PAMG-1

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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

0.5 mL volume supplied in sterile plastic tubes. The material has been prepared from buffered material spiked with amniotic fluid.

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 should be stored refrigerated (2-8 °C).

STORAGE AND PROCEDURE FOR SAMPLES RECEIVED BY BULK DISPATCH

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 ambient temperature (18-30°C) for 24 hours and assay as described in PROCEDURE.

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. Mix the sample well by gently inverting 5 to 6 times then gently swirling the vial for 5 to 10 seconds – ensure there are no air bubbles in the sample.
2. Wear gloves and handle the sample as a normal patient sample.
3. Follow manufacturer guidance for running the sample.
4. Remove test strip from foil pouch. Insert test strip into the reconstituted EQA sample.
5. 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.