Hematology Devices (for in vitro diagnostic use)

ABX CRP Rea

25/07/05
A95A00246AEN

REF 0501015

REAGENT 1 10mL

REAGENT 2 10mL

REAGENT 3 20mL

IVD CE

HORIBA ABX
BP 7290 - 34184 Montpellier
cedex 4 - France

Exclusive use

Micros
Micros CRP
Micros CRP 200
Pentra 60
Pentra 60 C+
Pentra 80
Pentra XL 80
Pentra 120
Pentra 120 Retic
Pentra DX 120
Slide Preparation System

1. Functions

This reagent is intended for in vitro diagnostic use solely on the ABX MICROS CRP 200 analyzer, for quantitative determination of CRP concentrations in human blood. Measurement of CRP aids in evaluation of the amount of injury to body tissues.

R1: Hemolysis reagent.

R2: Glycine Buffer.

R3: Latex reagent: Latex beads coated with anti-human C-reactive protein antibodies: 200µL/test.

2. Summary

CRP is one of the Acute Phase Proteins and is a sensitive marker of an inflammatory response.

CRP - C-Reactive Protein is a 118K Dalton pentameric polypeptide which is synthesized in hepatocytes in response to Interleukin-6 production by activated macrophages.

3. Measurements principles & performances

Measuring principles:

The assay involves immuno-turbidimetry. During the first stage, blood cells are lysed by reagent R1. Addition of R2 inhibits interference. Stage 3 involves the addition of reagent R3, which contains anti-CRP antibodies bound to latex beads.

Absorbance is measured at 850nm, and the absorbance is proportional to the CRP concentration of the sample.

Results: see section «Running specimen» in the instrument User Manual

Performance data: see section «Specifications» in the instrument User Manual.

Measurement procedure to be followed in using the device

Principle of the method, specific analytical performance characteristics, analytical sensitivity, diagnostic sensitivity, analytical specificity, diagnostic specificity, accuracy, repeatability, reproducibility (including control of known relevant interference), limits of detection, limitations of the method and information about the use of available reference measurement procedures and materials by the user: see «Section: Specifications» in the instrument User Manual.

4. Reagent preparation

The ABX MICROS CRP 200 reagents: R1, R2, and R3, ready-to-use (no reconstitution required).

1- Remove R1, R2 and R3 from refrigeration and place them in the ABX MICROS CRP 200.

2- Enter the three reagent sensitivity factors shown on the box lid («coef. reagent») see section «Maintenance and troubleshooting» in the instrument User Manual

3- Run the ABX CRP Trol controls and verify that they are within their assay limits noted on their packages.

For further details, see section «Quality Assurance» in the instrument User Manual.

5. Conservation & expiration

Storage conditions: temperature: 2 to 10° C (do not freeze).

Stability before opening: Refer to «Expiry date» packaging label.

Stability after opening: 2 months (or until the «Expiry date» whatever comes first).

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6. Specimen collection and mixing

1- May be used for whole blood, serum or plasma type samples
2- The reagent is ready to use
3- The CRP can be measured immediately by simply placing the sample in the instrument.
4- Mix R3 before use
5- EDTA-K3 containing anti-coagulated sample tubes should be used. Blood samples should be adequately mixed prior to CRP determination.
6- If the measured CRP exceeds the linearity limits of the system, samples can be centrifuged, and the plasma diluted with Physiological serum. The measured result is then multiplied by the dilution factor. see section «Running specimen» in the instrument User Manual.
7- The instrument is intended for "near patient testing". Samples should optimally be assayed within 6 hours post-draw. The results indicate sample stability claim of 48 hours with storage of either room temperature and 4°C for leukocyte counts and differentials.

7. Handling precautions

1- Read the instrument User Manual before use.
2- Do not ingest reagents and avoid contact with skin.
3- When handling blood and reagents, take necessary precautions to avoid contamination.
4- Take precautions to prevent dust contamination of the mixing cuvette.
5- R1, R2, R3 contain sodium azide. As sodium azide may react with lead or copper to form explosive metal azides, this reagent should be disposed of by flushing with copious amounts of water.
6- As with all diagnostic test procedure, result interpretation should be accompanied by careful consideration of all other test results and the clinical state of the patient.
7- Do not mix different reagent lots: use R1, R2 and R3 from the same lot.
8- Do not use frozen reagents
9- Do not change reagents after calibration
10- Use reagent as soon as possible after opening. Reseal the reagent when storing. Do not use expired reagents.
11- If the instrument does not show reliable results, repeat the measurement, as an undesirable substance may have impeded the reaction. see section «Running specimen» in the instrument User Manual

8. Limitations and waste disposal

Interfering substances: There is no known interference due to the presence of rheumatoid factor, bilirubin, lipids (more than 1000 mg/dl), or free hemoglobin in the sample. However, avoid alien substances such as dust, mold or detergent.

Safe waste disposal: see section «Specifications» in the instrument User Manual. Please refer to the MSDS associated with the reagent.

9. References

Tillet, W.S. et al.: Serological reactions in pneumonia with a non protein somatic fraction of pneumococcus.j. Exp. Med., 552, 561 (1930)