

Pre-Eclampsia EQA

INTENDED USE

Weqas Pre-Eclampsia EQA samples are for in-vitro diagnostic use as an external quality assessment material for testing of soluble fms-like tyrosine kinase-1 (sFlt-1) and placental growth factor (PlGF).

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

0.5 mL volume is supplied in sterile plastic tubes. The material has been prepared from pooled human plasma spiked with exogenous sFlt-1 and PlGF. The plasma is dispensed then stored at -20°C until dispatch.

STORAGE AND STABILITY

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 until analysis. Samples stored at -20°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 Pre-Eclampsia 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 Pre-Eclampsia 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 Pre-Eclampsia EQA samples cover a relevant pathological and analytical range as outlined below.

Analyte	Range
sFlt-1	500 - 5000 pg/mL
PlGF	25 - 1000 pg/mL
sFlt-1/PlGF Ratio	10 - 100
Pre-Eclampsia Risk	Qualitative

! CAUTION !

Human source material. Treat as potentially infectious.

Samples are pooled patient samples and have not been tested for HIV, Hepatitis B or C. Treat as potentially infectious.

The samples should be handled as for clinical specimens.