ThyroidPrint **RUO**

TECHNICAL SHEET IDYLLA™ THYROIDPRINT® ASSAY (RUO)

The Idylla™ ThyroidPrint® Assay is a qualitative, multi-variate, reverse transcription polymerase chain reaction (RT-PCR)-based assay with real-time detection. The Assay assesses a gene expression profile from a fine needle aspirate (FNA) sample collected from an indeterminate thyroid nodule (Bethesda III/IV) and reports either a 'HIGH' or 'LOW' Idylla™ ThyroidPrint® result based on a gene expression classifier score derived from 10 target genes. The Idylla™ ThyroidPrint® Assay procedure has been optimized for FNA samples collected and stored in ThyroidPrint® Collection Buffer. The 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.

FEATURES

The Idylla™ ThyroidPrint® Assay measures gene expression levels in 10 epithelial and stromal cell target genes relative to two reference genes listed in the table below.

Expressed Genes Detected by Idylla™ ThyroidPrint® Assay (RUO).*

Gene Name	Gene Name Abbreviation	Chromosome # / Transcript ID Number	Gene Function and Role
C-X-C motif chemokine receptor 3	CXCR3	Chromosome X / ENST00000373693.4	Tumor Inflammatory Microenvironment Target Genes
C-X-C motif chemokine ligand 10	CXCL10	Chromosome 4 / ENST00000306602.3	
C-C motif chemokine receptor 7	CCR7	Chromosome 17 / ENST00000246657.2	
Coxsackie virus and adenovirus receptor	CXADR	Chromosome 21 / ENST00000284878.12	
C-C motif chemokine receptor 3	CCR3	Chromosome 3 / ENST00000395940.3	
Keratin 19	KRT19	Chromosome 17 / ENST00000361566.7	Tumor Epithelial Target Genes
Claudin 1	CLDN1	Chromosome 3 / ENST00000295522.4	
TIMP metallopeptidase inhibitor 1	TIMP-1	Chromosome X / ENST00000218388.9	
Actin Filament Associated Protein 1 Like 2	AFAP1L2	Chromosome 10 / ENST00000304129.9	
Heme oxygenase 1	HMOX-1	Chromosome 22 / ENST00000216117.9	

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Expressed Genes Detected by Idylla™ ThyroidPrint® Assay (RUO).* (continued)

Gene Name	Gene Name Abbreviation	Chromosome # Transcript ID Number	Gene Function and Role
ERCC excision repair 3	ERCC3	Chromosome 2 ENST00000285398.7	Reference Genes
Glucuronidase beta	GUSB	Chromosome 7 ENST00000304895.9	

*Gonzalez et al., A 10-Gene Classifier for Indeterminate Thyroid Nodules: Development and Multicenter Accuracy Study. Thyroid, 2017

The relative weight of the expression value of each target gene is calculated by using the Idylla™ ThyroidPrint® Assay specific software generating a gene expression classifier score. The result is reported either as 'HIGH' or 'LOW' based on a pre-set cut-off value within the software. A 'HIGH' result is indicative of an atypical gene expression in the investigated target genes, while a 'LOW' result is indicative of a normal gene expression.

Specimen requirements

Sample type	FNA sample (maximum volume of 300 µL) collected from a thyroid nodule which has been previously reported to be indeterminate (Bethesda III and IV (International), Thy3a and Thy3f (UK), TIR3A and TIR 3B (Italian))

Total turnaround time

Time	Approx. 160 minutes

Catalog number

Idylla™ ThyroidPrint® Assay	TP0011/6