



Does visually over-loaded HM-JACKarc collection device impact faecal haemoglobin results?

The HM-JACKarc (Hitachi Chemical Diagnostic Systems Co., Ltd, Japan) is a quantitative faecal immunochemical test (FIT) for haemoglobin and uses the EXTEL HEMO-AUTO MC Collection Picker (collection device) to collect a sample of faeces.¹ The faecal sample is collected by scraping the device probe across the surface of the bowel motion, collecting faeces into two dimples present in the sampling region. The collection device is then passed through a 'collar' transferring a standard mass of 2 mg into 2 ml of the preservation buffer. The loaded collection device is returned to the laboratory for analysis. The buffer washes the faeces from the dimples and if haemoglobin is present it is eluted into the buffer.

We visually observed (by peeling back the barcode label) that the HM-JACKarc FIT samples received in the laboratory as part of a clinical study² had varying amounts of faeces loaded in to the collection device and that some samples had residual faeces stuck to one or both dimple(s) of the device.

In our previous study we demonstrated that artificially overloading of samples didn't impact the faecal haemoglobin concentration (f-Hb) significantly.³ In this study we further investigated with patient samples whether there was an association between the total mass of the collection device and corresponding f-Hb. We also investigated if faecal material that remained adhered to the dimple(s) of the device affected f-Hb.

A total of 327 HM-JACKarc collection devices (June 2018–July 2019) were weighed using a Sartorius BP210S Analytical Balance (Goettingen, Germany; weighing reproducibility SD $\leq \pm 0.0001$ g). As a control the average total mass of empty collection devices with same lot numbers were recorded. f-Hb was quantitated on an HM-JACKarc analyser according to the manufacturer's instructions. Internal quality controls were examined before and after examination. The data

were analysed using Spearman's Rho statistical analysis on samples with f-Hb above the limit of detection ($\geq 2 \mu\text{g Hb/g faeces}$, $n = 112$).⁴

There was no correlation between the total mass of participants' collection devices (g) and the amount of f-Hb ($\mu\text{g Hb/g faeces}$) measured ($R_S = -0.05$, $p = 0.6$, $n = 112$). This is consistent with our previous findings that loading of excess faeces around the dimple(s) of the collection device and higher up had no significant impact on the f-Hb.³

Sixty-three collection devices that had faeces adhered to one or both of the dimple(s) were picked out for further investigation. The collection devices were shaken vigorously up and down for 1 min and reanalysed. If the sample still remained in the dimple (s), the collection device was vortexed for up to 5 min before being re-examined ($n = 24$). The data were analysed using Wilcoxon signed rank test and Friedman test, respectively. Two samples were excluded from the analysis because the FIT value was above $400 \mu\text{g Hb/g faeces}$ (the upper limit of quantitation), while f-Hb results below the measurement range ($< 2 \mu\text{g Hb/g faeces}$) were recorded as undetectable for statistical analysis.⁴

Collection devices that were shaken did not produce statistically different results for f-Hb compared to their initial non-shaken result ($p = 0.14$, $n = 61$). Collection devices that were shaken and then vortexed to dislodge the faecal material from the dimple(s) also did not produce statistically different results when compared to initial, shaken or vortexed results ($p = 0.22$, $n = 24$).

In conclusion, the EXTEL HEMO-AUTO MC Collection Picker is robustly designed⁵ so that excess faecal sample loaded by participants, or material remaining in the dimple(s) does not affect the f-Hb.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

Ethical approval

Not applicable.

Guarantor


ZZ.


Contributorship

ZZ processed the samples, carried out the data analysis and prepared the manuscript with input from CP and SB. CP conceived the study with input from SB.

ORCID iDs

Zahoor Zahida  <https://orcid.org/0000-0002-7487-7097>

Piggott Carolyn  <https://orcid.org/0000-0002-6343-6202>

Benton Sally C  <https://orcid.org/0000-0001-9230-9088>

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Zahoor Zahida^{1,2} , Piggott Carolyn^{1,2} 
and Benton Sally C^{1,2} 

¹NHS Bowel Cancer Screening Programme – Southern Hub, Royal Surrey County Hospital, England, UK

²Berkshire and Surrey Pathology Services, Royal Surrey County Hospital, England, UK

Corresponding author:

Zahoor Zahida, NHS Bowel Cancer Screening Programme – Southern Hub, 20 Priestley Road, Surrey Research Park, Guildford, GU2 7YS, UK.

Email: zahida.zahoor@nhs.net

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DOI: 10.1177/0004563220976749 available online at <http://acb.sagepub.com>