000: 21-45.
2. Tillet, W. S. et al.: Serological reactions in pneumonia with a nonprotein somatic fraction of pneumococcus. J. Exp. Med., 52, **561** (1930). 2.