

Faecal immunochemical test EQAS schemes: IFCC FIT Working Group survey

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Background

Faecal immunochemical tests (FIT) for fecal haemoglobin (f-Hb) are used to triage patients for lower gastrointestinal tract investigations in colorectal cancer (CRC) screening programmes, and increasingly in patients with symptoms of CRC.

External quality assessment schemes (EQAS) enable clinical laboratories to monitor FIT performance compared with other users. EQAS for FIT exist worldwide, and though ISO standards exist, there is no guidance specifically for FIT.

Setting up EQAS to measure faecal biomarkers is challenging. Samples are collected by patients into manufacturer-specific preservative buffers, and there are many collection bottle designs with potentially different faecal mass and buffer volumes. It is challenging to establish one EQAS that resembles the FIT procedure and there is no consensus of criteria to specifically guide schemes for this test, though ISO standards [1] are available to guide best practice for EQAS.

Results

- 24 EQAS schemes offering FIT programmes were identified, though assay information was not easily available on all EQAS websites.
- There were 16 survey responses, which the IFCC FIT Working Group considered a good response. Some questions were not answered by all respondents, the reasons for this are unknown.
- A range of programmes exist covering different testing environments and different patient groups (CRC screening programmes, symptomatic testing, qualitative and quantitative testing, laboratories and point of care testing).
- There were 1-12 sample distributions per year. Results were reported in units including ng/mL, µg/L, µg/g and ng/g. The recommended units for reporting f-Hb are µg Hb/g faeces [2].
- 11 concentration ranges were covered (figure 1). There is no harmonisation of FIT methods so it is difficult to comment on the upper end of the ranges. Each user would need to establish if the range covered meets their needs.
- Faecal based samples are ideal; 69% of schemes did not provide faecal-based samples (figure 2), if faeces based then 88% did not provide samples in the bottles that patients use (figure 3). For schemes providing faecal-based samples, 63% used a generic buffer rather than each method’s own sample extraction buffer, which may impact the measured result (figure 4) [3].
- For source of target values, 63% of schemes used the method group consensus (figure 5). FITs are not yet traceable to a higher order measurement standard or reference material so different numeric results can be obtained with different methods.
- Performance was reported using 5 different methods, 50% used state-of-the-art analytical goals.

Figure 1. Fit concentration ranges covered by programmes, as ng/mL and µg Hb/g faeces.

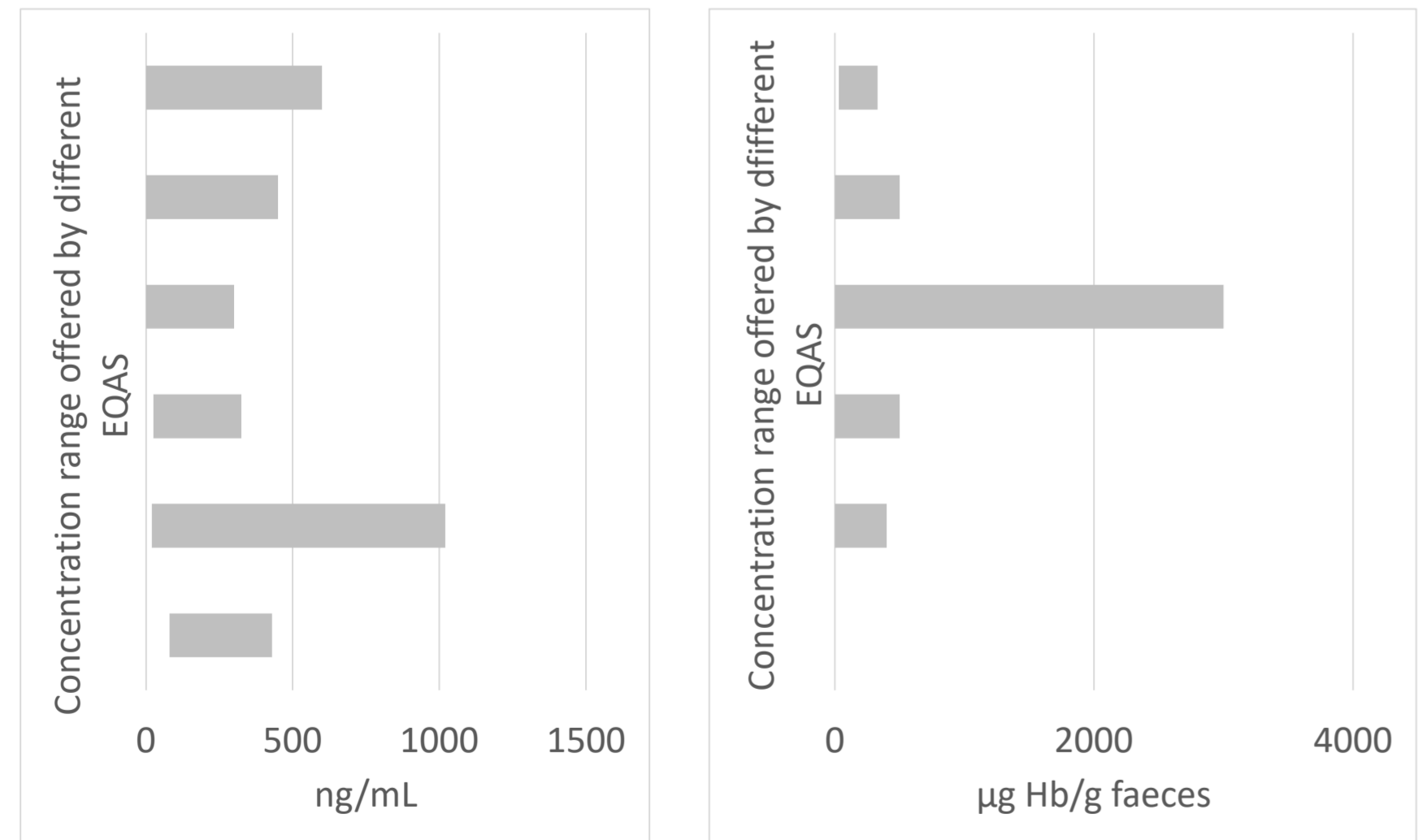


Figure 2. Are samples faecal based?

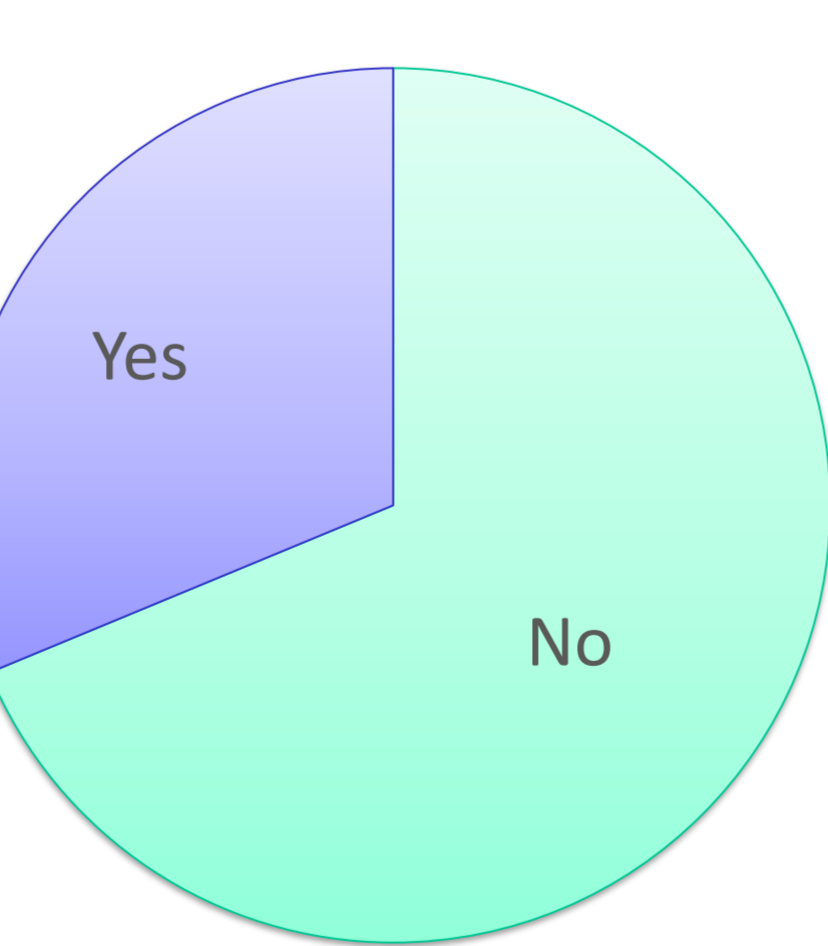


Figure 3. If faeces based, are samples in patient bottles?

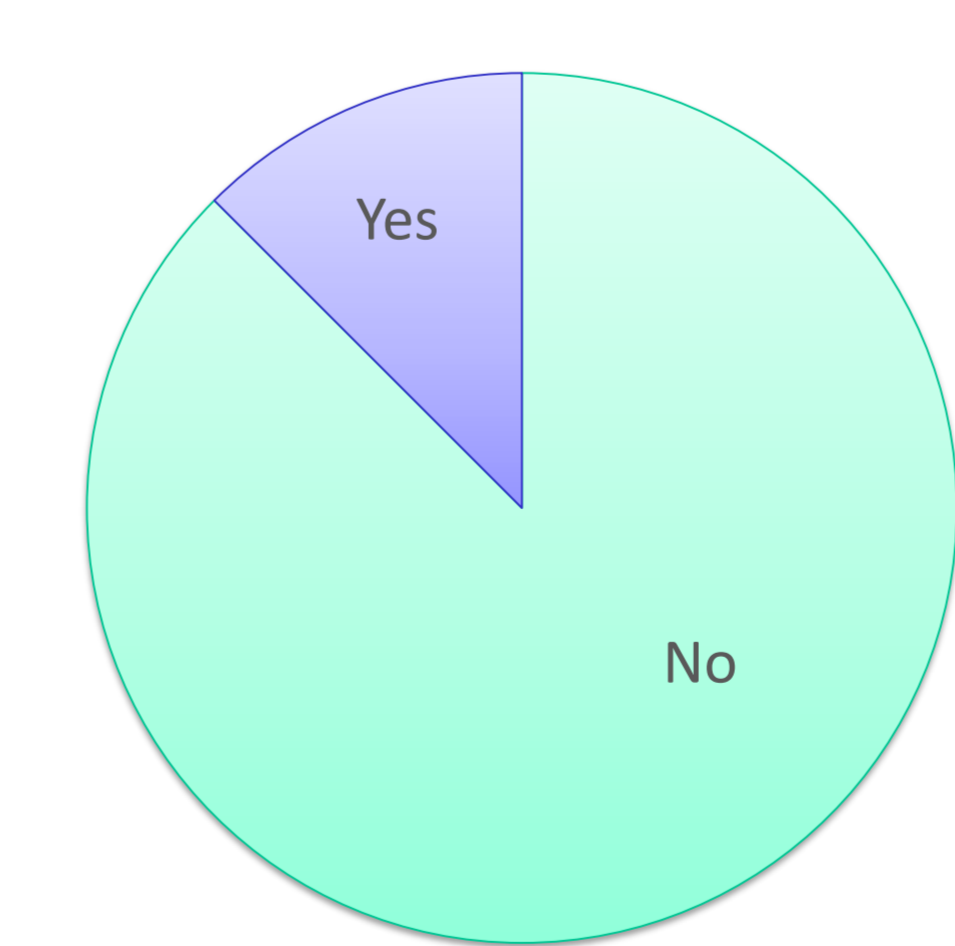


Figure 4. Type of sample buffer used

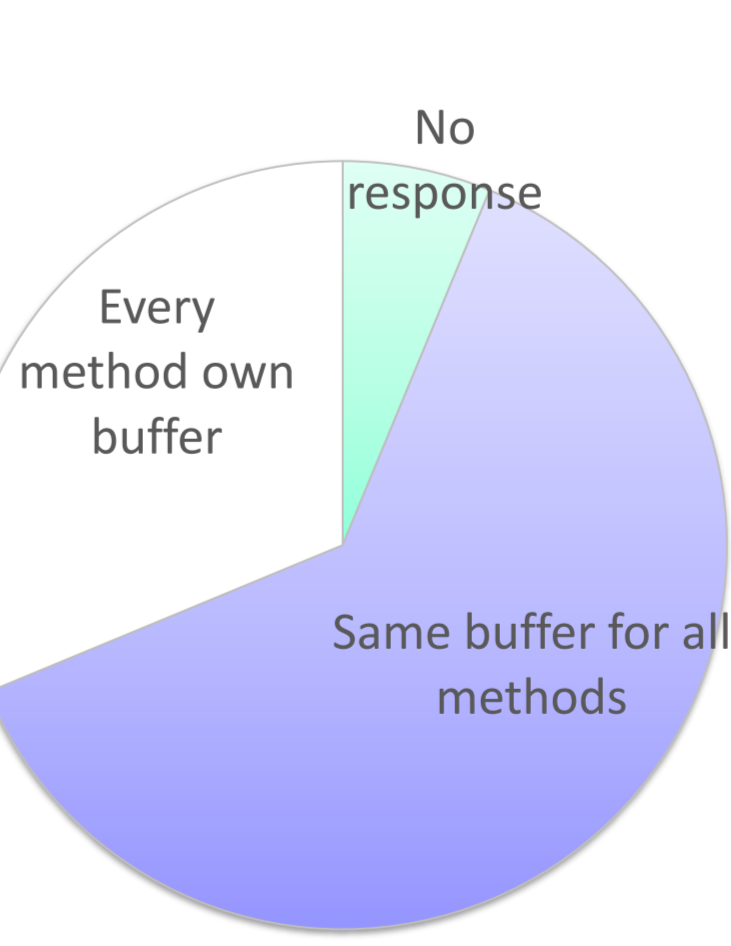
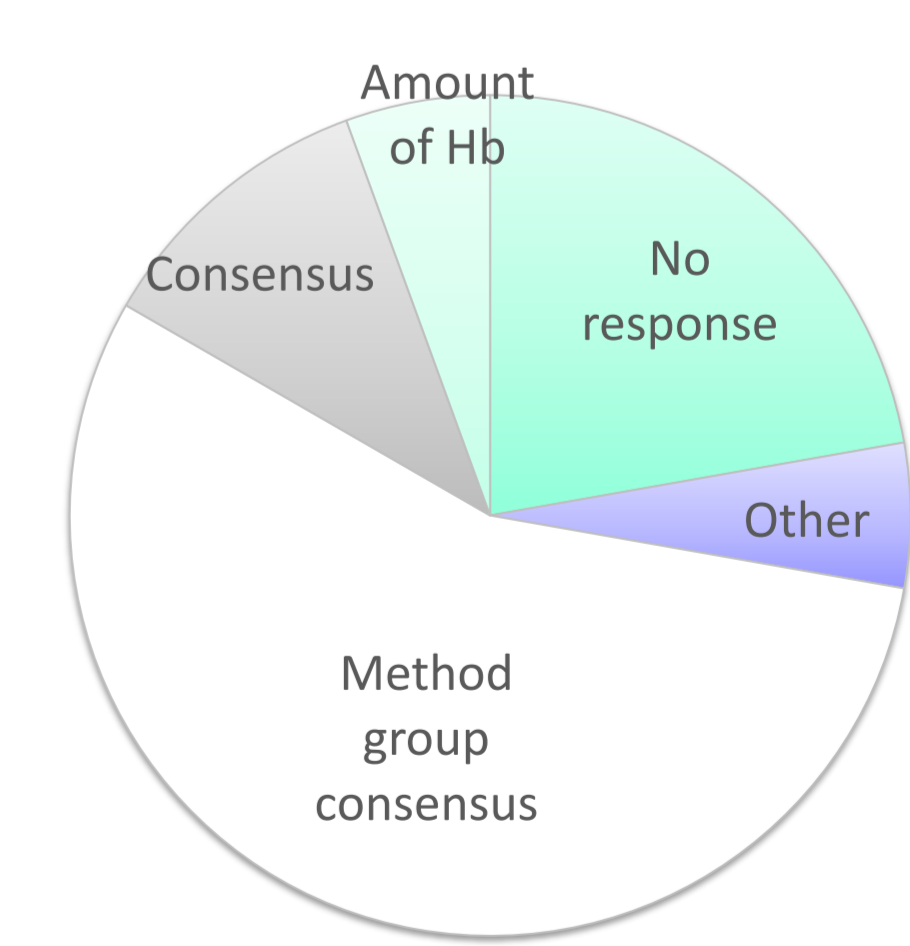


Figure 5. Source of target values.



Conclusion The IFCC FIT Working Group concluded that the survey has given some useful information about EQAS for FIT, and that wide differences currently exist between schemes.

As a result of the survey the group is considering ‘What does an ideal FIT EQAS look like?’ and aims to provide guidance to enable schemes to be fit for purpose.

References

1. ISO/IEC 17043:2023 Conformity assessment – general requirements for the competence of proficiency testing providers.
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3. Deprez L, Piggott C, van der Hagen E, Frasa M, Benton SC. Comparison and commutability study among four faecal immunochemical tests (FIT) systems. CCLM 2023;62(1):50-59.

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