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Who should perform the FIT analysis?

Pros and cons of FIT as a POCT v analysis in hospital laboratories.

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Point of Care Testing (POCT), in simple terms, is “laboratory testing” performed in a non-laboratory setting. A huge literature exists, as do regulations and/or recommendations in many countries, and ISO standards. POCT is done in many settings including wards, units and clinics in secondary and tertiary care and in primary care including in community clinics, community pharmacies, GP surgeries, health centres, the independent sector, industrial medical centres, mobile units, diagnostic centres, and residences.

Faecal immunochemical tests for haemoglobin (FIT) can be qualitative tests, giving positive/negative results. Some advantages include: (a) simple to do (as pregnancy tests); (b) inexpensive, even in small numbers; (c) no need for instrumentation; (d) can be done by others in health care than professionals in laboratory medicine (and by the public?); (e) easy to store since no refrigeration of components needed; (f) no calibration is needed; (g) integral quality monitors are always present; (h) results are available within minutes and are easy to interpret; (i) cards can be posted easily since very stable, while tube devices are less so, although improving. Some disadvantages include: (a) it is not simple to interpret faint lines; (b) colour development is dynamic – negatives become positive! (c) no real quality control with appropriate matrix is possible; (d) difficult and time consuming to do large numbers; (e) no automation is possible, although some small readers available; (f) it is impossible to download data directly with possibilities of transcription mistakes; (g) faecal haemoglobin cut-off concentrations are NOT the same for different FIT and are set by manufacturer; (h) lot-to-lot variation is possible and some acceptance quality checks are needed.

Quantitative FIT allow measurement of faecal haemoglobin concentrations. Some disadvantages include: (a) expensive if few FIT analyses done; (b) need for instrumentation, installation, training, etc; (c) need to evaluate/validate for accreditation systems and then prepare complex documentation; (d) difficult to choose which FIT system since most rather comparable in general terms; (e) cannot be done by others than professionals in laboratory medicine; (f) refrigeration required for latex reagent and quality controls and calibrators; (g) cards not used as specimen collection devices; (h) tube devices lead to stability of haemoglobin issues, although this is becoming less important as products evolve. Some advantages include: (a) high quality analyses with good reproducibility; (b) easy to monitor quality using TQM techniques with “guaranteed” quality through ISO15198 accreditation; (c) high throughput of samples; (d) no visual interpretation of results; (e) download data into LIS via middleware possible, eliminating transcription errors and facilitating record keeping; (f) linkage with other data – for example, age and gender – may be important for the future for risk scoring or monitoring; (g) cut-off faecal haemoglobin concentration(s) for referral for colonoscopy can be set by programme organisers.

POCT is highly suitable where smaller screening initiatives only are possible, including where large set-up costs are prohibitive. But care is needed and guidelines should be followed. See: www.mhra.gov.uk/Publications/Safetyguidance/DeviceBulletins/CON071082 Hospital laboratories should perform FIT for large programmatic screening efforts, especially when health services are well organised nationally or regionally and financed properly.