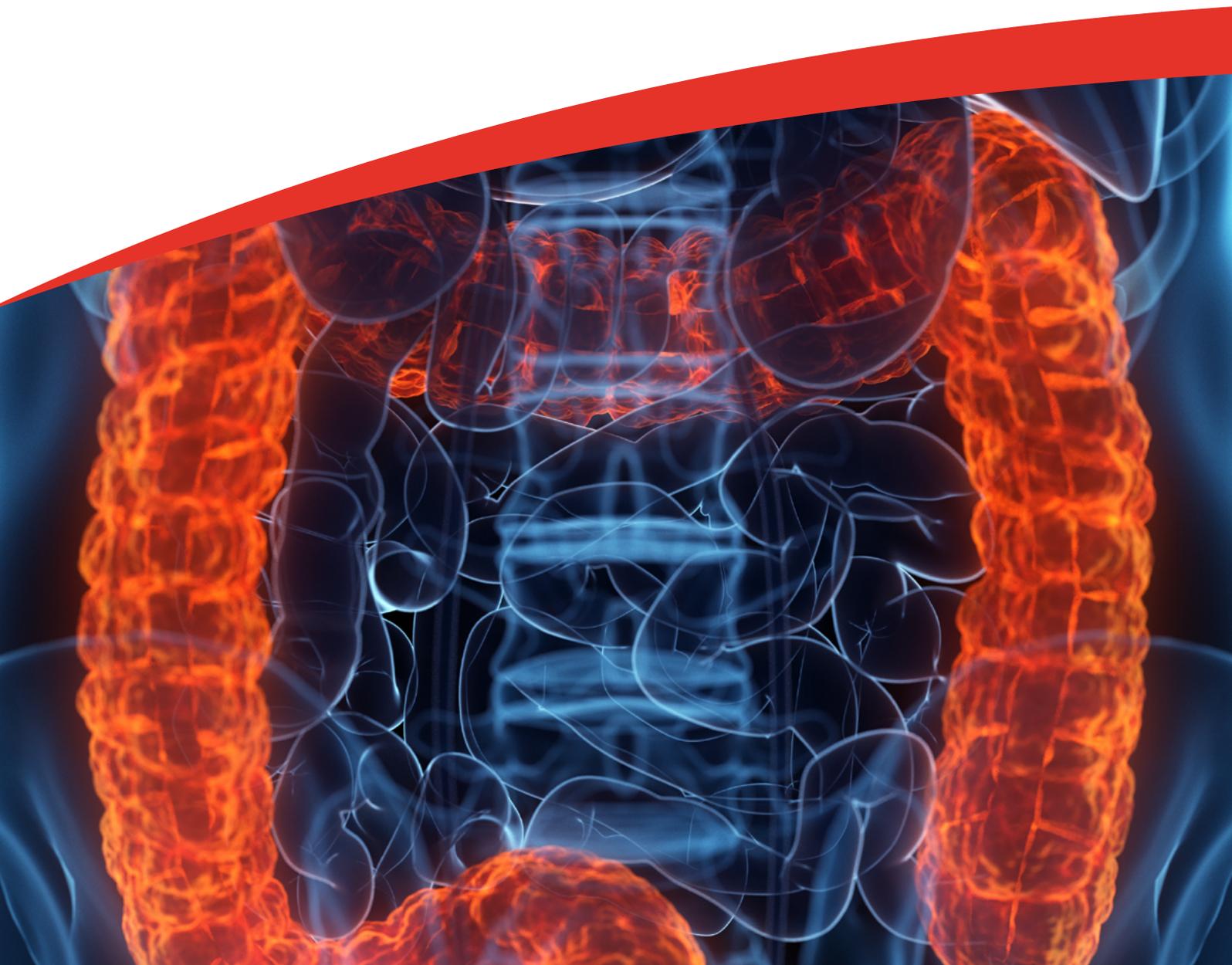




Case Study

# PredictImmune partner with Almac Diagnostic Services for Bioinformatics & Software expertise

Collaboration leads to successful launch of PredictSURE IBD™ for inflammatory bowel disease prognosis and therapy guidance.



PredictImmune and Almac have partnered over the last two years to develop and validate the gene expression software algorithm used to interpret the results from the world's first validated and CE-marked prognostic test for inflammatory bowel disease. PredictImmune selected Almac Diagnostic Services as their preferred provider for bioinformatics, software design and development solutions to support the successful commercialisation and launch of **PredictSURE IBD™**.

## **PredictSURE IBD™**

A simple, CE-marked, whole blood test, providing long-term prognostic data that can guide clinical management in inflammatory bowel disease (Crohn's disease and ulcerative colitis).



## The scientific challenge

Immune-mediated conditions are chronic, debilitating diseases with significant inter-patient variability in both disease severity and outcome. This variability means that two patients presenting with very similar symptoms and the same disease, may subsequently follow very different clinical courses. These usually range from:

- 1) Aggressive, relapsing disease to
- 2) A quiescent controlled course

One of the biggest challenges for physicians treating immune-mediated diseases is the inability to effectively discriminate between patients with an aggressive or milder disease course at the point of diagnosis; the consequence is that all patients are treated with the same “one-size-fits-all” strategy. Physicians, payers and patients all recognise a critical need for a prognostic test for inflammatory bowel disease (IBD) to facilitate differential treatment with the potential of giving the right treatment to the right patient at the right time.

### Innovation:

PredictImmune, is a spin-out of Cambridge University. The company is focused on developing prognostic tests that fill a significant gap in the market. Its initial focus has been on the development of PredictSURE IBD™, the first validated prognostic test for IBD, and the first prognostic test for immune-mediated diseases that has the potential to inform treatment choice for IBD patients.

Using machine learning approaches, PredictImmune’s scientists established a prognostic gene expression assay to predict the future disease course for individual patients, which can subsequently be used to improve clinical management strategies for patients with both Crohn’s disease and ulcerative colitis.

The gene expression signature assay was identified in CD8+ T cells using microarray technology and translated into a more accessible prognostic clinical test – PredictSURE IBD™; a quantitative PCR (qPCR) based assay to predict clinical progression in IBD.

### Collaboration:

Translation of the gene expression signature assay into a clinically validated test required the design of an accompanying software program to generate calculated risk scores for individual patients based on the weighted gene expression prognostic model. This led to PredictImmune approaching Almac Diagnostic Services’ Bioinformatics Team for its expertise in software development, including certification to IEC62304 (Medical device software – Software life cycle processes).

After considering the best options internally, Almac Diagnostic Services hosted an on-site workshop with PredictImmune, which was attended by key representatives from the laboratory operations, risk management, design control & software development teams, to ensure PredictImmune could fully leverage Almac’s extensive experience in assay design and risk management.

The objective of the workshop was to understand and discuss PredictImmune’s IBD prognostic test software requirements, to identify where risk mitigations were needed within the algorithm software and to further facilitate the identification of detailed user requirements for software development.

PredictImmune’s confidence in Almac’s software development capabilities led to the beginning of a successful partnership.

## The Almac solution

Almac Diagnostic Services' Bioinformatics and Software Development teams worked collaboratively with research specialists at PredictImmune, to bring their expertise and experience in software development and risk management to deliver PredictImmune's vision for the test.

Led by a skilled project management team, a strong relationship was forged, with regular planned meetings and a high degree of communication; helping to achieve successful progression against key project milestone activities for the software design and delivery, on time and within budget.

### **Design and validation of the PredictSURE IBD™ software programme:**

PredictImmune requested Almac Diagnostic Services to perform the development of a portable software solution for their whole blood prognostic gene expression algorithm. This utilised gene expression measurements in the form of ixo files obtained from the chosen qPCR platform platform.

### **Prototype and Version Control:**

Almac Diagnostic Services was further engaged in the development of PredictSURE IBD™ to establish the first software release (version 1.0.0) of the application based on the original PredictSURE IBD™ test specifications.

The design of the (version 1.0.0) IBD whole blood prognostic gene expression algorithm software, was initially released as a 'prototype' to support an early application of PredictSURE IBD™.

Following modification of the test parameters, this PredictSURE IBD™ software prototype was subsequently revised and released to production (version 2.0.0).

### **Certification & Launch:**

#### **December 2018: CE Mark Achievement**

PredictImmune successfully received CE IVD certification for its qPCR prognostic biomarker test for IBD – PredictSURE IBD™, the world's first validated biomarker prognostic test in inflammatory mediated diseases.

#### [Read the Press Release](#)

#### **April 2019: UK & Ireland Launch**

PredictImmune's CE mark accreditation has enabled the company to take its prognostic IBD test to market, launching in the UK and Ireland, with a further launch planned for Europe later in the year.

#### [Read the Press Release](#)

*"Almac Diagnostic Services has been delighted to work with PredictImmune, bringing our bioinformatics and software development expertise to the fore to assist in the development of this vitally important prognostic test. It is a positive step forward towards personalised medicine in IBD for sufferers of Crohn's disease and ulcerative colitis, which will undoubtedly help guide better patient treatment decisions and reduce cost in the healthcare system with improved outcomes."*

*Michael Sloan, Almac Diagnostic Services – Global VP of Commercial Operations.*

## Future collaboration

Since the release of PredictSURE IBD™ test, Almac Diagnostic Services has continued to work closely on the next phase of ongoing development and validation of PredictImmune's IBD prognostic test.

*"As a small Company aiming to deliver on some big challenges, PredictImmune relies on the expertise and support of our partners to help us meet our challenging commercial goals. Almac have worked closely with us over the last couple of years, supporting us in both the design and development of software that has enabled us to launch our first prognostic product - PredictSURE IBD™ in record time. We look forward to continuing the successful partnership with Almac Diagnostic Services as we focus on the development of pioneering prognostic tools to improve outcomes for patients with chronic, debilitating immune-mediated diseases such as Lupus and IBD."*

Paul Kinnon, Predictimmune C.E.O

## About PredictSURE IBD™

Award-winning PredictSURE IBD™ is the world's first validated and CE-marked prognostic test for guiding treatment options in inflammatory bowel disease (Crohn's disease and ulcerative colitis). PredictSURE IBD™ is based upon 10 years of extensive research on gene expression profiling of CD8+ T cells.

This whole blood-based biomarker test is a major step towards personalised medicine in IBD.

### Features:

- Easy to run, 17-gene qPCR molecular test
- Only 2.5ml blood sample needed
- Sophisticated proprietary algorithm
- Fast turnaround
- Simple to understand, on-line reporting

For more information visit the **PredictImmune [website](#)**.

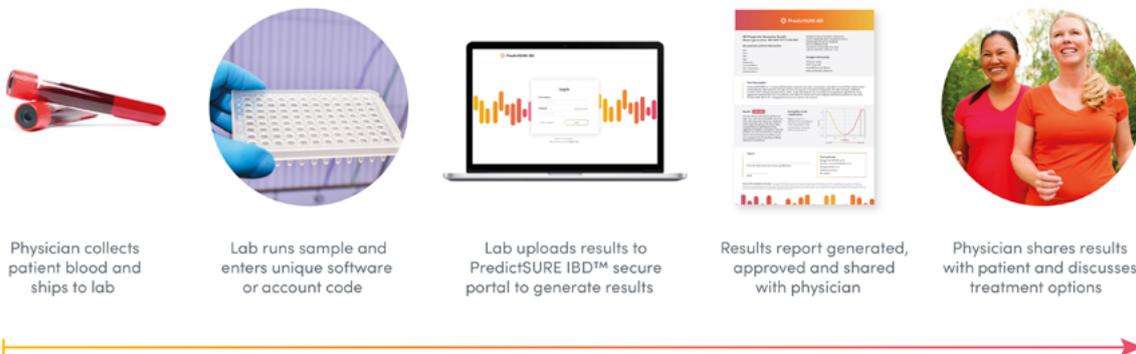
## Benefits of PredictSURE IBD™

The design of the innovative prognostic biomarker PredictSURE IBD™ prognostic test has had a major impact in offering personalised medicine in IBD. The easy-to-set-up biomarker test combines a sophisticated proprietary algorithm which has successfully allowed users to identify patient clinical course, differentiating between aggressive or milder disease outcomes.

**The capability to retrieve additional information with the IBD prognostic test has meant greater support utility for treatment choices for patients.** It offers gastroenterologists an enhanced understanding of their patients' long-term prognosis at the point of diagnosis. This, in turn, could help patients better plan their lives based on the knowledge of the future of their disease outcome.

**Through better stratification to streamlined treatment strategies by reducing both direct and indirect costs to the healthcare system.**

## PredictSURE IBD™ workflow



## Notes

[almacgroup.com](http://almacgroup.com)

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