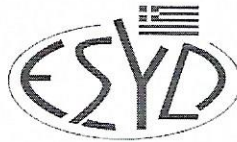


# Hellenic Accreditation System



## Annex G1/1 to the Certificate No. 1108

### 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)	<p>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)</p> <p>CE-IVD approved FDA cleared assay EGFR MUTATIONS <b>G719X</b> (2156G&gt;C, 2155G&gt;A, 2155G&gt;T) <b>Ex19Del:</b> 2240_2251del12, 2239_2247del9, 2238_2255del18, 2235_2249del15, 2236_2250del15, 2239_2253del15, 2239_2256del18, 2237_2254del18 2240_2254del15, 2240_2257del18, 2239_2248TTAAGAGAAG&gt;C, 2239_2251&gt;C, 2237_2255&gt;T, 2235_2255&gt;AAT, 2237_2252&gt;T, 2239_2258&gt;CA, 2239_2256&gt;CAA, 2237_2253&gt;TTGCT, 2238_2252&gt;GCA, 2238_2248&gt;GC, 2237_2251del15, 2236_2253del18, 2235_2248&gt;AATTC, 2235_2252&gt;AAT, 2235_2251&gt;AATTC, 2253_2276del24, 2237_2257&gt;TCT, 2238_2252del15, 2233_2247del15</p>	<p><b>Cobas z 480 Analyzer ,ROCHE DIAGNOSTICS*</b></p> <p>Real time PCR for the semi-quantitative measurement of mutations.</p> <p>COBAS® EGFR Mutation Test v2 CE-IVD approved FDA cleared assay</p>

Tested materials/ products	Types of test/ Properties to be measured	Applied Standards/ Techniques to be used
1. Peripheral blood, plasma (EDTA), (Liquid Biopsy) cont.	<p><b>S768I</b> (2303G&gt;T)  <b>T790M</b> (2369C&gt;T)  <b>Ex20Ins</b>  2307_2308ins9GCCAGCGTG,  2319_2320insCAC,  2310_2311insGGT,  2311_2312ins9GCGTGGACA,  2309_2310AC&gt;CCAGCGTGGA  <b>L858R</b> 2573T&gt;G, 2573_2574TG&gt;GT  <b>L861Q</b> (2582T&gt;A)</p>	
2. Peripheral blood (Cellsave Preservative Tubes) (Liquid Biopsy)	Identification and enumeration of Circulating Tumor Cells (CTCs)	<p><b>CELLSEARCH SYSTEM  CIRCULATING TUMOR CELL  KIT , Menarini*</b>  CE-IVD approved FDA cleared assay</p>

\*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**

The Accreditation Certificate No. **1108**, to ELOT EN ISO 15189:2012, is valid until 28/12.2021.

Athens, December 28<sup>th</sup>, 2017



Konstantinos Voutsinas  
Managing Director, ESYD