idylla ThyroidPrint

Latest performance data show that the new sample-to-result Idylla™ ThyroidPrint® Assay (RUO) can accurately identify benign thyroid nodules with indeterminate cytology

INTRODUCTION

Thyroid nodules are a frequent condition, affecting up to 60% of the adult population.¹ Although most thyroid nodules have little clinical significance, in many cases a fine needle aspirate (FNA) biopsy will be performed to determine its nature. In 70% of these cases, an FNA will be reported as benign and in 10% of the cases as cancer, based on cytological examination. However, in the remaining 20% of the cases, the thyroid nodule will be reported as indeterminate (Bethesda III/IV). These nodules are managed through diagnostic surgery which is the standard approach. After surgery, up to 75% of these nodules are determined to be benign.² Every year, unnecessary diagnostic surgery exposes thousands of patients to potential short-term (surgical complications) and long-term side effects (need for permanent hormone replacement therapy).

THYROIDPRINT® GENE SIGNATURE

The **2023 European Thyroid Association guidelines** mention that molecular tests, such as gene expression classifiers and mutational analyses are useful tools in evaluating nodules with indeterminate cytology.¹ These tests can help with the avoidance of unnecessary surgeries by better assessing the risk of malignancy of indeterminate thyroid nodules.

ThyroidPrint[®] is a novel qPCR-based 10-gene classifier with its signature representing both the tumor microenvironment *(CXCR3, CXCL10, CCR3, CCR7, and CXADR)* and tumor epithelial cells *(TIMP1, CLDN1, KTR19, AFAPL2, and HMOX1).* The signature's qPCR data is analyzed by a neural network algorithm that predicts the probability of indeterminate thyroid nodules being benign.³

In a validation study reporting two independent, multicenter clinical cohorts, ThyroidPrint® predicted benign thyroid nodules with a negative predictive value of 95%, while properly classifying 88% of benign cases.⁴

In a recent clinical utility study, ThyroidPrint® was shown to

Moreover, the **new guidelines** of the **Spanish Society** of Endocrinology and Nutrition (SEEN) describe that molecular signatures, such as ThyroidPrint[®] can help endocrinologists make more informed decisions about nodule management, potentially reducing the need for unnecessary surgeries.⁶

IDYLLA[™] THYROIDPRINT[®] ASSAY (RUO)

To increase test access, ThyroidPrint® was recently migrated to the Idylla[™] sample-to-result cartridge system which can be run in decentralized laboratories. The Idylla[™] ThyroidPrint® Assay covers the entire process in approximately 160 minutes with less than 5 minutes hands-on-time.

CLINICAL VALIDATION DATA

A multicenter prospective double-blinded clinical validation trial based on 172 FNA samples showed that the classifier correctly identified 45 of 49 surgical cases, yielding a sensitivity of 92% and 102 of 123 non-surgical tumors yielding a specificity of 82%.

The Idylla[™] Assay achieved a negative predictive value of 96% (95% CI 91–99), and a positive predictive value of 67% (95% CI 59–76). The obtained sensitivity and specificity demonstrate that the performance is preserved by transferring the 10-gene classifier to the cartridge. Moreover, the validation was performed across several cancer subtypes including the more frequent papillary and follicular thyroid cancer variants also including the less prevalent oncocytic neoplasms and medullary thyroid cancer.

In conclusion, the study indicates that the Idylla[™] Assay could have potentially spared almost 2 in every 3 surgeries with a false negative rate of just 4%.⁷

Study	ThyroidPrint* LDT Clinical Validation*	Idylla™ ThyroidPrint [●] Clinical Validation ^{**}
Cases	270	172
Benign call rate	63% (170/270)	62% (106/172)
Sensitivity	91%	92%
Specificity	88%	82%
NPV	95%	96%
PPV	78%	67%

*Zafereo et al. Thyroid 2020, **González et al. Thyroid 2024

reduce unnecessary surgeries by 67%.⁵

The Idylla[™] ThyroidPrint[®] Assay (RUO) enables laboratories to conduct further research on risk stratification of indeterminate thyroid nodules



Biocartis' mission is to transform patient care by delivering rapid and reliable molecular information to our patients. For patients with thyroid nodules, the Idylla[™] ThyroidPrint[®] Assay empowers physicians by delivering test results that enable fast clinical decision making and, as a consequence, assist in avoiding unnecessary surgeries. This is a critical step toward more personalized and less invasive care for patients with thyroid nodules.

Michael Korn, Chief Medical & Scientific Officer of Biocartis commented

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