Results of EQA Pilot Study for Faecal Immunological Tests (FIT) for Haemoglobin using a Novel Ready-to-Use Sample Material

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INTRODUCTION

The primary screening method for colorectal cancer is faecal immunochemical tests (FIT) detecting human haemoglobin (hHb) in faeces. There are several tests on the market both for laboratory-based analyzers and point-of-care testing (POCT). To ensure high quality results, the tests should be monitored with appropriate quality assessment procedures including participation in external quality assessment (EQA) programs. By participating in an EQA program using a patient sample-like material, clinical laboratories and POCT sites can fulfil the ISO 15189 requirements of monitoring the complete laboratory process from pre- to postanalytical phases in addition to the quantitative analytical phase of FIT. Labquality has performed an EQA pilot study for FIT using a novel ready-to-use stool-like sample containing human haemoglobin. Here we present the first results of an international EQA pilot study using this sample material.

CONCLUSIONS

By using this new faecal-like EQA sample the following benefits are recognized:

- the complete analytical process including the preanalytical, analytical and postanalytical phases are covered in the scheme
- a scheme providing ready-to-use faecal-like material is more compliant to ISO 15189 requirements compared to schemes where liquid or lyophilized samples are used
- the sample material is compatible with all tests included in the study
- the sample material was positively received by the majority of the participants of the study, the composition of the material was suitable and it was easy to use accordinng to the responses on the pilot feed-back questionnaire

RESULTS

Sample S001 contained no added hHb and all participants (40/40) reported a result corresponding to the lower detection limit of their test in use or a low numeric result most likely explained by unspecific background. All reported a negative interpretation (Table 1).

Sample S002 was a strong positive sample for hHb. The measured value exceeded the upper detection limit of 4/9 tests (Exdia iFOB, Precision Biosensor; Fecal Occult Blood (iFOB) Neo, Boditech; FOB Test, VedaLab; NADAL FOB Quant test, Nal von Minden). The mean values and CV% were 116 µg/g and 8% for iFOBT, Aidian; 192 ug/g and 4% for Standard iFOB FIA, SD Biosensor; 144 µg/g and 45% for FOB assay kit FOB Gold, Sentinel Diagnostics (different clinical chemistry analyzers used); 91 µg/g and 26% for OC-Sensor FIT, Eiken Chemical. All participants responded a positive qualitative clinical interpretation (Table 1).

Test name, Manufacturer (Measuring range)*	Analyzer/Reader, Manufacturer	N (tot =40)	S001				S002			
			Mean µg/g (range)	Median µg/g	CV%	Qualitative inter-pretation	Mean µg/g (range)	Median µg/g	CV%	Qualitative inter-pretation
Exdia iFOB, Precision Biosensor (5-200 µg/g)	Exdia TRF Analyzer, Precision Biosensor	6	<5	-	-	neg	>200	-	-	pos
Fecal Occult Blood (iFOB) Neo, Boditech (2.5-100 µg/g)	iChroma/iChroma II, Boditech	5	<2.5	-	-	neg	>100	-	-	pos
FOB Test, VedaLab (1.4-71.4 µg/g)	EasyReader+, Veda-Lab	3	<1.4	-	-	neg	>71.4	-	-	pos
NADAL FOB Quant Test, Nal von Minden (2-75 µg/g)**	Colibri, Nal von Minden	5	2	-	-	neg	75	75	-	pos
OC-Sensor FIT, Eiken Chemical (5-200 µg/g)	OC-Sensor PLEDIA, Eiken Chemical	5	0 (0-<5)	-	-	neg	91 (54-110)	108	28.2	pos
QuikRead go iFOBT, Aidian (10-250 µg/g)	QuikRead Go, Aidian	5	<10	-	-	neg	116 (107-131)	116	8.0	pos
Standard iFOB FIA, SD Biosensor (5-200 µg/g)	Standard F100, 200, SD Biosensor***	5	<5	-	-	neg	192 (181-199)	194	4.0	pos
FOB Gold, Sentinel Diagnostics (3-170 µg/g)	Overall results, different analyzers listed below	5	(0.7-<3)	-	-		144 (106-242)	115	45.3	pos
	Atellica, Siemens	1	<3	-	-	neg	>170	-	-	pos
	Cobas, Roche	1	1.5	-	-	neg	106	-	-	pos
	SentiFit270, Sentinel Diagnostics	1	2.5	-	-	neg	108	-	-	pos
	Alinity c, Abbott	2	0.7-5.2	-	-	neg	182 (121-242)	182	47	pos
FOB Turbilatex, Certest (Not known)	Biolis 24i	1	3.2	-	-	neg	130	-	-	pos

* As reported by manufacturer if participants have reported deviating measuring range of test.
** Correct reporting should presumambly be <2 for S001 and >75 for S002.
*** One deviating numeric results has been deleted as an outlier, no analyzer had been reported.

Table 1. Summary of tests and analyzers used in the pilot study and the quantitative numerical results and qualitative interpretation.

Sample material	Number of responders
The composition of the sample material was suitable.	28/35
We liked the sample material and it was easy to use.	26/35
It is beneficial that the sample can be stored in the refrigerator and not in the freezer until use.	34/35

Table 2. Results from the feedback questionnaire to all pilot participants.

Fig. 1. The ready-to-use EQA sample is applied by the sampling rod of the test specific sample collection kit and the analysis is performed according to instructions of the test manufacturer.

The clear majority of the responders on the pilot study feedback questionnaire found the sample composition to be suitable and to be easy to use. Storage in the refridgerator was also considered very beneficial (Table 2).

METHODS

40 participants from 8 different countries using 9 different FIT reagents were recruited for the pilot study. A ready-to-use, paste-like artificial stool sample material containing human Hb uniformly was shipped to the participants at ambient temperature. The sample material is designed and developed by HECTEF (Health Care Technology Foundation, Japan) specifically for EQA for FIT. The sample material is stable enough to be stored in refrigerator temperature (+2 - +8 °C) and shipped at ambient temperature to participants[1].

The participants were instructed to collect the sample with their test specific sample collection kit and perform analysis according to the manufacturer's instructions as a regular patient sample (Figure 1). Quantitative results (µg Hb/g faeces) and qualitative interpretations (pos/neg) were reported in Labquality's electronic platform LabScala. The quantitative target value was a method group consensus mean. A questionnaire regarding the usability of the sample material was sent to all participants.

1) Analytical performance of the novel EQA material for Fecal immunochmical test for hemoglobin, M. Yamada & S. Takehara, Poster presentation Labquality Days 2024.

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