



BNP-32 EQA

INTENDED USE

Weqas BNP-32 EQA samples are for in-vitro diagnostic use as an external quality assessment material for testing of BNP-32.

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

0.7mL volume supplied in sterile plastic tubes. The material is Human EDTA plasma, with an antibiotic added to maintain sterility and protease inhibitors to improve stability. The material is dispensed and stored at -70°C until dispatch.

STORAGE AND STABILITY

The samples are dispatched on dry-ice and should remain frozen until receipt. The samples are stable for 30 minutes at ambient temperature (18-30°C), at -20°C for three days and for 14 months at -70°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 -20°C (or at -70°C if available) until analysis.

Samples stored frozen prior to analysis must be thawed, brought to ambient temperature (18-30°C) and assayed within 30 minutes. DO NOT leave samples at ambient temperature (18-30°C) for any prolonged period as this may influence results.

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 then gently swirling the vial for 5 – 10 seconds - ensure there are no air bubbles in the sample.
2. Wear gloves and handle the sample as a normal patient sample.
3. Carefully remove the lid from the sample.
4. Apply the sample to the testing strip as per manufacturer instructions.
5. Safely dispose of excess sample in accordance with local waste policy guidelines.

Always wear gloves to avoid contamination.

LIMITATIONS OF PROCEDURE

BNP-32 EQA samples should be analysed according to the instructions within this document. If there is evidence of microbial contamination or excessive turbidity in the product, discard the vial.

The BNP-32 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 BNP-32 EQA samples cover a relevant pathological and analytical range as outlined below.

Analyte	Approx Range
BNP-32	20-3000 ng/L
BNP-32 (Triage)	20-1000 ng/L

! CAUTION !

1. For in vitro diagnostic use only.
2. The base material has been tested in accordance with FDA regulations and found to be negative for HIV Ab, Hep B surface antigen, HCV Ab and RPR.
3. This product should not be disposed of in general waste. Consult local environmental authorities for proper disposal.

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.