Which FIT's Best?
Guildford Medical Device Evaluation Centre (GMEC)
Evaluation of Quantitative Faecal Immunochemical Tests for Haemoglobin

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research report

The excellent clinical outcome data demonstrated in many publications, require faecal haemoglobin cut-offs for referral for further investigation, at the low end of the analytical range of the available FIT systems.

The choice of laboratory method is therefore important to the objective evaluation of patients, not only for haemoglobin stability in the specimen collection device, but also for its low bias and small imprecision at the lower limit of the analytical working range.

Four FIT analytical systems were evaluated by the Guildford Medical Device Evaluation Centre (GMEC) in 2013.

The resulting report is available online: http://194.97.148.137/assets/downloads/pdf/activities/fit_reports/gmec_fit_evaluation_report.pdf
Extracts of data from that report are represented here.

In this study, the HM-JACKarc system, supplied by Alpha Laboratories, was described as one of the more precise methods (Table 1). Its analytical working range correlated well to the expected values of spiked faecal samples. The ability to detect haemoglobin at both the lower and higher limits of the analytical range was confirmed (Figure 1). HM-JACKarc demonstrated a high sensitivity with a lower limit of detection of just 0.6 μg Hb/g faeces, making it ideal for symptomatic testing (Table 2). In addition, sample stability was proven at 20C throughout the 30 day period of the study (Table 3).

HM-JACK arc

Confirmed by GMEC:

■ Stability of sample in the collection tube claims of the pack insert
 • 120 days at 4-8°C
 • 14 days at 25°C
■ The Hook capacity greater than 200,000 μg of Hb / g faeces
■ Linearity across the measurement range (7-400 μg of Hb / g faeces)
■ Described as very sensitive at the low end with LOD as 0.6 μg of Hb / g faeces

Table 1. HM-JACKarc Precision

Buffer Samples	GMEC data mean	sr	Manufacturer data			Consistent/ not consistent with claim
			σ mean	σr	Verification value	
HM-JACKarc (μg Hb/ g faeces)	13.5	0.9	11.3	0.6	0.9	NSD
	58.8	1.3	56.1	2.4	3.5	Consistent
	319.4	5.4	279.5	7.9	11.6	Consistent

KEY:
sr – GMEC measured estimate of repeatability
σr – manufacturers' claimed repeatability
NSD – Not statistically different from manufacturers' claim
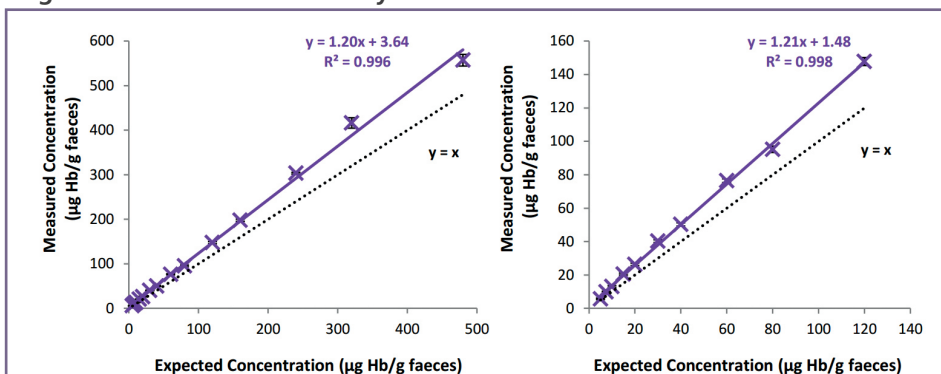
Figure 1. HM-JACKarc Linearity

Table 2. HM-JACKarc Sensitivity

Measured lower limit of detection for each analyser.
Quoted lower limits of detection were provided by each manufacturer in their data sheets.

	Mean concentration of 20 un-spiked collection tubes (μg Hb/g faeces)	Standard deviation	Lower limit of detection (μg Hb/g faeces)	Quoted lower limit of detection (μg Hb/g faeces)
HM-JACKarc	0.3	0.1	**0.6**	7
NS-PLUS C15	0.0	0.0	**0.0**	4
OC-SENSOR DIANA	2.1	0.9	**3.8**	10
FOB Gold/BioMajesty	0.5	0.4	**1.3**	2.55

Table 3. HM-JACKarc Sample Stability

HM-JACKarc Measured Stability of Diluted Hb and Faecal Samples Spiked with Hb			
Temperature	- 20˚C	4˚C	20˚C
Concentration (μg Hb/g faeces)	All concs	All concs	All concs
Hb in buffer	STS	STS	STS
Hb in faeces	STS	STS	STS

KEY:

STS – Stable throughout study (30 days) i.e. the concentration of Hb did not fall below 50% of the initial concentration during the study.
Concs – haemoglobin concentrations.
Four concentrations of Hb were tested ranging from the detection limit to a strong positive FIT result.

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