

PredictImmune: Predicting outcomes in Inflammatory Bowel Disease Starts with the PAXgene Blood RNA system

dictSure IBD¹



Dr Karen Hills, Executive Director, Medical Affairs and Market Access and Dr Paul Lyons, Vice President Platform Delivery, PredictImmune[™], share how the[®] team overcame challenges in blood specimen preservation for better sample quality and pre-analytical workflow standardization in their clinical diagnostic applications.

Karen, originally from Yorkshire came to Cambridge to study her PhD, fell in love with the city and never left. She is a keen runner who has completed over 75 marathons/ultra-marathons), has a black belt in karate and happily married with a 10 year old daughter who keeps her very busy.

Q: Tell us about Predictimmune?

PredictImmune is a VC-funded Cambridge start-up who have licensed the PredictSURE® IBD[™] test from Cambridge Enterprise (the Venture Capital arm of the University of Cambridge). The company also has access to tests for other diseases areas such as multiple sclerosis, ANCA associated vasculitis and systemic lupus erythematosus). PredictImmune is the manufacturer and distributer of PredictSURE IBD, a CE marked assay (since 2018) which has been available for commercial use through the East Genomic Laboratory Hub (EGLH) since early 2019. PredictImmune currently has two ongoing clinical trials: the <u>PROFILE</u> study and <u>PRECIOUS</u> study. KSL Diagnostics, a US national reference laboratory, have partnered with PredictImmune and are working toward making the test available in the US and Canada in 2023.

https://www.ksldx.com/
https://youtu.be/9GyL8af7xh4

Inflammatory Bowel Dise Gene Signature Assay Co

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Q: What challenges did you face in your preanalytical steps for sample preparation?

The PredictSURE IBD assay measures the expression level of 15 informative and 2 reference genes in whole blood from patients with active IBD. Given the literature showing that even short storage times led to significant changes in transcript levels, a major challenge we encountered was ensuring that the transcript levels of these 17 genes were stabilized at ambient temperature from the point of blood collection at clinical sites to the point at which RNA was extracted and analyzed at a centralized testing laboratory. It was essential for the samples to remain high quality during testing laboratories. The major issue we encountered was the ability to robustly collect and store whole blood samples for downstream transcriptomics, especially when the blood was to be collected at remote sites. It was essential maintain sample stability during transportation to testing laboratories.

Q: Why did you choose the PAXgene® Blood RNA System for your molecular diagnostic applications?

The PAXgene Blood RNA system was the only IVD cleared solution for the EU market. We did consider competitor Blood RNA Tubes in parallel, but the published research and clinical evidence base available was significantly larger for the PAXgene Blood RNA Tubes. This helped with our decision to proceed with PreAnalytiX and select the PAXgene Blood RNA System.

"The PAXgene system offered an attractive end to end solution for sample collection right through to RNA isolation, from blood collection in the PAXgene Blood RNA tubes. We also liked the the option of automation using the QIAsymphony PAXgene Blood RNA Kit."

The benefits we found in using the PAXgene Blood RNA System were:

"The RNA is stable at room temperature (18-25°C) for up to 72 hours which works well with PredictImmune's business model of having centralized testing labs in each territory. This allows sufficient time for samples to be shipped from distributed blood collection sites to the centralized labs for processing. The PAXgene Blood RNA Tubes are reasonably priced and simple to use."

To date the PAXgene Blood Tubes have been used for:

- Initial research leading to the discovery of the CD8+ T-cell signature
- All validation and clinical studies (including PROFILE & PRECIOUS)
- Pilot programmes with UK, US and European labs
- Set up and validation of lab partners in the UK, US and Israel
- Overall, over 1200 patients have been tested as part of these activities
- Exploratory studies with potential pharmaceutical partners



Dr Paul Lyons Vice President Platform Delivery, Predictimmune

Paul spent his formative years on the South Coast of England but has lived the last 25 years in Cambridge. He is happily married with two teenage daughters and when not working can usually be found riding or racing a bicycle.





Explore more at: www.preanalytix.com