EQA for FIT Point-of-Care Tests (POCT) – Should preanalytics be included?

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Objectives

Colorectal cancer is a common cancer and cause of death worldwide. Screening is often done with fecal immunochemical tests (FIT) detecting human hemoglobin and there are several tests on the market both for point-of-care-testing (POCT) and for laboratory analyzers. The results are used for diagnosing patients and it is important that the results are correct. This means that the test should be monitored with quality assessment procedures. Labquality has organized a quantitative fecal blood program since 2020. We present results from 8 EQA rounds including either liquid samples monitoring the analytical phase only or lyophilized fecal samples monitoring both the preanalytical and analytical phase.

Methods

Participant results with method information were gathered. For this study, only POCT with a total of >30 results were included. Samples were pretested using the QuikReadGo iFOBT test (Aidian). Results were compared within method groups using method mean as target value. Lyophilized fecal samples were used on 2 rounds and liquid samples on 6 rounds. The sample handling was carefully instructed and detailed illustrations of the process was included for handling of the lyophilized samples.

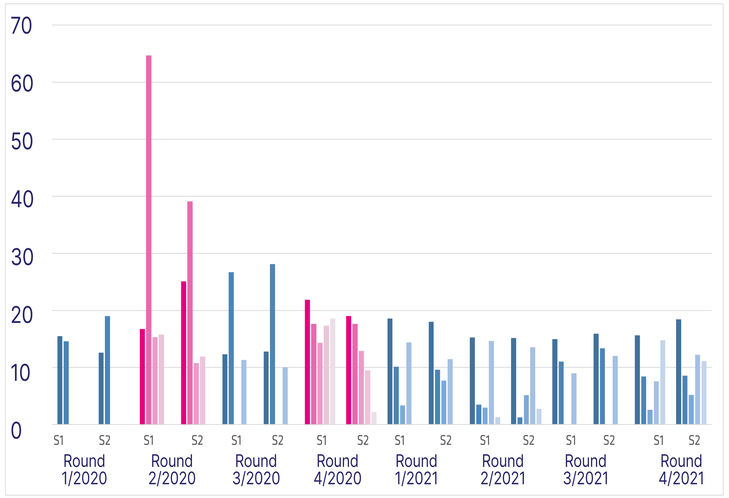
Limitations of the study: samples are not totally commutable and the methods are not quantitively comparable due to different cut offs. Due to the samples being different in all the rounds, no statistical differences were considered.

Results

There were 153 to 306 participants on each round distributed in 5 different method groups QuikReadGo iFOBT representing the largest group (Table 1).

All methods performed in general slightly better on rounds where liquid samples were used compared to rounds with lyophilized samples as can be seen in figure 1. The overall CV% for the liquid samples was 13% vs. 20% for the lyophilized samples. The number of results outside the method groups' own target area were smaller for liquid samples than for lyophilized samples (data not shown).

There were 3 to 6 fold differences in the lyophilized sample results, ranging from 10 to 179 µg/g in the different samples (figure 2). For low concentration lyophilized samples, interpretations varied a lot both between and within the method groups. For the higher concentration lyophilized samples, 67 to 100 % interpreted them as positive within the method groups (data not shown).



Conclusion

Based on our results, differences between method groups and interpretations exist which is to be expected since different tests use different cut offs. Our results show that there is more variation on rounds where EQA samples are lyophilized and include preanalytical steps mimicking the sample treatment of patient samples. The reconstitution of the lyophilized samples could, however, have an effect on the results since POCT-sites might not be familiar with laboratory processes such as sample reconstitution. The EQA process should preferably also cover the extra-analytical phases even though in this case, the preanalytical phase of sample collection to the FIT-tube is often performed by the patient. When alternating using authentic lyophilized faecal samples and artificial liquid samples in different EQA rounds, a balance can be found and the inclusion of the preanalytical phase will make the EQA round more challenging.

Figure 1. Performance between methods represented with CV% on the different rounds for different samples.

- QuikRead Go iFOBT/QuikRead Go (Aidian)
- Boditech iChroma iFOB Neo/iChroma II (Boditech)
- Nal von Minden Nadal FOB Quant/Colibri analyzer (Nal von Minden)
- SD Biosensor Standard F iFOB FIA/ Standard F100, F200 (SD Biosensor)
- Veda-Lab iFOB/Easy Reader, Easy Reader+ (Veda-Lab)

Method	Method principle	Cut-off (ug/g)	1/2020	2/2020	3/2020	4/2020	1/2021	2/2021	3/2021	4/2021
QuikRead Go iFOBT/QuikRead Go (Aidian)	Immunoturbidimetry	15	166	122	186	182	133	147	247	182
Boditech iChroma iFOB Neo/iChroma II (Boditech)	Immunochromatography	10	3	11	22	15	9	7	17	15
Nal von Minden Nadal FOB Quant/Colibri analyzer (Nal von Minden)	Immunochromatography	nd		1		5	4	15	1	6
SD Biosensor Standard F iFOB FIA/ Standard F100, F200 (SD Biosensor)	Immunochromatography	15-20		19	34	20	14	13	41	18
Veda-Lab iFOB/Easy Reader, Easy Reader+ (Veda-Lab)	Immunochromatography	nd				34		2		
Participants together			169	153	242	246	160	186	306	221

Table 1. Number of results in different method groups on different rounds. Rounds where lyophilized samples were used are highlighted.

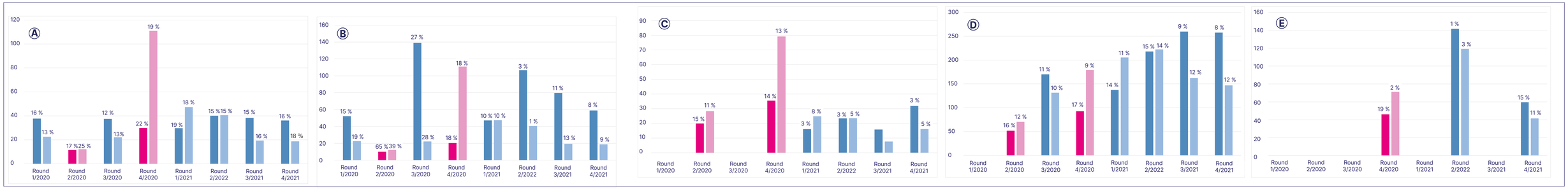


Figure 2. Performance of the methods represented with CV% and the mean value µg/g.

QuikRead Go iFOBT/QuikRead Go (Aidian) (A), Boditech iChroma iFOB Neo/iChroma II (Boditech) (B), Nal von Minden Nadal FOB Quant/Colibri analyzer (Nal von Minden) (C), SD Biosensor Standard F iFOB FIA/Standard F100, F200 (SD Biosensor) (D), Veda-Lab iFOB/Easy Reader, Easy Reader+ (Veda-Lab) (E). Lyofilized samples are shown in pink.