A FIT Sample

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

The NICE NG12 guidelines on cancer recognition and referral were issued in 2015. They have reintroduced Faecal Occult Blood Tests (FOBT) back into the diagnostic pathway for those low risk patients with suspected lower gastrointestinal cancers. This has put a strain on pathology departments to provide a test for the presence of blood in faeces.

It presents a challenge, given that in response to the former 2005 guidelines, many pathology departments discontinued their FOBT, which were, at that time, the traditional guaiac-based tests (gFOBT)

For some, the decision that now has to be made to satisfy NG12, is which test to implement. Technology has moved on to more analytically and clinically sensitive methods such as the quantitative Faecal Immunochemical Test for haemoglobin (FIT) on systems like the Kyowa Medex HM-JACKarc.

However, the second major challenge has been the logistics of getting a quality sample from the patient to the laboratory for analysis. In part, this is dependent on the technology to be employed for the detection of faecal haemoglobin (f-Hb). 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). The moiety being examined in gFOBT is the haem component of the haemoglobin molecule. Young et al. 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.

With the move to a more sensitive technology based on an immunoassay specific for human haemoglobin, it is important to protect the haemoglobin in the faecal sample from degradation. Brown and Fraser performed a similar study to Young et al. 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 10 µg of Hb/ g faeces, the negative predictive value (NPV) for cancer is very high (100% in the hallmark study by McDonald et al.). Similarly high NPVs of 94%, are seen for higher risk adenomas (HRA) and Inflammatory Bowel Disease (IBD).

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

See overleaf for References
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References


