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Foetal Fibronectin EQA

INTENDED USE
Weqas *Foetal fibronectin EQA* samples are for in-vitro diagnostic use as an external quality assessment material for testing of foetal fibronectin in cervicovaginal samples collected between 24 weeks, 0 days and 34 weeks, 6 days gestation.

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
0.6 mL volume is supplied in sterile plastic tubes. The material is a buffered base containing anti-proteases, detergents, proteins and preservatives to which is added purified human foetal fibronectin.

STORAGE AND STABILITY
The samples are stable for 5 days at ambient temperature (18-30°C), for 14 days at 2-8°C and for 12 months at -20°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 until analysis.
Samples stored at 2-8°C must be brought to ambient temperature (18-30°C) prior to analysis.

PROCEDURE
Note: For the EQA sample *the "Dacron swab/buffer" step is **NOT** required but is run on the meter exactly same way as a patient sample.*
The samples should be treated 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 ready for analysis.
3. Carefully remove the lid from the sample.
4. Using an appropriate pipette, pipette 200ul onto the cassette; follow the manufacturer's instructions on dosing the cassette well.
5 .Please ensure the operators details the date, the cassette/strip lot number are all recorded.

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

LIMITATIONS OF PROCEDURE
Foetal fibronectin EQA samples should be analysed according to the instructions within this document.

The *Foetal fibronectin EQA* requires 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.

ANALYTES COVERED
The *Foetal Fibronectin EQA* samples cover a relevant pathological and analytical range for the analyte listed below;

Analyte
Foetal Fibronectin

! 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.