



Porphyrin EQA

INTENDED USE

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

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

Urine TUP and PBG

4.2mL The material has been prepared from sterile urine from healthy donors with an antibiotic added to maintain sterility.

Plasma

1.5mL volume supplied in sterile plastic tubes. The material is Human EDTA plasma, with an antibiotic added to maintain sterility.

Faecal

Human faecal material supplied from patients.

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 for one week. If there is a further delay in analysis please store at -20°C.

Please ensure that the samples are well mixed before analysis do not centrifuge the samples. Ensure samples are protected from light.

PROCEDURE

- 1) Treat as you would a patient sample in line with laboratory procedure.

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 Weqas Porphyrin 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 Porphyrin EQA samples cover a relevant pathological and analytical range as outlined below.

Analyte	Analytical Range
Quantitative TUP	0 – 4000 nmol/L
Quantitative PBG	0 – 170 mmol/L
TUP / Creatinine Ratio	0 - >500 nmol/mol
PBG / Creatinine Ratio	0 - >30 µmol/mmol
Plasma Porphyrin	8 – 200 nmol/L
Faecal Porphyrin	35 – 700 nmol/g

! CAUTION !

1. For in vitro diagnostic use only.
2. 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.