Hematology

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REF 0501016

CAL 2 x 1 mL

IVD CE

HORIBA ABX SAS
Parc Euromédecine - Rue du Caducée
B.P. 7290
34184 MONTPELLIER Cedex 4
FRANCE

ABX CRP Std

- ABX Micros CRP/CRP200

Hematology Devices (for *in vitro* diagnostic use)

Intended Use [a]

ABX CRP Std is a serum CRP calibrator intended for *in vitro* diagnostic use and designed for use in calibration of HORIBA Medical hematology blood cell counters with CRP parameter measurement by immuno-turbidimetry technique.
Refer to the packaging for the CRP assay values.

Warnings and Precautions

- **ABX CRP Std** 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.
- Human source material. Treat as potentially infectious. Each plasma donor unit used in the preparation of this product has been tested by an FDA approved method and found negative for the presence of HBsAg, HCV and antibody to HIV1/2. Because no known test method can offer complete assurance that hepatitis B virus, Human Immunodeficiency Virus (HIV) or other infectious agents are absent, the products 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 Material Safety Data Sheet (MSDS) associated with **ABX CRP Std**.

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:

ABX CRP Std is similar in appearance to human serum.

Composition:

ABX CRP Std is a human-based CRP calibrator.

Storage and Shelf Life after First Opening

- **Storage condition:** 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 Std** is stable for 3 months (or until the "expiration date" whatever comes first) at 2-10°C (35-50°F) after opening.
  ABX CRP Std 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.

[a] Modification from index B to C: new reagent leaflet form (Rev.3).

ABX CRP Std

Specimen

Not applicable.

Procedure

ABX CRP Std is ready to use.
The calibration on HORIBA Medical instruments is an important procedure, which may need to be performed during certain technical situations such as installation, maintenance and service interventions. Calibration should not be performed to compensate for a drift in results due to a blockage on the instrument.
Frequent re-calibration needs to be reported to HORIBA Medical Technical Support to determine the actual cause and appropriate remedy. After calibration, ensure the values for MCV, MCH and MCHC on patient samples agree with usual population means for these parameters.

1. Bring **ABX CRP Std** 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 Std** using the barcode reader or manuallly.
3. Gently invert the tube 8 to 10 times immediately before sampling.
4. Run **ABX CRP Std** 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

ABX CRP Std is a stable preparation used to calibrate blood cell counters with CRP parameter. Calibration value has been obtained from replicate analyses on instruments which have been calibrated to CRP value obtained from reference methodes. **ABX CRP Std** is run on the instrument in the same way as a patient blood sample.

Performance Characteristics and Limitations

Refer to the packaging for the target values and their tolerances regarding the instrument used.
See paragraph Traceability of Calibrators and Control Materials.

Calculation and Interpretation of Results

Refer to the instrument user manual for calibration 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 Std** 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 Std** 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 Std** in the tube.

Temperature limits

Do not use **ABX CRP Std** if it has been frozen or kept at excessive heat.
Before using **ABX CRP Std**, 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 Comparaison 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

ABX CRP Std

Traceability of Calibrators and Control Materials

HORIBA Medical CRP controls and calibrators are traceable to standard reference methods.
The CRP values are determined according with the standard serum CRM470.

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. 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 - Third Edition. CLSI (NCCLS), document M29-A3 (2005) **25** (10).