

IDYLLA™ THYROIDPRINT® ASSAY

First-in-class cartridge-based
assay for risk stratification of
indeterminate thyroid nodules



GENEPRO DX

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**THINK IDYLLA™
BECAUSE TIME MATTERS**

Idylla™ ThyroidPrint® Assay is for Research Use Only, not for use in diagnostic procedures.

INDETERMINATE THYROID NODULES SCIENTIFIC BACKGROUND

Thyroid nodules are a **frequent** condition, affecting up to 30-40% of the adult population. 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 cases, an FNA* will be reported as benign and in 10% of cases as cancer, based on cytological examination.

However, in the remaining **20%** of cases, the thyroid nodule will be reported as **indeterminate**. Thyroid cytology is reported based on the 2023 Bethesda System for Reporting Thyroid Cytopathology¹. The cytology report is considered indeterminate if the report is called as atypia of undetermined significance (AUS) (**Bethesda III**) or follicular neoplasm (FN) (**Bethesda IV**)¹.

INTRODUCING IDYLLA™ THYROIDPRINT® ASSAY

Idylla™ ThyroidPrint®, developed by GeneproDX, assesses the gene expression profile of FNA* samples to enable laboratories to conduct further research on risk stratification of indeterminate thyroid nodules.

PRELIMINARY PERFORMANCE DATA

LDT vs Idylla™	ThyroidPrint® LDT**2	Idylla™ ThyroidPrint® Assay ³
Sensitivity	91%	92%
Specificity	88%	82%
NPV	95%	96%
PPV	78%	66%

The high sensitivity and specificity in combination with the ease of use and short turnaround time make the Idylla™ ThyroidPrint® Assay first-in-class for risk stratification of indeterminate thyroid nodules.

*FNA: Fine Needle Aspirate

**Laboratory Developed Test

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IDYLLA™ THYROIDPRINT® ASSAY



Fully automated molecular testing suitable for any lab setting



Gene expression signature based on 10 target genes in combination with a proprietary algorithm



Less than 5 minutes hands-on time (HOT)
Assay turnaround time (TAT) of approx. 160 minutes



FNA sample from a thyroid nodule which has been classified as indeterminate (Bethesda III/IV)*



Catalog number: TP0011/6

SPECIMEN REQUIREMENTS

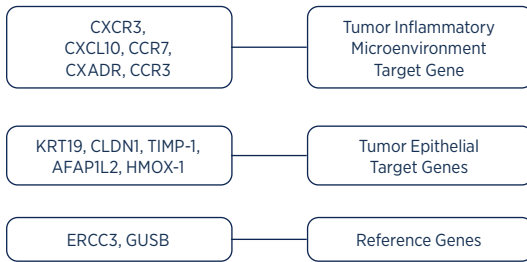
FNA from an indeterminate thyroid nodule collected in ThyroidPrint® Collection Buffer



*Bethesda III and IV (International)/Thy3a and Thy3f (UK)/TIR3A and TIR 3B (Italian)
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A NEW GENE SIGNATURE

The Idylla™ ThyroidPrint® Assay is a novel RT-qPCR-based molecular signature that assesses a gene expression profile from a fresh FNA sample collected from an indeterminate thyroid nodule. The signature qPCR data is analyzed by a proprietary algorithm, which reports a classifier result based on expression levels of a combination of 10 epithelial and stromal cell target genes relative to two reference genes^{2,4,5}.



FULLY AUTOMATED SAMPLE-TO-RESULT REPORTING ON IDYLLA™ PLATFORM

Idylla™ ThyroidPrint® Assay covers the entire process from sample to result, including fully integrated sample preparation, nucleic acid extraction, reverse transcription of RNA, real-time PCR amplification and detection, data analysis, and result reporting as applicable. An automated console report will be generated with either a 'HIGH' or 'LOW' result.

A '**HIGH**' result is indicative of an **atypical gene expression**. While a '**LOW**' result is indicative of a **normal gene expression**.

A RAPID TEST - PERFORMED WITHIN 160 MINUTES IN YOUR LABORATORY

IDYLLA™ THYROIDPRINT® ASSAY



IDYLLA™ WORKFLOW



Scan sample & Cartridge

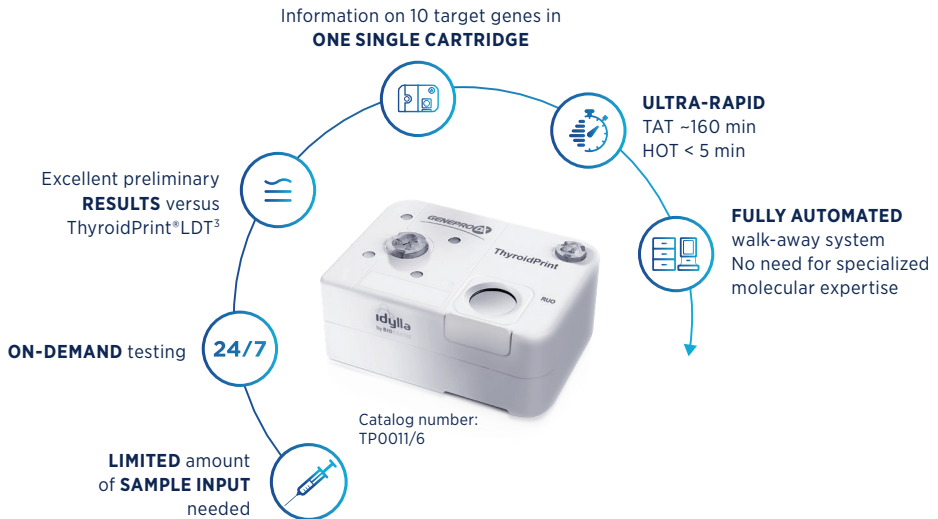


Insert sample in the Cartridge



Insert Cartridge in the Idylla™ Instrument and obtain the result within 3 hours

FIRST-IN-CLASS CARTRIDGE-BASED ASSAY FOR INDETERMINATE THYROID NODULES



REFERENCES

(1) Ali SZ et al. Thyroid 2023; (2) Zafereo et al., Thyroid, 2020; (3) unpublished data (internal analysis based on 132 indeterminate samples compared to the surgical gold standard); (4) Gonzalez et al. Thyroid 2017; (5) Olmos et al. Endocrine-Related Cancer 2023

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