Berkshire & Surrey Pathology Services

A joint venture between Ashford and St. Peter's Hospitals NHS Foundation Trust, Frimley Health NHS Foundation Trust, Royal Berkshire NHS Foundation Trust and Royal Surrey County Hospital NHS Foundation Trust. Legal entity host Frimley Health NHS Foundation Trust

Pathology Solutions

NHS Bowel Cancer Screening Programme

Evaluation of a faecal calprotectin method using the OC-SENSOR PLEDIA.

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Background

- Faecal calprotectin (f-cal) is often used to aid the diagnosis of inflammatory bowel disease (IBD) over irritable bowel syndrome (IBS) and to monitor ongoing prognosis.
- Currently patients send faecal samples in 'poo-pots' to laboratories for analysis where an aliquot of the sample is removed by the lab staff and transferred to an extraction device.
- This is an unpleasant job and consumes a large amount of time within the laboratory.
- The extraction fluid is then either decanted from the device or in some instances the devices are loaded directly onto analysers for analysis.
- The faecal immunochemical test (FIT) for haemoglobin is used for bowel cancer screening and also for triaging patients with symptoms suggestive of bowel cancer.
- The use of this test requires samples to be transferred directly into a collection device by patients.
- Eiken Chemical Co., Ltd. (Japan) have developed a calprotectin method (OC-FCa) using the same faecal immunochemical test (FIT) collection device and analyser (OC-SENSOR PLEDIA) used for faecal haemoglobin (f-Hb), including for bowel cancer screening programmes.
- Using this method, a calprotectin result can be obtained simultaneously with a f-Hb result from the same device.

Aim

- This study aimed to perform an analytical evaluation of the Eiken OC-FCa using the OC-SENSOR PLEDIA.

Method

Using calprotectin solutions provided by Eiken we determined:

- **Limit of blank** (LOB), **limit of detection** (LOD) and **limit of quantitation** (LOQ)
- **Within-run imprecision -** 2 concentrations, n=20, **between-run imprecision -** 3 concentrations over 20 days, n=80.
- **Linearity** - 10 dilutions (1.0-0.1) over the analytical range 20-2720 µg calprotectin/g faeces for 2 separate starting points of 2758 and 335 µg/g.
- **Prozone** - 6 dilutions of 1 sample, expected concentrations 1563-50,016 µg/g.
- **Recovery** - 2 series, volume replacement of low concentration sample (70 µg/g) with high concentration sample (1013 µg/g) or buffer, n=24.

Using patient samples we assessed:

- **Carryover** - Two pools were created, one high (H) and one low (L), using patient samples measuring 2689 µg/g and 93 µg/g respectively. Three aliquots of each solution were measured, one set following the other. The carryover factor (k) was calculated from the equation: k = (L1 − L3)/(H3 − L3).
- A **method comparison** with the BÜHLMANN fCAL® turbo (BÜHLMANN Laboratories AG, Switzerland), n=39.

Results

Table 1. Results for the analytical evaluation of the Eiken OC-Fca using the OC-SENSOR PLEDIA

Detectability characteristics	LOB	3 µg/g		
	LOD	8 µg/g		
	LOQ	20 µg/g		
Imprecision	Within-run	247 µg/g 1.7%		516 µg/g 1.2%
	Between-run	49 µg/g 4.9%	98 µg/g 2.5%	992 µg/g 1.1%
Linearity	R^2 values >0.99 for both assessments			
Prozone	Samples at theoretical concentration of 37512 and 50016 µg/g gave 'PRC' (Prozone error code). Samples between 3126 and 25008 µg/g gave 'OR' (Over-range) error code.			
Recovery	99.6%			
Carryover	k = -0.06%			

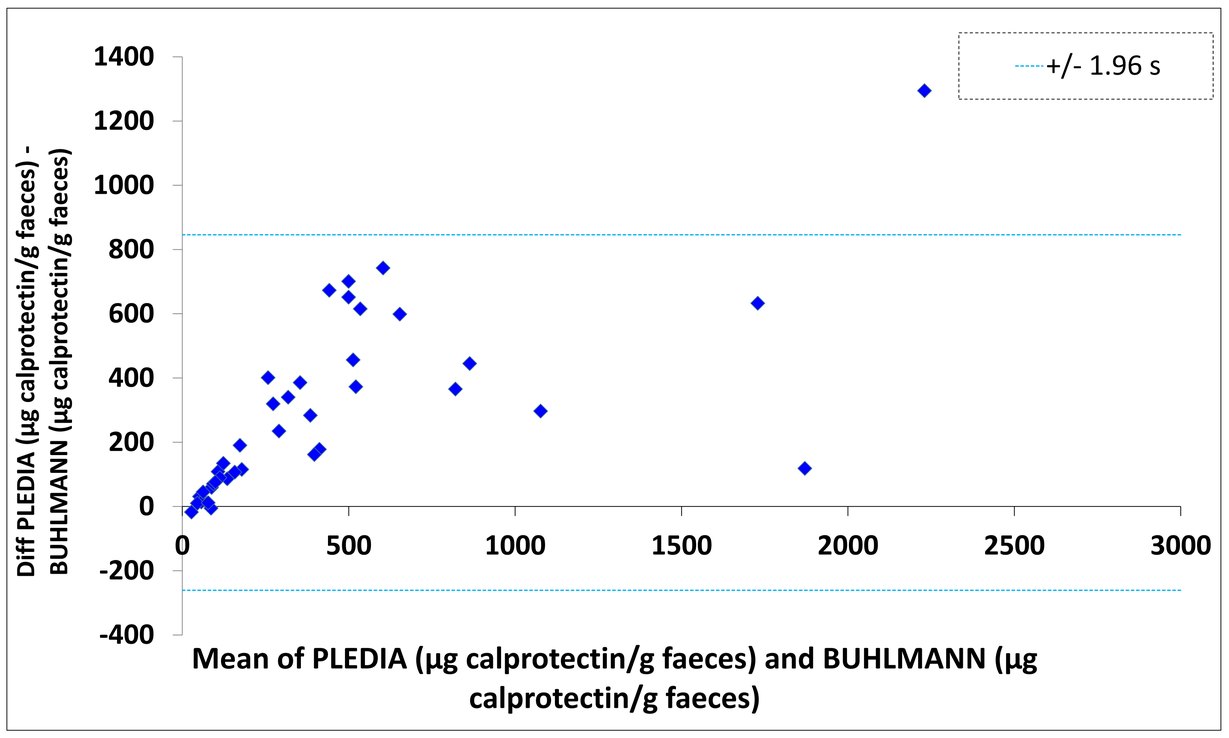

Figure 1. Bland-Altman plot of the sample comparison between the Eiken OC-Fca and BÜHLMANN fCAL® turbo methods.

Conclusion

- The OC-FCa method performed well in all aspects of the evaluation – matching or exceeding the manufacturers claims where comparible.
- The method comparison showed a clear positive bias when compared to the BÜHLMANN fCAL® turbo.
- With the lack of standardisation for faecal calprotectin a clinical study is required to evaluate the impact of the positive bias and establish suitable cut-off levels.
- The OC-FCa offers the potential to screen for both Hb and calprotectin from a single sample to aid primary care with the distinction between bowel cancer, IBD and IBS which often present with overlapping symptoms.

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