



**ARTICLE**

Utility of a Molecular Classifier as a Complement to High-Resolution Computed Tomography to Identify Usual Interstitial Pneumonia. *Am J Respir Crit Care Med* Vol 203, Iss 2, p211-220.

**CLINICAL QUESTION**

Can the Envisia Genomic Classifier add impactful information to achieve clinical consensus diagnosis in multidisciplinary discussion? If yes, what does the Envisia Genomic Classifier add to high-resolution computed tomography (HRCT) and clinical information?

**SUMMARY**

An early and accurate diagnosis of idiopathic pulmonary fibrosis (IPF) is important to identify appropriate therapeutic options, predict risk of progression and to provide an overall prognosis. Usual interstitial pneumonia (UIP) is the defining morphology of IPF. Guidelines for diagnosing IPF conditionally recommend surgical lung biopsy to establish a histopathologic diagnosis of UIP when a clinical consensus diagnosis cannot be reached in multidisciplinary discussion using available clinical and radiographic data. This study aims to validate the accuracy and reproducibility of the molecular diagnosis of UIP via less invasive transbronchial lung biopsy to accurately predict histopathologic UIP, facilitating a clinical diagnosis of IPF in the appropriate clinical context.

Ninety-six patients with diagnostic lung pathology as well as transbronchial lung biopsy for molecular testing with Envisia Genomic Classifier were included in this analysis. The classifier results were scored against reference pathology. UIP identified on HRCT as documented by features in local radiologists' reports was compared with histopathology. For these 96 patients, the Envisia Classifier achieved a specificity of 92.1% and a sensitivity of 60.3% in identifying a histology-proven UIP pattern.

**Table 5.** UIP Diagnostic Yield from Local Radiology in Conjunction with Envisia Genomic Classifier Testing

Local Radiology + Envisia Classifier	Pathology Reference Standard	
	UIP (n = 53)	Non-UIP (n = 32)
Definite/probable UIP or Envisia Classifier UIP, n	42	3
Indeterminate for UIP/consistent with non-IPF and Envisia Classifier non-UIP, n	11	29
Sensitivity, % (95% CI)	79.2 (65.9–89.2)	
Specificity, % (95% CI)	90.6 (75.0–98.0)	
NPV, % (95% CI)	72.5 (56.1–85.4)	
PPV, % (95% CI)	93.3 (81.7–98.6)	
UIP prevalence, %	62.4	

This study redemonstrates that a molecular UIP pattern determined from transbronchial biopsies using the Envisia Genomic Classifier has high reproducibility and accuracy for the detection of histopathologic UIP. This method is less invasive and can be used in conjunction with clinical data, HRCT, and multidisciplinary discussion to aid in achieving a clinical consensus diagnosis of IPF.



## GROUP OPINION

Idiopathic pulmonary fibrosis (IPF) can be challenging to diagnose. An early and accurate diagnosis of IPF is important to identify appropriate therapeutic options, predict risk of progression and provide an overall prognosis, yet surgical lung biopsy are associated with considerable morbidity and mortality. The Envisia Classifier via transbronchial lung biopsy is a less invasive means to identify UIP and, when used in conjunction with HRCT and clinical information, facilitate a clinical consensus diagnosis for IPF.

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