

Laboratory Bulletin for Clinicians

August 21, 2019

Starting August 15, 2019, the Ministry of Health (Ministry) has approved fecal calprotectin (FC) testing as an insured benefit for inflammatory bowel disease (IBD) patients in BC who are being treated with a biologic agent. Testing is available for adult and pediatric patients who meet these criteria.

At this time, the Ministry has not insured fecal calprotectin testing for other clinical indications.

FC is a biomarker of intestinal inflammation and is a non-invasive means of monitoring IBD activity which includes response to therapy, and disease relapse. BC's Agency for Pathology and Laboratory Medicine is leading additional work to review the value of FC testing for other clinical indications.

Initially, LifeLabs will provide FC testing, with additional testing sites anticipated to be available in the coming months.

Who should be tested?

FC can be requested for any patient treated with a biologic agent to:

- 1. Confirm IBD response to treatment
- 2. Confirm remission of IBD activity
- 3. Assist in the identification of IBD relapse

How to order?

Use the standard outpatient requisition to order FC.

- Mark either "MSP" or "Patient", as appropriate, in the <u>Bill to</u> box at the top of the requisition
 - a. MSP billing only applies to IBD patients on biologic therapy. Testing for all other clinical indication is patient pay, at this time.
- 2. Indicate on the requisition that the patient is an "IBD patient on biologic therapy"

How to interpret the results?

Results by the Lifelabs' method are 40% lower than those previously reported by the more commonly used Buhlmann assay.

FC results vary by methodology. It is important to take this into consideration when interpreting FC in the context of remission or relapse. The difference is due to the purity of the material used for standardization of the assays and is therefore, expected to be consistent across specimens. The recommended decision levels from Bressler B. *et al.* [Bressler B., *et al.* Gastroenterol Hepatol. 2015 Oct;29(7):369-72] and other studies were based on assays that used older, less well characterized, standard material.

Bressler et al. Decision Points: For remission: FC <100 ug/g For relapse: FC >250 ug/g LifeLabs' Adjusted Decision Points:
For remission: FC <60 ug/g
For relapse: FC >150 ug/g



Please note that for patients with previous FC results, the LifeLabs' results are expected to be 40% lower than those which were sent out of province (such as those performed through industry sponsored patient support programs).

Contact

Meghan McLennan BC's Agency for Pathology and Laboratory Medicine Tel: (604) 714-2824

Email: meghan.mclennan@phsa.ca