Home based fecal calprotectin testing: a Canadian user performance evaluation study of IB*Doc*®

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BACKGROUND

- Fecal calprotectin (FC) is a stool biomarker that has previously been shown to be sensitive and specific for mucosal inflammation in patients with Inflammatory Bowel Disease (IBD)(1).
- FC is useful to diagnose or monitor IBD activity, although the test is limited by the requirement for patients to collect and return stool samples.
- Previous study showed sample return rate of 78%(2). Therefore, a home based FC test may improve patient adherence and the sample return rate.

OBJECTIVE

- Determine the usability of a FC home kit (IB*Doc*®)
- Determine the comprehensibility of instructions provided to an independent non-healthcare professional

METHODS

- Included participants were ≥19 years of age, diagnosed with IBD (ulcerative colitis or Crohn's disease) and at least 30% of participants demonstrated active disease (defined by Harvey-Bradshaw Index (CD) >5 or partial Mayo score (UC) >2).
- Participants with acute, severe diarrhea or chronic use of non-steroidal anti-inflammatory drugs were excluded.
- Participants were given a demonstration at the clinic on how to use the FC kit to assay their stool extract at home.
- Participants completed the IB*Doc*® kit as well as provided samples to be used by study coordinator for comparative ELISA measurement.
- A self-reported patient questionnaire using 5-point Likert scales (1 = "strongly disagree", 5 = "strongly agree) was used to determine ease-of-use of the study procedures and instructions

RESULTS

- Total of 61 participants were enrolled in the study with 34% (21) being male with an average age of 34.8 +/- 9.0 years.
- 97% (59/61) agree that they understand the instruction of the app with 80% (49/61) strongly agreeing, giving an average rating of 4.8+/-0.50, suggesting that a majority of participants understood the instructions.
- 77% (47/61) participants agree that they understand the way the result is displayed with 59% (36/61) of participants strongly agreeing with an average rating of 4.3+/-1.1.
- 78% (48/61) agree that the home kit is easy to use with 59% (36/61) of participants strongly agreeing with an average rating of 4.4+/-1.00.

Table comparing FC values from patient IB*Doc*® and ELISA reference measurement

ELISA Reference \ IB*Doc*® Result Patient	Normal ≤100	Moderate 101-299	High ≥300	TA/Total
Normal ≤100	19	2	0	19/21
Moderate 101-299	3	8	1	8/12
High ≥300	0	0	18	18/18
TA/Total	19/22	8/10	18/19	45/51

Total Target Agreement: 88 %

No false positives or negatives

Table comparing FC values from ELISA reference measurement and patient prepared ELISA reference measurement

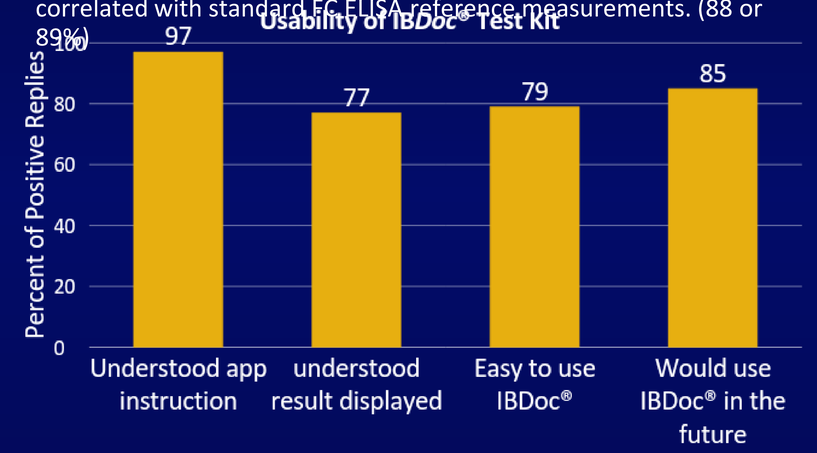
ELISA Reference \ Extract Patient	Normal ≤100	Moderate 101-299	High ≥300	TA/Total
Normal ≤100	22	5	0	22/27
Moderate 101-299	2	14	0	14/16
High ≥300	0	0	19	19/19
TA/Total	22/24	14/19	19/19	55/61

Total Target Agreement: 89 %

No false positives or negatives

RESULTS

- 85% (52/61) of participants agree that they were willing to use the home kit in the future with 66% (40/61) of participants strongly agreeing, giving an average rating of 4.5+/-0.89.
- Patient IB*Doc*® results from participant prepared ELISA assay strongly correlated with standard FC ELISA reference measurements. (88 or 89%)



CONCLUSION

- The IB*Doc*® test kit was understood by participants, with a majority of participants finding it easy to use, with an understandable display and a product that they are likely to use in the future.
- FC measurements obtained by participants using the IB*Doc*® were strongly correlated with the standard FC ELISA measurements.
- Further studies are needed to determine whether patients will continue to use it outside of a clinical trial setting and whether it will positively impact patient care for those with known or suspected IBD.

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References

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