Survey for Fecal Occult Blood, FOB

EQA Provider:	ESfEQA GmbH Heidelberg
Survey Coordinator:	Dr. D. Groche

Instructions for Use

Notes:

The samples should be considered as potentially infectious. The usual precautions in the laboratory for potential hazardous samples apply for these samples. Components from human origin have been tested and found to be non-reactive for HBsAg, anti-HIV 1/2 and anti-HCV. The samples should be used by trained personnel only.

These controls are intended for *in vitro* diagnostic use only by trained personnel.

Potentially Biohazardous Material. This control does contain components from non-human sources and may transmit infectious disease.

Various tasks of the proficiency testing scheme may occasionally be given over to qualified subcontractors. However, ESfEQA is responsible to the participants for the subcontractor's work.

Results from sample analysis may only be disclosed to colleagues from other laboratories after the testing period has been concluded.

By registering for and participating in this EQA participants agree to accept the general terms and conditions of ESfEQA GmbH. These can be retrieved online at www.esfeqa.eu.

1. Intended Use

The samples are intended for use as qualitative and quantitative control material for External Quality Assessment (EQA) in medical laboratories for the following analytes:

Fecal Occult Blood (quantitative)

Fecal Occult Blood (qualitative), cut-off 50 µg/L

2. Product Description

The liquid samples are simulated extracted stool samples and are ready-to-use.

3. Storage and Stability

The samples should be stored upright at 2-8 °C. They are stable at least until the deadline for data submission as indicated on the sample labels. After opening the samples are stable for 7 days at 2-8 °C.

4. Sample Preparation and Analysis

The samples are ready to use.

The samples simulate faeces dissolved in extraction buffer. Therefore, no further dilution with extraction buffer of the FOB reagent manufacturer is required.

The analysis of the faeces in the buffer should be done in accordance with the instructions of the instrument and reagent manufacturer. Please note, that for some instruments (e.g. OC-Sensor Diana and Pledia) prior to analysis transfer of sample material into specific cups used for analysis of QC-material and calibrator is required.

The quantitative results shall be reported in a unit corresponding to mass/volume, e.g. µg/l representing the concentration of haemoglobin in the extraction buffer. In case that the analytical device reports the results in a mass/mass unit (e.g. µg/g faeces), the manufacturer-specific characteristics of the collection tube needs to be considered. The following equation shall be used for the conversion:
µg haemoglobin / L = (µg haemoglobin / g faeces) x (mass of faeces collected (mg) / volume of buffer (mL)

5. Dates and Submission of Test Results

Testing Periods: Please refer to the sample labels. Results can be submitted anytime within the testing period indicated on the sample labels.

Quantitative results are reported with a value and a unit. The participant determines the number of digits for reporting. Results as '< below measuring range' or '< 50' cannot be accepted.

For results above the measuring range and below the Limit of Quantification (LoQ) the obtained value should be reported. For results below the Limit of Detection, this limit should be reported.

Samples having higher concentrations as the test range shall be reported as the upper test range limit.

Please submit your results electronically to ESfEQA at https://teqa.esfeqa.eu.

Contact your local distributor of ESfEQA programs or ESfEQA directly if you need assistance with registration in TEQA. Alternatively, though not preferred, use the result form provided on the ESfEQA website.

Indicate instrument, method and reagent for the submission of quantitative results and the reagent for qualitative results.

6. Deadline for Data Submission

The deadlines for submitting results are indicated on the sample labels (time zone GMT +1).

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7. Reports and Certificates

The data will be evaluated by ESfEQA.

The individual laboratory reports and certificates can be retrieved online at https://teqa.esfeqa.eu.

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