Inflammatory Bowel Disease significantly reduces the quality of life of 20 million individuals globally and 1.4 million Americans. Presently, treatment options include a very expensive biologic agent-based approach or thiopurine analog therapy. Use of thiopurine analogs is less costly, but it currently requires expensive, imprecise testing to ensure that patients aren’t harmed by long-term use.

The Solution

Present limitations of current testing solutions for inflammatory bowel disease (IBD) represent a major setback for clinicians seeking to safely use long-term thiopurine therapy. University of Michigan researchers Ulysses Balis, M.D., and Peter Higgins, M.D., Ph.D., have developed and implemented a computational algorithm, ThioMon, which results in highly cost-effective and accurate testing, allowing for a simplified treatment of IBD with thiopurine analogs such as Azathioprine.

ThioMon is a machine-learning algorithm that uses a patient’s existing routine clinical lab test results to offer a superior prediction of biological response to Azathioprine therapy that is more accurate, less expensive, and faster than the existing metabolite test, with results available in hours versus one-two weeks.

This project was funded by the University of Michigan Translational Research and Commercialization for Life Sciences Program, also known as MTRAC. MTRAC works to “fast forward” projects that have a high potential for commercial success, with the ultimate goal of positively impacting human health.

MTRAC has been made possible by the Michigan Economic Development Corporation, the Michigan Institute for Clinical and Health Research, and the generosity of friends of the University of Michigan.
The ThioMon test algorithm would be made available as an internationally-offered subscription service from University of Michigan MLabs.

### Commercialization Strategy

- The ThioMon test algorithm would be made available as an internationally-offered subscription service from University of Michigan MLabs.

### Intellectual Property

- One patent filed and pending, additional patent to be filed for federated LIS architecture use.

### Overall Commercialization

Regulatory risk assessment will be occurring. As a reference lab, MLabs can currently offer the test to any hospital or clinic that can ship blood samples to U-M Health System. At present, FDA approval of laboratory-developed tests is not necessary.

### MTRAC Project Key Milestones

1. Final selection of a local research partner to carry out the split study
2. Execution of subcontract, local/remote IRB review, and continued exploration of establishment of partnered federated laboratories
3. Final publication of the findings and activation of first remote commercial clients
4. Local implementation of a full automated pipelined data delivery model, study design, and establishment of study size
5. Collection of IBD patient samples for split study analysis
6. Data analysis to validate repeatability at multiple sites

### Regulatory Pathway

MTRAC funding allowed us to conduct a split sample study, a standard requirement for clinical test validation, that has prepared us to make ThioMon available nationally and internationally. And their business support has been fundamental in building our outside industry relationships and preparing our product for market.

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**ThioMon is a new computational-based diagnostic test**

- allows for quicker, more accurate, and less expensive treatment options for patients with IBD by predicting and maintaining optimal biological response with respect to thiopurine monitoring.

**Significant Need**

- In contrast to current methods, ThioMon offers IBD patients a more accurate, less costly test for thiopurine therapy toxicity monitoring, allowing safe treatment without adverse effects such as hepatotoxicity, shingles, lymphoma, and other complications of immunosuppression. The ThioMon test has a 24-hour turnaround time, versus one-two weeks for other tests.

**Compelling Science**

- Computational diagnostic laboratory test based on machine-learning algorithms.

**Competitive Advantage**

- ThioMon testing for possible thiopurine analog therapeutic level and toxicity is more accurate and less expensive than the current testing options, resulting in safer treatment for patients.