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Quantitative Faecal Hb EQA

INTENDED USE
Weqas Faecal Immunochemical Testing (FIT) EQA samples are for in-vitro diagnostic use as an external quality assessment material for testing for the presence of Haemoglobin in faeces.

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
Material is dispensed aseptically into buffered vials specific to each instrument manufacturer. The base material is organic material which closely mirrors the basic constituents of human faeces. This material is then spiked with human whole blood (Hb) to cover the pathological and analytical range for Faecal Immunochemical tests (FIT).

STORAGE
Please store as per routine patient samples.

PROCEDURE
The samples should be treated the same as patient specimens and run in accordance with the instructions accompanying the test system being used.

Safely dispose of excess sample in accordance with local waste policy guidelines.

Always wear gloves to avoid contamination.

LIMITATIONS OF PROCEDURE
The Weqas FIT EQA samples should be analysed according to the instructions within this document. If there is evidence of microbial or fungal contamination in the product, discard the vial.

The Weqas FIT 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 FIT EQA samples cover a relevant pathological and analytical range as outlined below.

Analyte	Approx Range
Quantitative FIT	0 – 800 µg / g

! CAUTION !
Human source material.
The base material is organic material spiked with human whole blood (Hb). Each unit of whole blood used in the manufacture of this product has been tested by CE marked IVD methods and found to be non-reactive for the presence of HBsAg and antibody to HIV-1/2, HCV and HIV-1 Ag. While these methods are highly accurate, they do not guarantee that all infected units will be detected. Because no known test method can offer complete assurance that the hepatitis B virus, hepatitis C virus, human immunodeficiency virus (HIV) or other infectious agents are absent, all products containing human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.

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.