

OVERVIEW

The Envisia™ Genomic Classifier is the first commercial test to improve diagnosis for patients undergoing evaluation for interstitial lung diseases (ILDs), including idiopathic pulmonary fibrosis (IPF). The genomic test helps physicians more confidently distinguish IPF from other ILDs, without the need for surgery, guiding optimal treatment plans to improve patient outcomes. The Envisia classifier is used as a complement to high-resolution computed tomography (HRCT) imaging and clinical factors.

ILDs AND IPF: AT A GLANCE

- ILDs include all of the diseases that cause inflammation and/or scarring in the lung. IPF is among the most common and deadly ILDs. It results in progressive, life-threatening lung scarring for unknown reasons.
- IPF has a poor prognosis. Median survival is approximately 2.5-3.5 years.¹
- In 2014, the U.S. Food and Drug Administration approved the first two anti-fibrotic therapies to help delay progression of IPF.



>100,000

people in the United States have ILDs, including IPF, and the number is rising.²

THE DIAGNOSTIC CHALLENGE

Physicians routinely use HRCT along with a clinical work-up to diagnose IPF. This approach, however, frequently provides inconclusive results, which can lead to delayed and inappropriate treatment, unnecessary healthcare costs and significant patient anxiety. Additionally, many patients will undergo invasive, costly and potentially risky surgery to secure a more definitive diagnosis. Some patients are too frail for surgery and may never receive an accurate diagnosis.

According to a Pulmonary Fibrosis Foundation survey, among people with IPF and other ILDs:³

55%

reported being misdiagnosed at least once



43%

required more than a year to get an accurate diagnosis



21%

of patients who said they were diagnosed with IPF reported treatment during the diagnostic process with systemic corticosteroids, a potentially harmful therapy for people with the disease



THE ENVISIA GENOMIC CLASSIFIER: A BETTER DIAGNOSTIC APPROACH

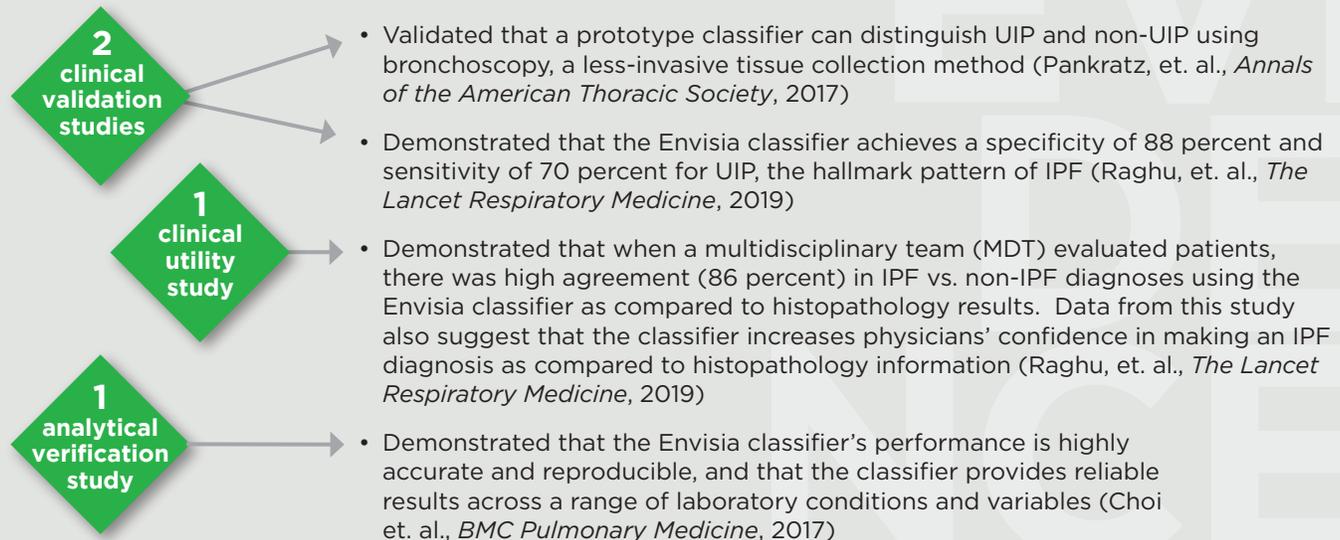
The Envisia Genomic Classifier helps distinguish IPF from other ILDs by providing important diagnostic information - as a complement to HRCT and clinical factors - that was previously only available through invasive surgery. Data published in *The Lancet Respiratory Medicine* show that the Envisia classifier detects the usual interstitial pneumonia (UIP) pattern, whose presence is essential to IPF diagnosis, with high accuracy (88 percent specificity and 70 percent sensitivity).⁴ This high specificity means that the test minimizes false positive results, thus providing physicians with greater confidence in their diagnosis. Seventy percent sensitivity means that the test would be expected to identify more than two thirds of UIP cases; in comparison, data show that HRCT alone has a sensitivity of 43 percent.⁵

The 190-gene Envisia classifier was developed by combining RNA whole-transcriptome sequencing and machine learning, which enables the most refined genomic approach possible for distinguishing between UIP and non-UIP. The test is performed on patient samples obtained through transbronchial bronchoscopy, a nonsurgical procedure commonly used in lung evaluation.

Physicians collect the patient samples and send them to Veracyte for genomic analysis in the company's CLIA laboratory in South San Francisco. Test results are provided to the ordering physician within two weeks of order submission.

In March 2019, the Envisia classifier became the first genomic test for improving IPF diagnosis to be covered for Medicare patients. As of March 2019, 30 institutions across the United States were participating in Veracyte's Early Access Program for the Envisia classifier, offering it to patients undergoing evaluation for IPF or other ILDs. The company expects to expand national access to the classifier in 2019.

The Envisia Genomic Classifier is supported by robust evidence demonstrating its performance, clinical utility and reproducibility.



Cautionary Note Regarding Forward-Looking Statements

This fact sheet contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "expect," "believe," "should," "may," "will" and similar references to future periods. Examples of forward-looking statements include, among others, the expected impacts of Veracyte's collaboration with Johnson & Johnson in developing interventions for lung cancer, on Veracyte's financial and operating results, on the timing of the commercialization of the Percepta classifier, and on the size of Veracyte's addressable market. Forward-looking statements are neither historical facts nor assurances of future performance, but are based only on our current beliefs, expectations and assumptions. These statements involve risks and uncertainties, which could cause actual results to differ materially from our predictions, and include, but are not limited to: our ability to achieve milestones under the collaboration agreement with Johnson & Johnson; our ability to achieve and maintain Medicare coverage for our tests; the benefits of our tests and the applicability of clinical results to actual outcomes; the laws and regulations applicable to our business, including potential regulation by the Food and Drug Administration or other regulatory bodies; our ability to successfully achieve and maintain adoption of and reimbursement for our products; the amount by which use of our products are able to reduce invasive procedures and misdiagnosis, and reduce healthcare costs; the occurrence and outcomes of clinical studies; and other risks set forth in our filings with the Securities and Exchange Commission, including the risks set forth in our quarterly report on Form 10-Q for the quarter ended September 30, 2018. These forward-looking statements speak only as of the date hereof and Veracyte specifically disclaims any obligation to update these forward-looking statements or reasons why actual results might differ, whether as a result of new information, future events or otherwise, except as required by law.

1: Kim H, et. al., Preliminary result of definitive radiotherapy in patients with non-small cell lung cancer who have underlying IPF: comparison between X-ray and proton therapy. *Radiat Oncol*. 2019; 14. 2: Internal Veracyte estimates. 3: Cosgrove GP, et. al. Barriers to timely diagnosis of interstitial lung disease in the real world: the INTENSITY survey. *BMC Pulm Med* 2018; 18(1): 9. 4: Raghu, et. al. Usual interstitial pneumonia: prospective validation of a molecular classifier in conventional transbronchial lung biopsy for the diagnosis of UIP. *Lancet Respir Med*. 2019; in press. 5: Choi Y, et. al. Identification of usual interstitial pneumonia pattern using RNA-seq and machine learning: challenges and solutions. *BMC Genomics*. 2018; 19(Suppl 2)(101).