Hellenic Accreditation System

Annex F1/1 to the Certificate No. **1484**

SCOPE of ACCREDITATION

Laboratory of Translational Oncology

of

the SCHOOL OF MEDICINE of the UNIVERSITY OF CRETE

Materials / products tested	Types of tests / Properties to be measured	Applied Methods / Techniques to be used
Molecular tests		
Biopsies and Surgical Specimens Formalin-Fixed, Paraffin-Embedded Tissue [FFPE] obtained from excisional or needle biopsies and surgically resected specimens	**1. Qualitative detection of clinically significant mutations in the *EGFR* Gene (Exons 18, 19, 20, 21). Detailed list of mutations tested** ***Idylla™ EGFR Mutation Test:*** **Exon 18**: G719A (c.2156G>C), G719C (c.2155G>T; c.2154_2155delinsTT), G719S (c.2155G>A); **Exon 19**: Del9 (c.2238_2248delinsGC, c.2239_2248delinsC, c.2240_2248del, cc.2239_2247del), Del12 (c.2239_2251delinsC, c.2240_2251del), Del15 (c.2235_2249del, c.2236_2250del, c.2239_2253del, c.2240_2254del, c.2238_2252del, c.2237_2251del, c.2235_2252delinsAAT, c.2237_2252delinsT, c.2234_2248del, c.2236_2253delinsCTA, c.2237_2253delinsTA, c.2235_2251delinsAG, c.2236_2253delinsCAA, c.2230_2249delinsGTCAA), Del18 (c.2240_2257del, c.2237_2255delinsT, c.2239_2256del, c.2236_2253del, c.2239_2258delinsCA, c.2237_2254del, c.2238_2255del, c.2237_2257delinsTCT, c.2236_2255delinsAT, c.2236_2256delinsATC, c.2237_2256delinsTT, c.2237_2256delinsTC, c.2235_2255delinsGGT), Del21 (c.2238_2258del, c.2236_2256del), Del24 (c.2253_2276del); **Exon 20**: T790M (c.2369C>T), S768I (c.2303G>T), insG (c.2310_2311insGGT), insASV9 (c.2308_2309insGCCAGCGTG), insASV11 (c.2308_2311delinsCCAGCGTGGAT), insSVD (c.2311_2312insGCGTGGACA), insH (c.2319_2320insCAC); **Exon 21**: L858R (c.2573T>G, c.2573_2574delinsGT, c.2573_2574delinsGA), L861Q (c.2582T>A)	Automated method Molecular Biology method using a CE-IVD mutation detection kit: - Biocartis Idylla™ System* The product contains the PlexPrime™ / PlexZyme™ technology, which allows for the simultaneous detection of multiple mutations in different exons of the same gene within a single reaction (multiplexing), offering high specificity and sensitivity. The procedure includes: • **Standardized processing and deparaffinization within the cartridge.** • **DNA extraction, amplification, and real-time fluorescent detection, and** • **Automated generation and interpretation of the qualitative result by the analyzer's console.** OE.M.01/version 1.3/date 07.08.2025
Biopsies and Surgical Specimens Formalin-Fixed, Paraffin-Embedded Tissue [FFPE] obtained from excisional or needle biopsies	**2. Qualitative detection of clinically significant mutations at codon 600 of the**	

and surgically resected specimens (continued)	***BRAF* gene.** **Detailed list of mutations tested *Idylla*™ *BRAF Mutation Test:* Exon 15**: Codon 600: V600E (c.1799T>A), V600E2 (c.1799_1800delinsAA), V600D (c.1799_1800delinsAT; c.1799_1800delinsAC), V600K (c.1798_1799delinsAA), V600R (c.1798_1799delinsAG), and V600M (c.1798G>A) **3. Qualitative detection of clinically significant mutations in the *KRAS* Gene (Exon 2 (codons 12, 13), Exon 3 (codons 59, 61), and Exon 4 (codons 117, 146).** **Detailed list of mutations tested *Idylla*™ *KRAS Mutation Test:* Exon 2**; Codon 12: G12C (c.34G>T) G12R (c.34G>C) G12S (c.34G>A) G12A (c.35G>C) G12D (c.35G>A) G12V (c.35G>T), Codon 13: G13D (c.38G>A). **Exon 3**; Codon 59: A59E (c.176C>A), A59G (c.176C>G), A59T (c.175G>A), Codon 61: Q61K (c.181C>A; c.180_181delinsAA) Q61L (c.182A>T), Q61R (c.182A>G), Q61H (c.183A>C; c.183A>T) **Exon 4**; Codon 117: K117N (c.351A>C; c.351A>T) Codon 146: A146P (c.436G>C), A146T (c.436G>A), A146V (c.437C>T)	

** Reference to the commercial name of a specific analyzer/kit, refers to a specific analytical method and protocol*

Site of assessment: **Permanent laboratory premises, University Campus, Voutes, Heraklion, Crete, Greece.**
Approved signatories: **Dimitrios Mavroudis, Maria Sfakianaki**

The Accreditation Certificate No. **1484**, to ELOT EN ISO 15189:2022, is valid until 17.12.2030.

Athens, 18th of December 2025

Evangelos Apostolos Konstantinou
CEO of ESYD