A FIT Sample

New Faecal Immunochemical Test Systems could Improve Sample Integrity for Faecal Haemoglobin

One of the challenges in clinical diagnostics is the logistics of getting a quality sample from the patient to the laboratory for analysis.

When considering the detection of faecal haemoglobin (f-Hb), this is partly dependent on the technology to be employed. In the days of guaiac-based faecal testing, samples were sent in traditional blue-capped "stool pots". This was clearly wrong, since haemoglobin in native faeces is very unstable (Brown and Fraser[1]). It degrades rapidly at physiological and ambient temperatures. In passed faeces, which contains digestive enzymes, bacteria and fungi, it will degrade even more quickly.

The moiety being examined in gFOBT is the haem component of the haemoglobin molecule. Young et al.[2] demonstrated that, with gFOBT, the degradation was more pronounced in the samples that were not dried, as when collected into a traditional faecal pot, versus a thin dried smeared sample (taken directly onto the gFOBT card).

The conclusion was that sampling directly onto the card should be made as soon as possible following defecation. In addition, analysis of gFOBT should be delayed for a few days so that potential interference from plant peroxidases, leading to false positive results, can be minimised.[3]

With the move to a more sensitive technology based on an immunoassay specific for human haemoglobin, it is vital to stabilise the haemoglobin present in the specimen collection device, prior to analysis, to protect it from degradation and maintain integrity.

Brown and Fraser[1] performed a similar study to Young et al[2]. However, they used both qualitative and quantitative FIT methods to analyse five haemoglobin spiked faecal samples, with daily sampling for up to 14 days. The conclusion was that false negative results for faecal haemoglobin could occur if sampling fresh into the tubes or onto the cards of FIT collection devices is delayed.

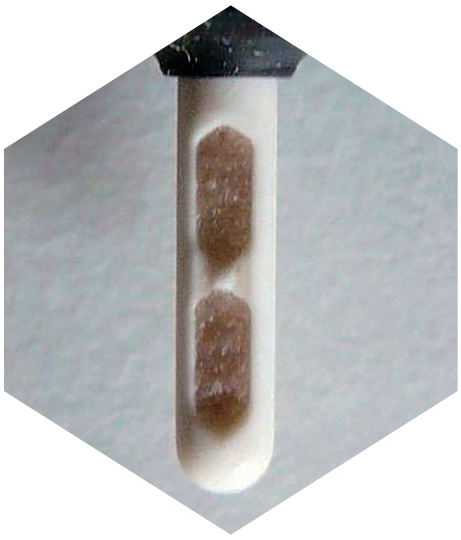
With NICE, through a Diagnostics Assessment Committee, now focussing on the benefits of the application of FIT as a means to triage patients with lower gastrointestinal (GI) symptoms, it is important that any loss of f-Hb is protected.

Using a low level cut-off of 10μg of Hb/ g faeces, the negative predictive value (NPV) for cancer is very high (100 % in the hallmark study by McDonald et al.[4]). Similarly high NPVs of 94%, are seen for higher risk adenomas (HRA) and Inflammatory Bowel Disease (IBD). Further studies in the UK have also shown a high degree of NPV when using FIT with cut-offs at this f-Hb concentration.[5,6,7]

The introduction of new quantitative FIT methods has vastly improved the method of faecal sample collection. This is an important aspect of the process since the clinical outcomes are dependent on the ability of the method to detect faecal haemoglobin at very low versus undetectable concentrations.

The HM-JACKarc specimen collection device contains a proprietary buffer which can stabilise f-Hb in samples for up to 14 days at ambient temperature (up to 25 °C) or up to 120 days in the fridge (4°C). This was confirmed in a study by Carroll et al.[8] investigating the performance characteristics of four FIT methods.[7]

With any method, sample integrity is key to the quality of result. Typically laboratories would be concerned that a layperson would be unable to provide a consistent sample. However, the collection device of the HM-JACKarc is unique, in that it has two hexagonal dimples on one side of the collection probe. This ensures that as the probe is pushed back into the collection device after sampling of the faeces, any excess faecal matter is removed and a consistent amount of sample is passed into the constant volume of buffer. This is irrespective of the consistency of the faecal sample which can vary from liquid to hard pellets.



Use of the HM-JACKarc specimen collection devices ensures stability of f-Hb and low variation in the ratio of faecal mass collected to volume of buffer. Such hygienic devices are simple for patients to use and encourage taking up the test in those who have concerns about handling faeces.

For more information on the HM-JACKarc quantitative FIT method please visit **www.alphalabs.co.uk/FIT**

References

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