

CRP Unit 50

Exclusive use: Microsemi CRP

Hematology Devices (for in vitro diagnostic use)

Two reagent kits are contained in the package.

REF 3200345511
REAGENT 1 5 mL approx.
REAGENT 2 5 mL approx.
REAGENT 3 10 mL approx.

IVD CE

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Intended Use

CRP Unit 50 is constituted of 3 reagents (R1, R2, R3) intended for in vitro diagnostic use on HORIBA Medical hematology analyzer with CRP measurement.

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

Warnings and Precautions

- It is the user's responsibility to verify that this document is applicable to the product use.
- Clinical diagnosis based on the results should be comprehensively judged by a physician in charge together with clinical presentation or other results.
- CRP Unit 50 is classified as non-hazardous in compliance with regulations 67/548/EEC - 1999/45/EC.
- CRP Unit 50 contains animal source material (BSA). Treat as potentially infectious because there is no approved test done on this raw material.
- 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 an uneasiness following skin contact, ingestion, or inhalation, consult a doctor.
- Refer to the Material Safety Data Sheet (MSDS) associated with CRP Unit 50.
- This reagent is destined for use with HORIBA Medical hematology analyzer specified above. HORIBA Medical cannot guarantee the correct functioning of this reagent with instruments other than those specified above, or with instruments not manufactured by HORIBA Medical.

Waste Management

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 colorless aqueous solution

R2: Limpid and colorless aqueous solution

R3: Creamy white aqueous solution

Composition

R1

Preservative	< 0.1%
Surfactant	1.0% to 2.0%

R2

Preservative	< 0.1%
Surfactant	< 0.1%

R3

Anti-human CRP antibody (rabbit) with Latex	0.1% to 0.5%
Preservative	< 0.1%

Storage and Shelf Life after First Opening

Storage condition

2°C to 10°C (35°F to 50°F)
Do not freeze.

Open stability

2 months maximum at 2°C to 10°C (35°F to 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.
- Control: Refer to the user manual for the specific control used with your instrument.
- Standard laboratory equipment

Specimen

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 (1, 2). 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 (3, 4). 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 K3-EDTA with the proper proportion of blood to anticoagulant as specified by the tube manufacturer. K2-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 sample stability at room temperature (25°C) and 4°C: The specimens were collected from the routine laboratory workload and stored at room temperature and 4°C. Sample stability was assessed over a period of 72 hours. The results (mean of consecutive test) conclude with a relative sample stability claim of 48 hours period at 4°C and room temperature.

Microsampling

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

- 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.

Procedure

These reagents are ready to use.

1. Open the cooling unit door, located on the right-hand side of the instrument.
2. If necessary, remove the empty CRP Unit 50 from the reagent compartment.
3. Remove CRP Unit 50 from refrigeration.
4. Peel off the seal gently on the top of the reagent container and place the CRP reagent immediately into the cooling unit.

Tip

When peeling off the seal, hold the CRP reagent container firmly and peel off the seal gently so that reagent does not splash.

5. Close the door. Verify that the cooling unit door is completely closed.
6. 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.

- **CRP Unit 50, R1**
  During the first stage, blood cells are lysed by reagent R1.
- **CRP Unit 50, R2**
  Addition of R2 inhibits interference.
- **CRP Unit 50, R3**
  Stage 3 involves the addition of reagent R3, which contains anti-CRP antibodies bound to latex beads. Absorbance is measured at 660 nm, and the absorbance is proportional to the CRP concentration of the sample.

Performance Characteristics and Limitations of the Method

Refer to the instrument 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 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 CRP Unit 50 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 color etc.) CRP Unit 50 should be replaced.
- **Temperature limits**
  Do not use CRP Unit 50 if it has been frozen or kept at excessive heat.

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 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

Conforms to Institute for Reference Materials and Measurements (IRMM).

Reference Intervals

Not applicable.

Reference

1. Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR 1910. 1030). Federal Register July 1, 1998; 6: 267-280.
2. Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline - Third Edition. CLSI (NCCLS), document M29-A3 (2005) 25 (10).
3. Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard - Sixth Edition. CLSI (NCCLS), document H3-A6 (2007) 27 (26).
4. Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard - Sixth Edition. CLSI (NCCLS), document H4- A6 (2008) 28 (25).
5. Tillet, W.S. et al.: Serological reactions in pneumonia with a nonprotein somatic fraction of pneumococcus.J. Exp. Med., 552, 561 (1930)