Birmingham Quality

Previously known as the *Wolfson EQA Laboratory*, Birmingham Quality provides primarily UK NEQAS External Quality Assessment Services in Clinical Chemistry

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WEO Expert Working Group
FIT for Screening

External Quality Assessment

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Introduction

- FOB and the Bowel Cancer Screening Programme
- FOB and FIT in the laboratory (non-screening hubs)

FOB EQA for the National Bowel Cancer Screening Programme

How the EQA specimens are made

All Bran breakfast cereal
(finely ground with a very expensive coffee grinder but still very 'lumpy')

Tinned pumpkin (added 'stickiness')

Sterile water containing a known amount of blood

Mix well using James Martin Food Mixer!

Gives realistic look and feel !

Is the existing material suitable for FIT and how are we going to find out?

(and for routine labs undertaking FOB tests using a variety of methods)

What did we do?

We opened up the EQA programme to any laboratory (i.e. non-Bowel Cancer Screening Hubs) undertaking FOB or Faecal Immunochemical Tests.

This gave us access to data generated using a variety of different methods.

Suitability of different matrices for FOB/FIT testing

Bran

Lumpy with large and non-uniform particle size – very difficult to make the specimens homogeneous. *Probably* good enough for qualitative card-based FOB screening test EQA but what about quantitative FIT tests?

Is it possible to use the bran-based material for EQA of FOB and FIT?

FIT trial with the bran and pumpkin-based material

3 of the bran-based samples prepared for the Hubs, were portioned into aliquots and distributed to any non-Hub lab performing FIT or FOB.

Looks realistic but, to cut a long story short – the qualitative results for both non-screening-lab FOB and FIT were okay but the quantitative results from the FIT tests were **rubbish**! The material was not homogeneous enough to cope with the small sample size.

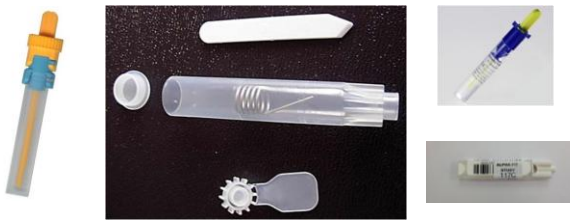
The challenge

There is a wide variety of kits available for detecting haemoglobin in stool. These kits use a range of different method principles and are distributed across a wide variety of different organisations: hospital laboratories, specialist bowel cancer screening hubs, private laboratories and GP practices.

We need to develop a suitable material to examine the performance of <u>all</u> the different types of kit available for detecting haemoglobin in stool.

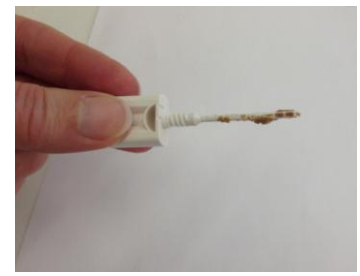
The material must be homogeneous and suitable for sampling using different types of stool collection devices.

Compatibility with stool sampling devices



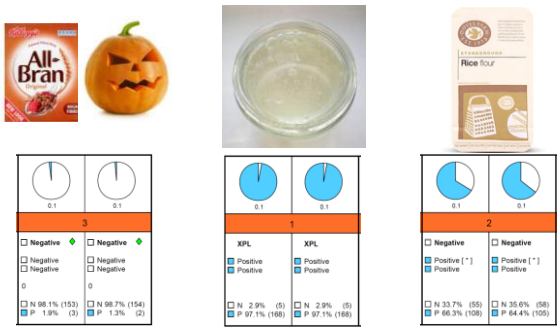
Along with a variety of different test cards for FOB and/or FIT

Compatibility with stool sampling devices



The quality of the specimen for analysis is dependent upon not only how homogeneous the artificial stool is but also on correct sampling technique. How well does it stick?

gFOBT results from three different matrices



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Suitability of different matrices for FOB/FIT testing

Bran & pumpkin

Lumpy with large and non-uniform particle size – very difficult to make the specimens homogeneous. *Probably* good enough for qualitative card-based FOB screening test EQA but certainly not for quantitative FIT tests.

Methyl cellulose

Uniform, very small particle size. Texture much more smooth and consistent than bran. Improved homogeneity (better within- and between-lab agreement for quantitative FIT) but appearance not particularly realistic and more importantly, does not behave like stool when applied to FIT/FOB test cards and does not 'stick' to the stool collection devices.

Do we still think it is possible to use the same material for the external quality assessment of FOB and FIT?

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Matrix of choice – then and now

An adequate combination of homogeneity and stickiness for qualitative testing.

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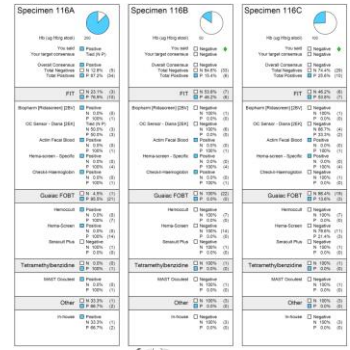
Results from current distribution

Bran and methyl cellulose



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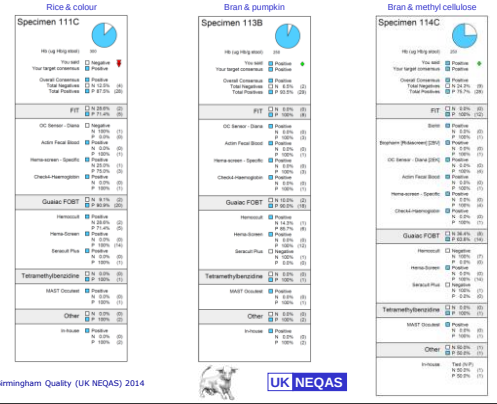
Results from different matrices

Rice & colour

Bran & pumpkin

Bran & methyl cellulose



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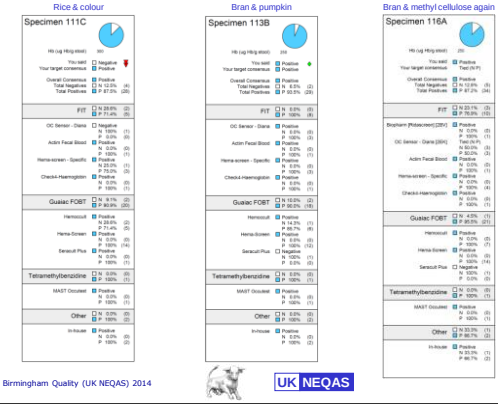
Results from different matrices

Rice & colour

Bran & pumpkin

Bran & methyl cellulose again



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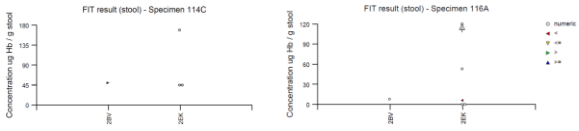
Numerical results from OC Sensor (same matrix and Hb addition on 2 separate occasions)



Homogeneity, sampling, both and/or or something else?

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Conclusions

By its very nature, stool is not homogeneous, but for EQA purposes, we need to ensure that we provide our participants with the best and most fair service that we possibly can. This involves the provision of a homogeneous stool matrix.

There is a lot more work for us to do in order to develop a perfect matrix for EQA of FIT testing.

We are currently undertaking an EQA material matrix study on the HM-JACKarc analyser in conjunction with Alpha laboratories and Kyowa Medex.

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