 

HORIBA

# CRP Unit 50 a

Exclusive use:
Microsemi CRP, Microsemi CRP LC-767G,
Yumizen H500 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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EC REP
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## Intended use b

Quantitative, automated in vitro diagnostic test for C-reactive protein measurement on whole-blood, plasma, and serum of human patient populations on HORIBA Medical cell counters in clinical laboratories. Measurement of C-reactive protein is an aid to assess the inflammatory status of the body. (1)

## Warnings and precautions c

- CRP Unit 50 is for professional in vitro diagnostic use only.
- 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 regulation (EC) N°.1272/2008.
- **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 (2).
- 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 Safety Data Sheet (SDS) 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.
- 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.
- To avoid losing the factor barcode, keep the outer box until all reagent is used up.
- For technical assistance, you can call +33 (0)4 67 14 15 16.

## 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 d

### Description

R1: Limpid and light yellowish 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 stability e

### 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 and within the expiration date

### Expiration date

Refer to "expiration date" on the reagent packaging label.

## Materials required but not provided f

- Microsemi CRP, Microsemi CRP LC-767G, and Yumizen H500 CRP
- Calibrator: ABX CRP Std.
- Control: Refer to the instrument user manual for the specific control used with your instrument.
- Standard laboratory equipment

## Specimen g

### Sample collection

Whole-blood, serum, and plasma 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 (3, 4).
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 (5, 6). 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.

Modifications

**a**: Instruments are added.
**b**: Description in "Intended use" is modified.
**c**: Items of "Warnings and precautions" are modified or added.
**d**: Color description for R1 is modified.
**e**: The condition of "Open stability" is modified.
**f**: Description in "Materials required but not provided" is modified.
**g**: Descriptions in "Sample collection" and "Microsampling" are modified. And "Interferences" is added.

● 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.
- 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.

● Interferences
- Total Bilirubin:
  No significant influence is observed up to 30 mg/dL.
- Chyle:
  No significant influence is observed up to 8 vol% with the addition of Intralipos™ injection 20 %.
- Rheumatoid factor:
  No significant influence is observed up to 500 IU/mL.

CRP values may not always be accurate due to non-specific reactions and other factors that can lead to false elevations or incorrect results.

## ■ Procedure h

These reagents are ready to use.
**Warning:** Do not discard the new CRP Unit 50 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 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 i
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.

## ■ 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: qcp.horiba-abx.com

## ■ Traceability of calibrators j
The calibrator is traceable to IRMM/ERM-DA472/IFCC.

## ■ Reference intervals k
Lower than 2.0 mg/L (7)

• Intralipos™ is a trademark of Otsuka Pharmaceutical Factory, Inc.

Modifications

**h**: A warning is added.
**i**: Description in "Calculation and interpretation of analytical results" is modified.
**j**: Description in "Traceability of calibrators" is modified.
**k**: Description in "Reference intervals" is modified.

## References I


1. Tillett, W. S et al. Serological reactions in pneumonia with a non-protein somatic fraction of pneumococcus. J Exp Med, 52 (4) (1930): 561-571.
2. Council Directive (2000/54/EC). Official Journal of the European Communities. No. L262 from October 17, 2000: 21-45.
3. Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR 1910. 1030). Federal Register July 1, 1998; 6: 267-280.
4. Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline - Fourth Edition. CLSI (NCCLS), document M29-A4 (2014) 34 (18).
5. Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard - Sixth Edition. CLSI (NCCLS), document H3-A6 (2007) 27 (26).
6. Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard - Sixth Edition. CLSI (NCCLS), document H4-A6 (2008) 28 (25).
7. Haruo Nakamura et al. Nihonjin no Kijunhanni to Doumyakukoka Risukudo Hyoka (Reference Intervals and Arteriosclerosis Risk Assessment in Japanese). Rinsho Kensa. 46 (9), (2002): 951-958.


Modifications

**I**: Items of "References" are modified or added.