

IDYLLA™ THYROIDPRINT® ASSAY (RUO)

RESULT REPORT GUIDANCE

The **Idylla™ ThyroidPrint® Assay (RUO)** is a multivariate qualitative assay based on reverse transcription polymerase chain reaction (RT-PCR) with real-time detection. The Assay evaluates a **gene expression profile of a fine needle aspirate (FNA)** sample collected from an indeterminate thyroid nodule (Bethesda III/IV) and reports a HIGH or LOW Idylla™ ThyroidPrint® Assay result, based on a gene expression classifier score derived from 10 target genes.

The Idylla™ ThyroidPrint® Assay covers the **entire process from sample to result**, including fully integrated sample preparation, nucleic acid extraction, RNA reverse transcription, real-time PCR amplification and detection, data analysis and results reporting, as applicable.

INTENDED PURPOSE

The Idylla™ ThyroidPrint® Assay (RUO) has been developed for **risk stratification of indeterminate thyroid nodules** (Bethesda III – atypia of undetermined significance and Bethesda IV- follicular neoplasm).

ASSAY METHODS

- The fine needle aspirate sample from an index indeterminate thyroid nodule should be collected in a **ThyroidPrint® Collection Buffer vial** (ref. GPX001), according to the supplier's instructions. This vial contains RNA Stabilization Reagent for optimal sample preservation.
- The gene expression of 10 markers is analyzed by **real-time PCR** (CCR3, CXCR3, CXCL10, TIMP1, CLDN1, CXADR, AFAP1L2, HMOX1, CCR7 and KRT19). A **classifier** calculates a **score**, and based on a pre-set classifier score cut-off value, the result will be reported as a **'HIGH' or 'LOW'**. A HIGH result is indicative of an atypical gene expression. While a LOW result is indicative of a normal gene expression.

INTERPRETATION OF CARTRIDGE VALIDITY

The Idylla™ ThyroidPrint® Assay can report three types of **Quality Status**:

- All reference genes and target genes have been properly amplified. The assay result is **VALID**.
- All reference genes have been properly amplified, but not all target genes have been amplified. The assay result is **NOT DETERMINED**.
- One or more reference genes are invalid or outside of the expected Cq range. The assay result is **INVALID**.

RESULTS

VALID RESULTS

In case the Idylla™ ThyroidPrint® Assay Cartridge generates a **VALID** quality status, two types of overall results can be reported:

- **LOW**: The classifier score is indicative of normal gene expression in the investigated target genes.
- **HIGH**: The classifier score is indicative of atypical gene expression in the investigated target genes.

NOT DETERMINED OR INVALID RESULTS

In case the Idylla™ ThyroidPrint® Assay Cartridge generates a **NOT DETERMINED** or **INVALID** quality status, no HIGH or LOW ThyroidPrint® result shall be displayed on the Results Report as there is insufficient data to reliably make the call or because of insufficient data quality. A NOT DETERMINED or INVALID result may be reported due to various factors, please refer to the Idylla™ ThyroidPrint® Assay Instructions (p.22).



PRELIMINARY DATA BASED ON THE LATEST AVAILABLE DATA

The below table shows that Idylla™ ThyroidPrint® Assay has **strong concordance** with ThyroidPrint® Laboratory Developed Test (LDT).



| Study | ThyroidPrint® LDT Clinical Validation ¹ | Idylla™ ThyroidPrint® Clinical Validation ² |
|------------------|---|---|
| Cases | 270 | 172 |
| Benign call rate | 63% (170/270) | 62% (106/172) |
| Sensitivity | 91% | 92% |
| Specificity | 88% | 83% |
| NPV | 95% | 97% |
| PPV | 78% | 68% |

¹Zafereo et al., 2020, ²González et al., 2024

The **Negative Predictive Value** is the most important assay criterion, as the clinical purpose of the Idylla™ ThyroidPrint® Assay is to help identify patients that can **safely forego diagnostic surgery**.

REFERENCES

González, H. et al. (2024). New sample-to-result Idylla™ ThyroidPrint® Assay accurately identifies benign thyroid nodules with indeterminate cytology: A multicenter-prospective double-blinded clinical validation trial. 46th Annual meeting of the European Thyroid Association. Poster presentation.

Zafereo, M. et al. (2020). A Thyroid Genetic Classifier Correctly Predicts Benign Nodules with Indeterminate Cytology: Two Independent, Multicenter, Prospective Validation Trials. *Thyroid: Official Journal of the American Thyroid Association*, 30(5), 704–712. <https://doi.org/10.1089/thy.2019.0490>

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