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phIGFBP-1 EQA (Pre-Term Labour Markers)

INTENDED USE
Weqas phIGFBP-1 EQA is for in vitro diagnostic use as an assayed quality control material; especially designed for application in External Quality Assurance Schemes to verify the precision and accuracy of instruments reporting qualitative phIGFBP-1. Weqas ph IGFBP-1 EQA is not intended for use as a standard.

SUMMARY
The use of EQA materials to objectively monitor the accuracy and precision of procedures is well established in clinical laboratories. Weqas ph-IGFBP-1 is EQA material prepared as four different levels covering the clinically relevant range. Each level has a known ph-IGFBP1 concentration and therefore a known qualitative interpretation.

PRODUCT DESCRIPTION
The base material is a phosphate buffered solution containing BSA, protease inhibitors and preservatives which is spiked with pooled amniotic fluid containing semi-purified IGFBP-1. The material is dispensed into 1mL aliquots and stored at -70°C until dispatch, and will thaw in transit.

STORAGE AND STABILITY
The sample should be used on the day you receive it and must be warmed to room temperature before analysis.

If you are unable to assay the sample on that day, please store it in fridge unopened and assay within 5 days of receipt.

Samples stored at 4°C prior to analysis must be allowed to warm to room temperature before use.

FREQUENCY
This will be carried out on a bimonthly basis.

STORAGE AND PROCEDURE FOR BATCHED SAMPLES
The samples should be stored at -70°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.

PROCEDURE
The Specimen extraction solution tube is NOT required; the test strip can be placed directly into the EQA sample received.

1. Mix the sample well by inverting 5 to 6times –ensure there are no air bubbles in the sample.
2. Wear gloves and handle the sample as if it were a normal patient sample ready to analyse for 'pre-term labour biomarkers'.
3. Carefully remove the lid from the sample.
4. Please follow the test procedure in the 'Instructions for use' leaflet in the kit, supplied by the manufacturer.
5. Please ensure to complete all information requested and record results on the return sheet.

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

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. 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.