



Diploma

Internal ERIC certification on the assessment of *IG* mutations

Národní Onkologický Ústav

PASS: The laboratory meets ERIC standards for IG mutation detection. In 5 CLL samples IG mutation status was assessed and interpreted correctly.

14 May 2025

Valid for 3 years

A handwritten signature in blue ink, appearing to read "Paolo Ghia".

Paolo Ghia

A handwritten signature in blue ink, appearing to read "Kostas Stamatopoulos".

Kostas Stamatopoulos

A handwritten signature in blue ink, appearing to read "Maria Karipidou".

Maria Karipidou

European Certifying Centers:

Institute of Applied Biosciences
Center for Research and Technology Hellas
6th Km Charilaou-Thermis,
57001, Thessaloniki, Greece

Hôpital Pitié-Salpêtrière
Division of Hematology
Dpt of Laboratory Medicine and Pathology
47-83 Boulevard de l'Hôpital
75013 Paris, France

May 14, 2025

Dear ERIC Member,

Thank you for your participation in the ERIC project for Harmonization of IGHV Somatic Hypermutation (SHM) Testing in chronic lymphocytic leukemia. Completing the survey about your experience in IGHV SHM analysis, the applied technique and details about reporting qualified your center for this test. Therefore, we provided 5 genomic DNA samples from different patients, as depicted below, to each lab for mutation status assessment and reporting of the findings.

Sample result overview

Sample ID	IGHV gene and allele	IGHD gene and allele	IGHJ gene and allele	IGHV gene % identity to germline	SHM status	Comments
ERIC 11-1	IGHV3-21*01	IGHD3-10*03	IGHJ6*02	99.30	unmutated	Subset #2
ERIC 11-2	IGHV3-13*05	IGHD2-2*01	IGHJ4*02	97.19	borderline	
ERIC 11-3	IGHV3-11*01 F	IGHD3-22*01	IGHJ4*02	100	unmutated	
ERIC 11-4	IGHV3-21*01	IGHD3-3*01	IGHJ6*02	96.18	mutated	
ERIC 11-5	IGHV4-39*01	IGHD6-13*01	IGHJ5*02	100	unmutated	Subset #8

Please see your results below together with the requirements necessary for the certificate.

Accreditation requirements and your result	Your result	Minimal requirements	Good laboratory practice requirements
Participating in ERIC IG survey	✓	✓	✓
Covering VH FR1 – VH CDR3 of all samples	✓	✓	✓
Identification of sample ERIC 11-1 as IGHV-unmutated	✓	✓	✓
Identification of sample ERIC 11-1 as belonging to stereotyped subset #2	✓	✓	✓
Identification of sample ERIC 11-2 as IGHV- borderline	✓	✓	✓
Identification of sample ERIC 11-3 as IGHV- unmutated	✓	✓	✓
Identification of sample ERIC 11-4 as IGHV-mutated	✓	✓	✓
Identification of sample ERIC 11-5 as IGHV- unmutated	✓	✓	✓
Identification of sample ERIC 11-5 as belonging to stereotyped subset #8	✓	✓	✓
Correct annotation	✓	✓	✓
Provided Lab specific report	✓	✓	✓
Correct interpretation	✓	✓	✓
Finished and submitted analysis before the deadline	✓	✓	✓