Hematology

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CONTROL 2 x 1 mL

IVD CE 2797

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

ABX CRP Trol I

- Yumizen H500 CRP

Hematology Devices (for *in vitro* diagnostic use)

Intended Use

The **ABX CRP Trol I** is a serum of C-reactive protein intended for *in vitro* diagnostic use and designed for use in monitoring the accuracy and precision of HORIBA hematology blood cell counters with C-reactive protein parameter measurement by immuno-turbidimetry technique in clinical laboratories.

Warnings and Precautions

- **ABX CRP Trol I** 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.
- This reagent is classified as non-hazardous in compliance with regulation (EC) N°.1272/2008.
- **Warning:** Human source material. Treat as potentially infectious. All products derived from blood are prepared exclusively from blood of donors tested individually and shown by approved methods to be free from HBsAg and antibodies to HCV and HIV. Because no known test method can offer complete assurance that hepatitis B virus, Human Immunodeficiency Virus (HIV) or other infectious agents are absent, the controls should be treated like patient specimens as potentially infectious and handled with appropriate cautions in accordance with good laboratory practices (1, 2, 3).
- Observe the standard laboratory precautions for use and follow national or local health and safety guidelines.
- Please refer to the Safety Data Sheet (SDS) associated with **ABX CRP Trol I**.
- Do not use the product if the recommended storage conditions, including temperature, are not followed.
- User must be trained by a HORIBA representative before attempting to operate the device.
- 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.
- 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.

Microbiological State

Not applicable.

Description and Composition

Description:

ABX CRP Trol I is similar in appearance to human serum.

Composition:

ABX CRP Trol I is a human serum-based CRP control.

ABX CRP Trol I

Storage and Stability

- **Storage condition (before opening):** 2-10°C (35-50°F).
  Do not freeze.
  Store the tubes vertically in their original packages when not in use.
  Storage in the door compartments of the refrigerator is not recommended.
- **Open stability: ABX CRP Trol I** is stable for 3 months (or until the "expiration date" whatever comes first) at 2-10°C (35-50°F) after opening.
  ABX CRP Trol I must be tightly capped after use.
- **Expiration date:** refer to "expiration date" reagent packaging label.

Materials Required but not Provided

- Automated hematology analyzer.
- Standard laboratory equipment.

Specimen

Not applicable.

Procedure

ABX CRP Trol I is ready to use.
An analysis of the control must be carried out on a daily basis and each time a calibration or a maintenance is carried out. The frequency of the controls depends on the laboratory requirements. Each laboratory must establish the quality assurance procedures to be followed. These must conform to the current accreditation requirements and pertinent regulations.

1. Bring **ABX CRP Trol I** to room temperature by rolling the tube between the palms of your hands. Do not shake.
2. Refer to the user manual to identify **ABX CRP Trol I** using the barcode reader or manuallly.
3. Gently invert the tube 8 to 10 times immediately before sampling.
4. Run **ABX CRP Trol I** according to the procedure described in the user manual.
5. Wipe threads and cap of the tube after use with lint-free gauze.
6. Recap and refrigerate the tube promptly after use.

Refer to the packaging for the CRP assay values.

Refer to the instrument user manual for detailed analysis and control procedures.

Methodology

The **ABX CRP Trol I** is a stable preparation used to monitor the accuracy and precision of HORIBA hematology blood cell counters with CRP measurement. Target value was obtained from replicate analysis on instruments calibrated to the certified reference material ERM®-DA472.
The **ABX CRP Trol I** is run on the instrument in the same way as a human serum sample (immuno-turbidimetry measurement).

Performance Characteristics and Limitations

The concentration is not lot specific and is: 0.50 +/- 0.15 mg/dL.
See paragraph Traceability of Calibrators and Control Materials.

Calculation and Interpretation of Results

Refer to the instrument user manual for control procedure and interpretation of results.

Changes in the Procedure and in the Performance

Packaging spoiling

In case of protective packaging spoiling, do not use **ABX CRP Trol I** 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 Trol I** should be replaced.

Incorrect mixing

Incomplete mixing of the tube prior to use invalidates both the sample that is withdrawn and the remainder of **ABX CRP Trol I** in the tube.

ABX CRP Trol I

Temperature limits

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

Internal Quality Control

HORIBA control bloods must be used to periodically assess the integrity of the reagents and the instrument in the specified ranges.
HORIBA 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

The CRP measurement is traceable to a certified reference material (ERM®-DA472).

Reference Intervals

Not applicable.

Reference

1. US Department of labor, Occupational Safety and Health Administration. 29 CFR 1910. 1030: Occupational Safety and Health Standards: Bloodborne pathogens.
2. Council Directive (2000/54/EC). Official Journal of the European Communities. No. L262 from October 17, 2000: 21-45.
3. Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline - Fourth Edition. CLSI (NCCLS), document M29-A4 (2014) **34** (18).