Classification criteria

EliA testing for antiphospholipid syndrome (APS) in relation to the new 2023 APS classification criteria

Why did EULAR/ACR update the APS classification criteria in 2023?[1]

- There were **no evidence-based definitions** incorporated in the revised **2006 criteria**
- New criteria ensure **high-quality, risk-stratified** epidemiologic studies and clinical trials
- Maximizing specificity can help to better understand disease pathophysiology and treatment effects

Why are the new APS classification criteria relevant for you and your lab?

- The classification criteria are intended to classify patients for medical research purposes[2]
- While the classification criteria were not developed for diagnosing APS, for facilitating and standardizing clinical research, they are often used as diagnostic criteria in the clinical setting[2]
- Lab professionals often have only limited information about patient samples, not knowing if they are used for clinical studies or patient diagnosis

What are the key changes in the new classification criteria?[1]

- Recommend delaying the use of the new automated platforms (chemiluminescence immunoassay, multiplex and flow cytometry) and instead using standardized enzyme-linked immunosorbent assay (ELISA) to determine antiphospholipid (aPL) antibodies
- Evaluate in combination both IgG anti-cardiolipin (aCL) and IgG anti-ß2-glycoprotein (aß2GPI) positivity
- Separately measure aCL/aß2GPI IgG and IgM isotypes
- 2 levels of aCL/aß2GPI positivity: **moderate** and **high positive results based** on ELISA technologies

2023 new APS classification criteria workflow[1]

Entry criteria includes
At least one clinical criterion
PLUS
A positive aPL test within three years of clinical criterion

Clinical domain

Laboratory domain (aPL test and criteria)

Score		Score	
Lupus Anti Coagulant (LAC) test		aPL by **solid phase** assay (persistent)	
Positive LAC (one time)	1	Moderate or high positive IgM (aCL and/ or aβ2GPI)	1
Positive LAC (persistent)	5	Moderate positive IgG (aCL and/or aβ2GPI)	4
		High positive IgG (aCL or aβ2GPI)	5
		High positive IgG (aCL and aβ2GPI)	7

Total score
if the sample met at least
3 points from clinical plus 3 points from laboratory domain
it is classified as APS for research purposes

Why are EliA™ aPL tests considered to be standardized ELISA-based assays?

- EliA aPL tests follow the **same principle and detection system** as ELISA[5-8]
- EliA aPL tests are **indirect ELISA assays** using fluorescence instead of colorimetry as the detection method[5-8]
- **Previous publications reported the equivalence** between commercial ELISA and FEIA method used in EliA APS assays [3]

How can our EliA aPL tests help you to maintain compliance with the new criteria?

- EliA aPL tests are **indirect ELISA assays** as part of the standardised ELISA testing recommended in the new criteria[1,9]
- EliA aPL tests include aCL, aβ2GPI, and both IgG and IgM isotypes for a full offering

For classification (medical research) purposes

	aCL IgG	aCL IgM	aβ2GPI IgG	aβ2GPI IgM
Unit	ELISA units	ELISA units	ELISA units	ELISA units
Moderate Positive	40 - 79	40 - 79	40 - 79	40 - 79
High Positive	> 80	> 80	> 80	> 80

For diagnostic (clinical) purposes

	EliA Cardiolipin IgG	EliA Cardiolipin IgM	EliA β2-Glycoprotein IgG	EliA β2-Glycoprotein IgM
Unit	GPL-U/ml	MPL-U/ml	EliA U/ml	EliA U/ml
Negative	< 10	< 10	< 7	< 7
Equivocal	10 - 40 (weak positive)	10 - 40 (weak positive)	7 - 10	7 - 10
Positive	> 40	> 40	> 10	> 10

References

1. Barbhaiya M. (2023) ACR/EULAR Antiphospholipid Syndrome Classification Criteria. Arthritis Rheumatol 75(10):1687-1702. **2.** Vandevelde, A., & Devreese, K. M. J. (2022). Laboratory Diagnosis of Antiphospholipid Syndrome: Insights and Hindrances. Journal of clinical medicine, 11(8), 2164. **3.** Mattia, E, et al. (2015) A contribution to detection of anticardiolipin and anti-β2glycoprotein I antibodies: Comparison between a home-made ELISA and a fluorescence enzyme immunoassay. Clin Chim Acta. 15(446):93-6. **4.** Villalta, D, et al. (2009) Accuracy of the first fully automated method for anti-cardiolipin and anti-beta2 glycoprotein I antibody detection for the diagnosis of antiphospholipid syndrome. Ann N Y Acad Sci. 1173:21-7. **5.** EliA β2-Glycoprotein I IgG Directions for Use. (2023) 250-5532-023 / UK. **6.** EliA β2-Glycoprotein I IgM Directions for Use. (2023) 250-5533-023 / UK. **7.** EliA Cardiolipin IgG Directions for Use. (2023) 250-5529-023 / UK. **8.** EliA Cardiolipin IgM Directions for Use. (2023) 250-5530-023 / UK. **9.** Crowther, J.R. (1995). Chapter 2 Basic Principles of ELISA.

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