Hellenic Accreditation System

Annex G1/1 to the Certificate No.1307

SCOPE of ACCREDITATION

of the

Molecular Histopathology Unit

of

Faculty of Medicine

of

School of Health Sciences

of

University of Thessaly

Tested materials/ products	Types of test/ Properties to be measured	Applied Standards/ Techniques used
Molecular Genetics		
Formalin-Fixed Paraffin-Embedded (FFPE) tissue specimens from solid tumors	Detection of mutations in 58 cancer predisposing genes: *AKT1, ALK, AR, ATM, BCL2, BRAF, BRCA1, BRCA2, CCND1, CCNE1, CDK4, CDK6, CDKN2A, CHEK1, CHEK2, CTNNB1, EGFR, ERBB2, ERBB4, ESR1, FGFR1, FGFR2, FGFR3, IDH1, IDH2, JAK2, JUN, KDR, KIT, KMT2C, KRAS, MAP2K1, MDM2, MDM4, MEN1, MET, MLH1, MSH2, MSH6, MTOR, MYC, NF1, NOTCH1, NRAS, PALB2, PDGFRA, PIK3CA, PIK3CB, PTEN, RAD50, RAD51, RB1, RET, ROS1, SMAD4, STAT3, STK11, TP53*	Next Generation Sequencing (NGS, Illumina MiSeq, Illumina) with the use of a solid tumor custom gene panel (OncoPMN_NGS_PANEL, CUSTOM PANEL SOLID TUMORS, ILLUMINA) of the Precision Medicine Hellenic network in Oncology. Laboratory protocols: O.520-5, edition 1, 1/04/2021, O.520-6, edition 1, 1/04/2021, O.520-7, edition 1, 1/04/2021
Formalin-Fixed Paraffin-Embedded (FFPE) tissue specimens from solid tumors	Detection of the following mutations G12C, G12X (G12S, G12R, G12V, G12D, G12A), G13X (G13C, G13S, G13R, G13D, G13A, G13V), A59X (A59E, A59G, A59S, A59T), Q61X (Q61K, Q61E, Q61P, Q61R, Q61L, Q61H), K117X (K117N) and A146X (A146P, A146T, A146V) in exons 2, 3 and 4 of the *KRAS* gene, in solid tumor specimens.	Real-time PCR (cobas® z480, Roche) with the use of KRAS Mutation Test v2 (LSR) kit (Roche) for the detection of specific mutations in the *KRAS* gene. Laboratory protocols: O.520-1, edition 1, 1/04/2021, O.520-3, edition 1, 1/04/2021

Tested materials/ products	Types of test/ Properties to be measured	Applied Standards/ Techniques used
Formalin-Fixed Paraffin-Embedded (FFPE) tissue specimens from solid tumors	Detection of the following mutations G466A, G466V, G469A, G469R, G469V και V600E/E2/D (BRAF V600E, V600E2, V600D), V600K, V600R and K601E in exons 11 and 15 of the *BRAF* gene, in solid tumor specimens.	Real-time PCR (cobas® z480, Roche) with the use of BRAF/NRAS Mutation Test (LSR) (Roche), for the detection of specific mutations in the *BRAF* gene. Laboratory protocols: O.520-1, edition 1, 1/04/2021, O.520-4, edition 1, 1/04/2021
Formalin-Fixed Paraffin-Embedded (FFPE) tissue specimens from solid tumors	Detection of the following mutations G12X (G12A, G12C, G12D, G12R, G12S, G12V) NRAS G13X (G13A, G13C, G13D, G13R, G13S, G13V) NRAS A18T, NRAS Q61X (Q61Ht, Q61Hc, Q61K, Q61L, Q61P, Q61R) NRAS Other Ex 3/4 (A59D, A59T, K117Nc, K117Nt, A146T, A146V) in exons 2, 3 and 4 of the *NRAS* gene in solid tumor specimens.	Real-time PCR (cobas® z480, Roche) with the use of BRAF/NRAS Mutation Test (LSR) (Roche), for the detection of specific mutations in the *NRAS* gene. Laboratory Protocols: O.520-1, edition 1, 1/04/2021, O.520-4, edition 1, 1/04/2021
Formalin-Fixed Paraffin-Embedded (FFPE) tissue specimens from solid tumors	Detection of the following mutations G719X, Exon 19 deletion, T790M, S768I, Exon 20 insertion, L858R, L861Q in exons 18, 19, 20 and 21 of the *EGFR* gene in solid tumor specimens.	Real-time PCR (cobas® z480, Roche) with the use of EGFR Mutation Test v2, cobas® z480 (Roche) kit for the detection of specific mutations in the *EGFR* gene. Πρωτόκολλα Εργαστηρίου: Ο.520-1, έκδοση 1, 1/04/2021, Ο.520-2, έκδοση 1, 1/04/2021

Site of assessment: **Molecular Histopathology Unit, Faculty of Medicine, School of Health Sciences, University of Thessaly, Biopolis, Panepistimiou 3, P.C. 41500.**
Approved signatories**: M. Samara, G. Koukoulis, M. Ioannou.**

The Accreditation Certificate No. 1307**,** to ELOT EN ISO 15189:2012, is valid until 06.09.2026.

Athens, September 07, 2022

Christos Nestoras
CEO of ESYD