



Qualitative Faecal Hb

INTENDED USE

Weqas Qualitative Faecal Hb 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 0.3g aliquots and stored at -20°C until dispatched. 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 Qualitative guaiac based tests (FOB) and Faecal Immunochemical tests (FIT).

STORAGE AND STABILITY

Unopened samples are stable for 9 months at -20°C.

The samples are dispatched frozen as a 10 week batch of material and should be stored at -20°C on arrival. Samples should be removed from the freezer at set intervals, determined by the schedule of distributions, and brought to room temperature before assay.

PROCEDURE

The samples should be treated the same as patient specimens and run in accordance with the instructions accompanying the test system being used. TWO SAMPLES SHOULD BE ANALYSED PER FORTNIGHT; EITHER AS A PAIR PER FORTNIGHT OR ONE PER WEEK IF PATIENT SAMPLES ARE BEING TESTED WEEKLY.

1. Wear gloves and handle the sample as a normal patient sample.
2. Carefully remove the blue lid from the universal container; the sample is on the scoop.
3. Apply the sample to the testing device as per the manufacturer instructions for your kit.
4. Safely dispose of excess sample in accordance with local waste policy guidelines.

Always wear gloves to avoid contamination.

LIMITATIONS OF PROCEDURE

The Weqas Qualitative Faecal Hb 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 Qualitative Faecal Hb 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 Qualitative Faecal Hb samples cover a relevant pathological and analytical range as outlined below.

Analyte	Approx Range
FOB	0 – 3.5 mg / g
hs FOB	0 – 3.5 mg / g
Qualitative FIT	0 – 3500 µg / g

! CAUTION !

Human source material.

The base material is organic material spiked with human whole blood (Hb).

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.