





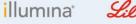


7-11 DE SEPTIEMBRE 2019



Con la colaboración de:









# Resultados de la EQA de los biomarcadores en NSCLC

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Con la colaboración de:



# **External Quality Assessment (EQA) Programs for Biomarker Testing in NSCLC**



The European Society of Pathology (ESP) has established world-wide EQA programs for biomarker testing in colorectal cancer (CRC) and in non-small-cell lung cancer (NSCLC).

## ESP Lung EQA Scheme: overview

#### http://lung.eqascheme.org HOWE | BARTICIE ALL LABS ALL CONTACTS LABS 2012 CONTACTS 2012 ADWIN ASSESSOR TICKETS FIND A LAB ESP Lung External Quality Assessment Scheme ESP Lung EQA Scheme Information for Participants EQA participant's area Change password Introduction Logout Cleo Keppens Registration Set up of the schemes and kind of samples ◆ ESP Lung EQA Scheme Data analysis and evaluation of EQA scheme results Communication of results Frequently Asked Questions Time line of the ESP Lung EQA scheme Steering committee members Participants previous EQA Confidentiality Introduction Example reports The European Society of Pathologye' (ESP) established an EQA program for testing biomark Nomendature aims to ensure optimal accuracy and proficiency in lung cancer biomarker testing across a Quality control The practical organization of this European EQA program is done in collaboration with the Biomedical Quality Assurance Research Unit of the KU Leuven, lead by Prof. Dr. E Dea O What is AUC H van Krieken, president of the ESR The scheme is supported by an educational grant fror This scheme is in collaboration with UK NEQAS ICCRISH. Useful links The ESP EQA schemes are accredited by BELAC conform the ISO 170432, which i Other EQA providers The ESP Lung EQA Scheme 2016 will be organized in four separate rounds: first AL ALK related Organizations and then by ROS1 testing (by FISH and/or IHC). It is possible to register separately for ea Websites of interest will be organized which includes a number of theoretical cases to evaluate the interpretat

		Lung	2012 a	Lung 2012 b		Lung 2014		Lung 2015		Lung 2016		Lung 2017		Lung 2018		Lung 2019**	
SP EQA	ESP EQA Subscheme	n	% success	n	% success	9	% success	n	% success	n	% success	n	% success	n	% success	n	% succes
ALK	ALKEISH	54	72.00%	104	68.00%	116	69.00%	111	79,00%	113	82.30%	116	79.00%	103	91.20%	109	
	ALK FISH Digital	67	82.00%	106	74,00%	81	educ										
	AXHO	29	52.00%	58	64.00%	96	70,00%	95	92.00%	102	88,20%	109	82.00%	99	89.90%	105	
	ALK technical							73	Avg. score: 3.8/5	92	85.00%	96	87.00%	93	95.70%		
	ALK RT PCR			8	edu	6	educ	13								-	
ROS	POST FISH					56	64,00%	68	78.00%	71	70.40%	85	82.00%	98	94.20%	101	
	ROS1 INC					31	90,00%	31	45,00%	36	94.40%	53	94,00%	66	86.20%	82	
	ROS Metercal									31	31.00%	52	90.00%	54	98.10%		
PDL1	POL1 INC											78	70.50%	85	84.70%	104	
	POL1 Individe											75	edu	74	95.90%		
MOL	EGFR			107	edu	144	61,00%	114	52.00%	97	71.10%	101	71.30%	104	81.60%	95	
	KRAS			92	edu				100			51	98.00%	56	91.10%	70	
	BIN											47	97.90%	55	96.40%	73	
	Edu			-						36	NA	19	NA				
MET														49	Avg. score: 9.0/10	47	



# Global delivery of external quality assessment for EGFR lung cancer liquid biopsy

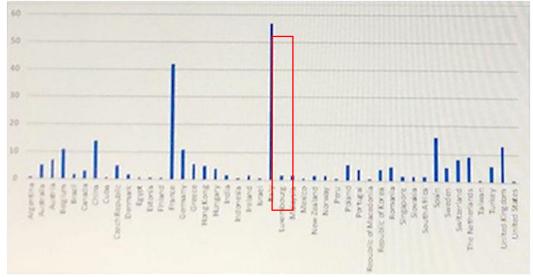


External Quality Assessment (EQA)

## Laboratory participation

- 304 laboratories registered
- 264 submitted results
- 45 countries worldwide

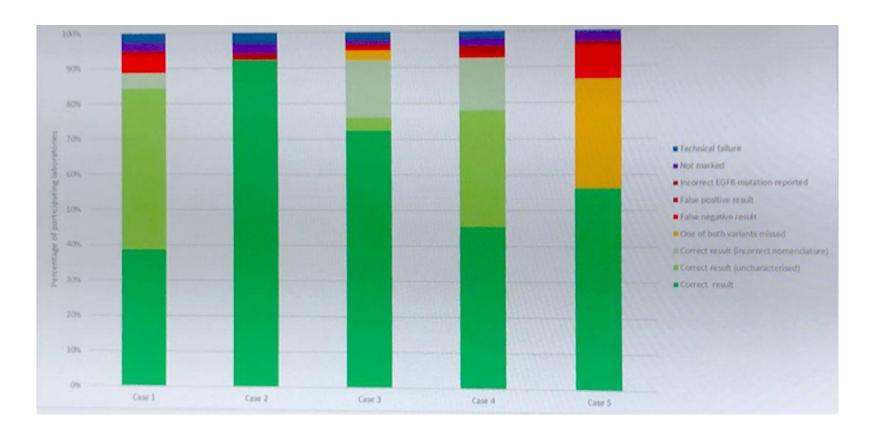






## **Breakdown of the Genotyping Scores**





Case 1: exon 19 del, 1% VAF; Case 2 WT; Case 3 L858R & T790M, 5% VAF; Case 4 exon 19 del, 5% VAF; Case 5: L858R & T790M 0.5% VAF



## Standards and Guidelines for the Interpretation and **Reporting of Sequence Variants in Cancer** AMP /ASCO / CAP



## **Evidence-based Categorization**

### Tier I: Variants of **Strong Clinical Significance**

Therapeutic, prognostic & diagnostic

#### Level A Evidence

FDA-approved therapy Included in professional guidelines

#### Level B Evidence

Well-powered studies with consensus from experts in the field

### Tier II: Variants of **Potential Clinical Significance**

Therapeutic, prognostic & diagnostic

#### Level C Evidence

FDA-approved therapies for different tumor types or investigational therapies

Multiple small published studies with some consensus

#### Level D Evidence

Preclinical trials or a few case reports without

### Tier III: Variants of **Unknown Clinical Significance**

Not observed at a significant allele frequency in the general or specific subpopulation databases, or pan-cancer or tumor-specific variant databases

No convincing published evidence of cancer association

### Tier IV: Benign or **Likely Benign Variants**

Observed at significant allele frequency in the general or specific subpopulation databases

No existing published evidence of cancer association





## Variant Nomenclature

# All detected genetic alterations should be annotated and reported as designated by the HUGO Gene Nomenclature Committee

- Gene name official gene symbol, may include colloquial gene name in the interpretation (KMT2A/MLL)
- Transcript ID transcript accession and version number (e.g. NM\_004006.2)
- Nucleotide change c.123G>A
- Amino acid change p.Lys76Asn
- Variant allele frequency
- Genomic coordinates at the discretion of laboratory director
- Exon number, protein domain, pathway involved at the discretion of laboratory director

