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UKAS PROFICIENCY TESTING 4301

CRP EQA

INTENDED USE
Weqas CRP EQA samples are for in-vitro diagnostic use as an external quality assessment material for testing of CRP.

SUMMARY
External Quality Assessment (EQA) or proficiency Testing (PT) is an essential part of providing quality laboratory diagnostic services, and participation in EQA is required for laboratory accreditation to ISO 15189 and ISO 17025. EQA is the inter laboratory comparison and performance evaluation that extends throughout all phases of the healthcare diagnostic testing cycle.

PRODUCT DESCRIPTION
0.5mL volume is supplied in sterile plastic tubes. The material has been prepared from sterile human serum, with an antibiotic added to maintain sterility. The serum is dispensed then stored at -20°C until dispatch.

STORAGE AND STABILITY
Unopened samples are stable for two (2) weeks in a refrigerator at 2-8°C.

The samples should be assayed on the day you receive them. If you are unable to assay the samples immediately upon receipt, please store at 2-8°C until analysis. Samples stored at 2-8°C prior to analysis must be brought to room temperature and assayed within 1 hour.

Samples should be stored at -20°C for long term storage.

PROCEDURE
The samples should be treated the same as patient specimens and run in accordance with the instructions accompanying the test system being used.

1. Mix the sample well by gently inverting 5 to 6 times.
2. Wear gloves and handle the sample as a normal patient sample.
3. Safely dispose of excess sample in accordance with local waste policy guidelines.

Always wear gloves to avoid contamination.

STORAGE AND PROCEDURE FOR BATCHED SAMPLES
The samples should be stored at -20°C on receipt. At the start of the return window for each distribution thaw the relevant samples at room temperature for 24 hours and assay as described in PROCEDURE.

LIMITATIONS OF PROCEDURE
The CRP EQA samples should be analysed according to the instructions within this document. If there is evidence of microbial contamination in the product, discard the vial.

The CRP EQA samples require storage as described in STORAGE AND STABILITY and handling as described in PROCEDURE.

Accurate and reproducible results are dependent upon properly functioning instruments and reagents and the use of correct procedures.

APPROXIMATE RANGE COVERED
The Weqas CRP EQA samples cover a relevant pathological and analytical range as outlined below.

Analyte	Approx Range
hsCRP	0 – 10 mg/L
CRP	10– 300 mg/L

! CAUTION !
Human source material. Treat as potentially infectious. Each unit of whole blood used in the manufacture of this product has been tested by CE marked IVD methods and found to be non-reactive for the presence of HBsAg and antibody to HIV-1/2, HCV and HIV-1 Ag. While these methods are highly accurate, they do not guarantee that all infected units will be detected. Because no known test method can offer complete assurance that the hepatitis B virus, hepatitis C virus, human immunodeficiency virus (HIV) or other infectious agents are absent, all products containing human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.

Although every effort is made to ensure that the material is free from any known infectious agent, the samples should be handled as for clinical specimens.