APPENDIX 1

FITTER standards checklist

for Labplus Auckland, New Zealand for the New Zealand Bowel Screening Pilot

Specimen collection and handling

Participants were sent a collection device called OC-Auto sampling bottle from Prohealth that provided supplies from Eiken Chemical Co. Ltd. The sample was self-collected by the participants. The green sample probe was removed by twisting and pulling from sampling device. The threaded end of green sample probe was scrapped over the surface of faecal sample until the grooves are filled. After the collection, the probe was placed back into the tube. As the probe passes through the septum into the tube, this allowed the removal of excess faecal material and the optimum amount of faecal material was delivered to the buffer contained within the tube. According to the manufacturer's specifications there is approximately 10mg of faeces in a 2 ml of buffer. This was transited to lab at room temperature. The sampling tubes were loaded into the analyser racks with the green probe end faced downwards. The OC-Sensor Diana analyser pierced the foil seal and squeezed the tube to force the buffer liquid through the filter into upper reservoir ready for analysing. Sample analysis was performed as soon as possible according to manufacturer's specifications. Any sample received later than 14 days of collection was marked as delayed and not processed.

Analysis

Specimens were stored at 2-10℃ upon receipt of the samples at the laboratory and processed daily on OC-Sensor Diana analyser platform. Samples were analysed using latex agglutination immuno-turbidometry method. The analytical working range was 50-1000ng/ml. Buffer conversion formula: µg Hb/g faeces = (ngHb/ml buffer)×2mL buffer/10mg faeces collected. Faecal haemoglobin above the upper limit was not diluted and re-analysed.

Quality management

Labplus Auckland holds a thorough quality management system and was accredited to ISO 15189 standards by International Accreditation New Zealand (IANZ). All New Zealand Bowel Screening Pilot FIT sample analysis were carried out by professionally accredited medical scientists who were blinded to the results of the reference investigation at time of analysis. The analysers were regularly calibrated according to manufacturer recommendations. For the New Zealand Bowel Screening Pilot, five quality controls were analysed prior to analysis of the samples. These were Level 1 and Level 2 quality control samples provided by the contractor Prohealth. Fit Quality Control was based on an in house quality control reagent which is a dilution of Level 2 control samples. In addition, ASE Low and ASE High quality controls supplied by Australian Scientific Enterprise were also analysed.

Attached table is an example reflecting quality control performance at the five levels of quality controls described:

QC	n	Mean (ng/mL)	S.D. (ng/mL)	CV (%)
LV1	43	149.9	1.8	1.2
LV2	43	460.6	6.4	1.4

FIT QC	59	215.6	4.8	2.2
ASE low	43	103.2	3.9	3.8
ASE high	46	256.8	5.5	2.2

Data handling

The New Zealand Bowel Screening Pilot FIT results were automatically uploaded to the Bowel Screening Pilot Register information technology system with single reading. This is inclusive of patient name, national health index number, date of birth, barcode number and the numeric faecal haemoglobin result.

Saw KS, *et al. BMJ Open Gastroenterol* 2023; 10:e001233. doi: 10.1136/bmjgast-2023-001233