QuikRead® iFOB sampling set with extended sample stability in FIT testing

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Introduction

QuikRead go® iFOBT is a faecal immunochemical test (FIT) for the detection and quantification of haemoglobin originating from occult blood in human faeces in cases of excess bleeding from the lower gastrointestinal tract, seen e.g. in ulcerative colitis, Crohn's disease, polyps, adenomas and colorectal cancer (CRC). The test can be used in routine physical examinations and in screening programmes for CRC.

Aims

Our aim was to extend the sample stability in the sampling buffer, and to evaluate the performance of the QuikRead go iFOBT test in detecting quantities of haemoglobin when used with (1) the novel QuikRead iFOB Sampling Set and (2) the current QuikRead FOB Sampling Set.

Methods

The sample stability in the buffer of the novel QuikRead iFOB Sampling Set was studied at different temperatures using a panel of negative samples, samples with known grades of disease and spiked faecal samples.

Freezed faecal samples (n=115) were analysed retrospectively and anonymously with the QuikRead go iFOBT test by using the novel QuikRead iFOB Sampling Set and the current QuikRead FOB Sampling Set. Due to the heterogenous sample material, the comparison between the two sampling sets was done using a qualitative approach with a cut-off set to 20 µg/g, which translates to 100 ng/ml for the QuikRead go iFOBT test.

Conclusions

The longer sample stability achieved with the novel QuikRead iFOB Sampling Set improves convenience in sample handling and integrity of the sample during transport. The hygienic sampling procedure and the accurate sample volume obtained with the sample collector of the novel QuikRead iFOB Sampling Set are further benefits of the product. When used with the novel QuikRead iFOB Sampling Set, the QuikRead go iFOBT test was found to be equally specific and sensitive as when used with the current QuikRead FOB Sampling Set.

Results

The novel QuikRead iFOB Sampling Set has five days' sample stability at 18...25°C and seven days at 2...8°C compared to one day at 18...25°C and five days at 2...8°C for the current QuikRead FOB Sampling Set.

Table 1. Performance of novel QuikRead iFOB Sampling Set / QR go iFOBT test compared to current QR FOB Sampling Set / QR go iFOBT test.

		QR iFOB Sampling set / QR go iFOBT		
		POSITIVE	NEGATIVE	*Total*
QR FOB Sampling set / QR go iFOBT test	POSITIVE	49	3	*52*
	NEGATIVE	0	63	*63*
	Total	*49*	*66*	*115*

Table 2. Agreement between novel QuikRead iFOB Sampling Set / QR go iFOBT test and current QR FOB Sampling Set / QR go iFOBT test

	Result
Overall agreement	97,4 %
Positive agreement	94,2 %
Negative agreement	100 %

The sensitivity and specificity of the novel QuikRead iFOB Sampling Set/QuikRead go iFOBT test, relative to the current QuikRead FOB Sampling Set/QuikRead go iFOBT test, were 94.2% (CI95 84.4-98.0) and 100% (CI95 94.3-100), respectively.

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