

PAMG-1

INTENDED USE

Weqas POCT PAMG-1 EQA is for in vitro diagnostic use as an external quality assessment material for testing of placental alpha-microglobulin-1 (PAMG-1), a marker of amniotic fluid present in vaginal discharge, to identify premature rupture of membranes (AmniSure) or assess risk of preterm labour (PartoSure).

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

Test vial: Lyophilised PAMG-1 protein or lyophilised sucrose.

Solution vial: Saline solution containing Triton X100 and sodium azide.

STORAGE AND STABILITY

The sample should be assayed on the day of receipt. If you are unable to assay the sample immediately upon receipt, samples can be stored at ambient temperature (18-30 °C).

STORAGE AND PROCEDURE FOR BATCHED SAMPLES

The samples can be stored at ambient temperature (18-30 °C).

PROCEDURE

Use of the swab is not required for this procedure.

The samples should be assayed in accordance with the instructions accompanying the test system being used.

1. Uncap both solution vial and test vial
2. Add contents of solution vial to test vial, recap and shake well for 30 seconds to ensure full reconstitution.
3. Remove test strip from foil pouch. Insert test strip into the reconstituted EQA sample.
4. Follow manufacturer instructions for test. Results may be either positive or negative.

Safely dispose of excess sample according to local waste policy guidelines.

ANALYTES COVERED

The Weqas POCT PAMG-1 EQA samples cover a relevant pathological and analytical range.

Analyte
PartoSure
AmniSure

LIMITATIONS OF PROCEDURE

The EQA samples supplied 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.

! CAUTION !

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