

## Envisia Genomic Classifier Demonstrates Consistent Performance Across Gender, Age Group, and Smoking Status

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**RATIONALE** Idiopathic pulmonary fibrosis (IPF) is a chronic fibrosing interstitial pneumonia that has either a radiologic and/or pathologic pattern of usual interstitial pneumonia (UIP). While IPF is more common in patients >65 years, males and ever smokers, the diagnosis can be challenging especially in those younger patients, females and never smokers. The Envisia Genomic Classifier (EGC) is a clinically validated molecular test for UIP in transbronchial biopsies (TBBx) that was developed as a “rule in” test with high specificity. UIP by EGC in combination with clinical factors and HRCT findings in the context of a multidisciplinary discussion has shown clinical utility in determining an IPF diagnosis. We assessed the performance of EGC in the detection of UIP in patients who were age 65 years old, female and never smokers. **METHODS** One hundred forty-four patients with complete information on gender, age and smoking status were included in this pooled, retrospective analysis of two independent validation cohorts of EGC. Patients were enrolled in the BRAVE (Bronchial Sample Collection for a Novel Genomic Test) clinical sample collection study and had undergone clinical evaluation for suspected fibrotic lung disease with standard-of-care (SOC) lung biopsies for histopathology. We compared the specificity and sensitivity of the EGC in younger ≤65 years old versus older >65 years old patients, female versus male patients and never smokers versus ever smokers. **RESULTS** As previously reported, the EGC showed 90.6% [Confidence Interval (CI): 80.7, 96.5] specificity and 62.5% (CI: 51.0, 73.1) sensitivity and for histology-proven UIP pattern among 144 patients. There was no significant difference in the performance of EGC in patients ≤65 years old, female or a never smoker compared to those that were >65 years old, male or ever smokers, respectively. **CONCLUSION** The EGC retains high specificity in a subset of patients (younger, female or never smokers) that are less likely to have a UIP pattern or IPF. This suggest that the EGC can provide useful diagnostic information to guide management in patients where an IPF diagnosis is less common. These results support the use of the EGC as a surrogate measure of pathologic UIP in patients whose clinical characteristics and HRCT scan are inconclusive for IPF.

	Specificity [Confidence Interval]	P value	Sensitivity [Confidence Interval]	P value
All patients (144)	90.6% [80.7, 96.5]	N/A	62.5% [51.0, 73.1]	N/A
Males (83)	92.3% [74.9, 99.1]	1.00	61.4% [47.6, 74.0]	0.75
Females (61)	89.5% [75.2, 97.1]		65.2% [42.7, 83.6]	
Age > 65 years old (75)	88.5% [69.8, 97.6]	0.68	67.3% [52.5, 80.1]	0.26
Age ≤ 65 years old (69)	92.1% [78.6, 98.3]		54.8% [36.0, 72.7]	
Ever Smokers (81)	90.0% [76.3, 97.2]	1.0	56.1% [39.7, 71.5]	0.23
Never smokers (63)	91.7% [73.0, 99.0]		69.2% [52.4, 83.0]	

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