HELLENIC ACCREDITATION SYSTEM

# Annex G1/4 to the Certificate No. **1108**-2

# SCOPE of ACCREDITATION

of the

## Analysis of Circulating Tumor Cells lab

of the

## Department of Chemistry,

of the

## National and Kapodistrian University of Athens

| Tested materials / products | Types of test / Properties to be measured | Applied Standards / Techniques to be used |
|---|---|---|
| **Biological testing** | | |
| 1. Peripheral blood, plasma (EDTA), (Liquid Biopsy) | 1. Detection of somatic mutations in exons 18, 19, 20, και 21 of the EGFR gene in patients with Non-Small Cell Lung cancer (NSCLC)<br>CE-IVD approved FDA cleared assay<br><br>EGFR MUTATIONS :<br>**<u>G719X</u>** (2156G>C,2155G>A, 2155G>T)<br>**<u>Ex19Del:</u>**<br>2240_2251del12, 2239_2247del9, 2238_2255del18, 2235_2249del15, 2236_2250del15, 2239_2253del15, 2239_2256del18, 2237_2254del18 2240_2254del15, 2240_2257del18, 2239_2248TTAAGAGAAG>C, 2239_2251>C, 2237_2255>T, 2235_2255>AAT, 2237_2252>T, 2239_2258>CA, 2239_2256>CAA, 2237_2253>TTGCT, 2238_2252>GCA, 2238_2248>GC, 2237_2251del15, 2236_2253del18, 2235_2248>AATTC, 2235_2252>AAT, 2235_2251>AATTC, 2253_2276del24, 2237_2257>TCT, 2238_2252del15, 2233_2247del15 | Cobas z 480 Analyzer, ROCHE DIAGNOSTICS*<br>Real time PCR for the semi-quantitative measurement of mutations.<br>CE-IVD approved FDA cleared assay<br><br>• **cobas® cfDNA Sample Preparation Kit:**<br>07573758001-08EN Doc Rev. 7.0<br>• **cobas® EGFR Mutation Test v2:**<br>07340761001-11EN Doc. Rev. 8.0<br><br>OE 504-A3 v2/ 19.12.2019<br>OE 504-A5 v2/ 19.12.2019 |
| Tested materials/ products | Types of test/ Properties to be measured | Applied Standards/ Techniques to be |

| | | used |
|---|---|---|
| 1. Peripheral blood, plasma (EDTA), (Liquid Biopsy) cont. | S768I (2303G>T)<br>T790M (2369C>T)<br>Ex20Ins<br>2307_2308ins9GCCAGCGTG,<br>2319_2320insCAC,<br>2310_2311insGGT,<br>2311_2312ins9GCGTGGACA,<br>2309_2310AC>CCAGCGTGGA<br>L858R 2573T>G, 2573_2574TG>GT<br>L861Q (2582T>A) | Cobas z 480 Analyzer, ROCHE DIAGNOSTICS*<br>Real time PCR for the semi-quantitative measurement of mutations.<br>CE-IVD approved FDA cleared assay<br>• **cobas® cfDNA Sample Preparation Kit:**<br>07573758001-08EN Doc Rev. 7.0<br>• **cobas® EGFR Mutation Test v2:**<br>07340761001-11EN Doc. Rev. 8.0<br>OE 504-A3 v2/ 19.12.2019<br>OE 504-A5 v2/ 19.12.2019 |
| 2. Peripheral blood (Cellsave Preservative Tubes)<br>(Liquid Biopsy) | Identification and enumeration of Circulating Tumor Cells (CTCs) | CELLSEARCH® system, MENARINI SILICON BIOSYSTEMS*<br>FDA cleared assay, IVD approved<br>• **Circulating Tumor Cell Kit (Epithelial):**<br>e631600006_EN, LBL-0018<br>• **Circulating Tumor Cell Control Kit:**<br>e631600016_EN, LBL-0022<br>• **CellSave Preservative Tube**<br>e631600046_EN, LBL-0026<br>OE 504-A1 v2/ 19.12.2019<br>OE 504-A2 v2/ 19.12.2019 |
| 3. Peripheral blood, plasma (EDTA), (Liquid Biopsy) | Detection and quantification of seven common variants in exons 5, 7, 8 of the *ESR1* gene (E380Q, S463P, L536R, Y537C, Y537N, Y537S and D538G) with droplet digital PCR | • **ddPCR QX600 system (Bio-Rad)**<br>OE 504A-6 V1<br>• **ddPLEX ESR1 Mutation Detection Kit (Bio-Rad)**<br>10000171375 Ver C 24-0244 0424<br>OE 504A-6 v1/ 10.02.2025<br>OE 504A-7 v1/ 10.02.2025<br>OE 508-5 v1/ 10.02.2025 |

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

Site of assessment: **Laboratory permanent premises: Department of Chemistry, National and Kapodistrian University of Athens, University Campus, 157 71 Zografou, Attiki, Greece.**
Approved signatory: **E. Lianidou**

This scope of Accreditation replaces the previous one dated 14.07.2022.
The Accreditation Certificate No. 1108-2, to ELOT EN ISO 15189:2022, is valid until 27.12.2026.

Athens, 31st July 2025

Konstantinou Evangelos Apostolos
*CEO of ESYD*