PredictSURE IBD™

IBD Prognostic Biomarker Results
Report generated: DD/MM/YYYY HH:MM

Tested at Clinical Genetics Laboratory
Level 6, Addenbrooke's Treatment Centre,
Cambridge University Hospitals
NHS Foundation Trust
Hills Road, Cambridge CB2 0QQ
Lab Accreditation Number: xxxx

Anonymised patient information

ID 1:
ID 2:
Sex:
Age:
Diagnosis:
Comorbidities:
Prior treatment:
Smoker status:

Sample information

Clinician name:
GMC/Doctor#:
Hospital/Account Name:
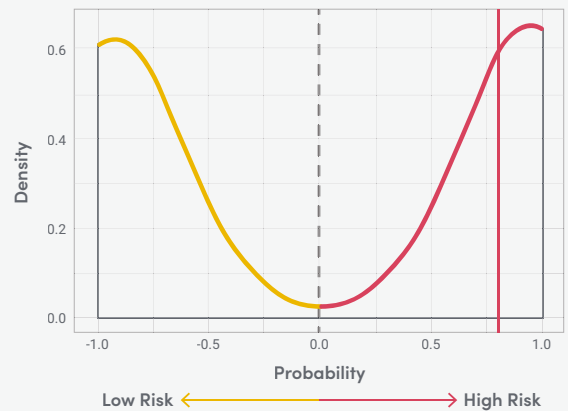Date of Sample Collection:

Test Description

PredictSURE IBD™ is a 17-gene qPCR-based prognostic test with a proprietary algorithm that stratifies inflammatory bowel disease (IBD) patients into high and low-risk groups at the point of diagnosis. The test has been validated in both Crohn's disease and ulcerative colitis. High-risk patients are more likely to a experience significantly more aggressive disease than low-risk patients, with need for earlier and more frequent treatment escalations over time. (PredictSURE IBD™ IFU; info@predictimmune for further information).

Results HIGH RISK

The test results identify this patient as high-risk, with 95% probability that they are in the high-risk subgroup. Patients in the high-risk group are more likely to experience a significantly more aggressive disease course than low-risk patients, as characterised by a shorter time to first treatment escalation and an increased risk of requiring multiple treatment escalations.

Probability of risk classification

Figure 1. Probability distribution for risk subgroup allocation. Where risk classification has been assigned, the probability of the classification result reported is indicated by the vertical solid red line.

Signed

_____

Prof./Dr. first name, last name, qualification

_____

Date

Testing Details
Reagent kit (PI001) lot #:
Quality control kit (PI002) lot #:
Analysis date/time:
Software version:
QC result:

PredictSURE IBD™: the first validated prognostic test for Crohn's disease and ulcerative colitis

The PredictSURE IBD™ test is performed on whole blood taken from patients with active IBD prior to starting treatment, and stratifies patients into two subgroups that correlate with clinical outcome. Test performance has been validated in an independent, prospective, blinded clinical study with 12 month clinical outcome data submitted in support of CE IVD marking[1].

In addition, an extended validation cohort (n=123, 66 Crohn's disease, 57 ulcerative colitis) showed that patients classified as 'high-risk' at diagnosis required earlier treatment escalation (Fig 1A, B) and escalation to more potent therapies (Fig 1C, D) than the corresponding low-risk subgroups in both Crohn's disease (Fig 1C) and ulcerative colitis (Fig 1D)[2].
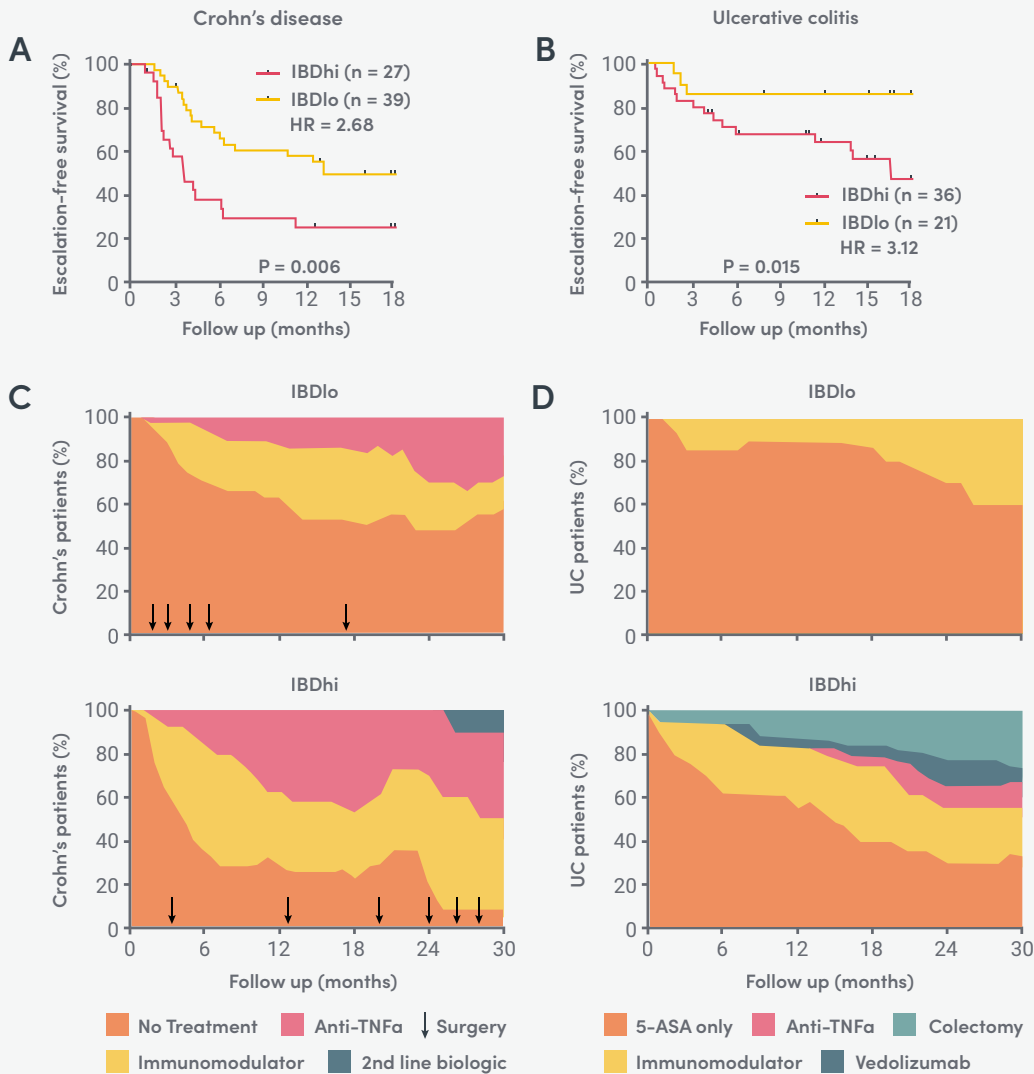

Figure 1 (A,B) Censored Kaplan-Meier curves showing treatment-free survival for Crohn's disease (A, n=66) and ulcerative colitis (B, n=57); P = log-rank test. HR: hazard ratio.   (C-D) Stacked density plots demonstrating maximum medical therapy required over 2.5 years follow up in high and low-risk subgroups for CD and UC. Treatments were plotted hierarchically (No treatment < Immunomodulator< anti-TNFα< second-line biologics (Vedolizumab or Ustekinumab) in CD and 5-ASA only< immunomodulator< anti-TNFα < Vedolizumab < Colectomy in UC). Arrows represent episodes of surgery for CD patients at the indicated timepoints.
Data censored at maximum follow-up for each patient.

Combined IBD analysis for PredictSURE IBD™ CE IVD Certification

The most relevant clinical performance characteristics of the PredictSURE IBD™ test in predicting the need for multiple (two or more) treatment escalations within the first 12 months from the moment of IBD diagnosis are: 90.8% of patients experiencing multiple escalations were in the high-risk group (sensitivity) and 98.2% of low-risk patients did not have multiple escalations (negative predictive value).

For more information on the discovery[3,4,5] and validation[1] of PredictSURE IBD™, download references from our website *https://www.predictimmune.com/publications-editorials*

REFERENCES

1. PredictSURE IBD™ Test IFU (current version) | 2. Biasci D, Lee JC, Noor NM, et al. doi:10.1136/gutjnl-2019-318343 | 3. Lee, J.C. et. al. (2011) J.C.I, vol. 121:4170-4179 |
4. McKinney E.F. et. al. (2010), Nature Med., vol 16(5):586-591 | 5. McKinney E.F. et. al. (2015), Nature, vol. 523:612-616