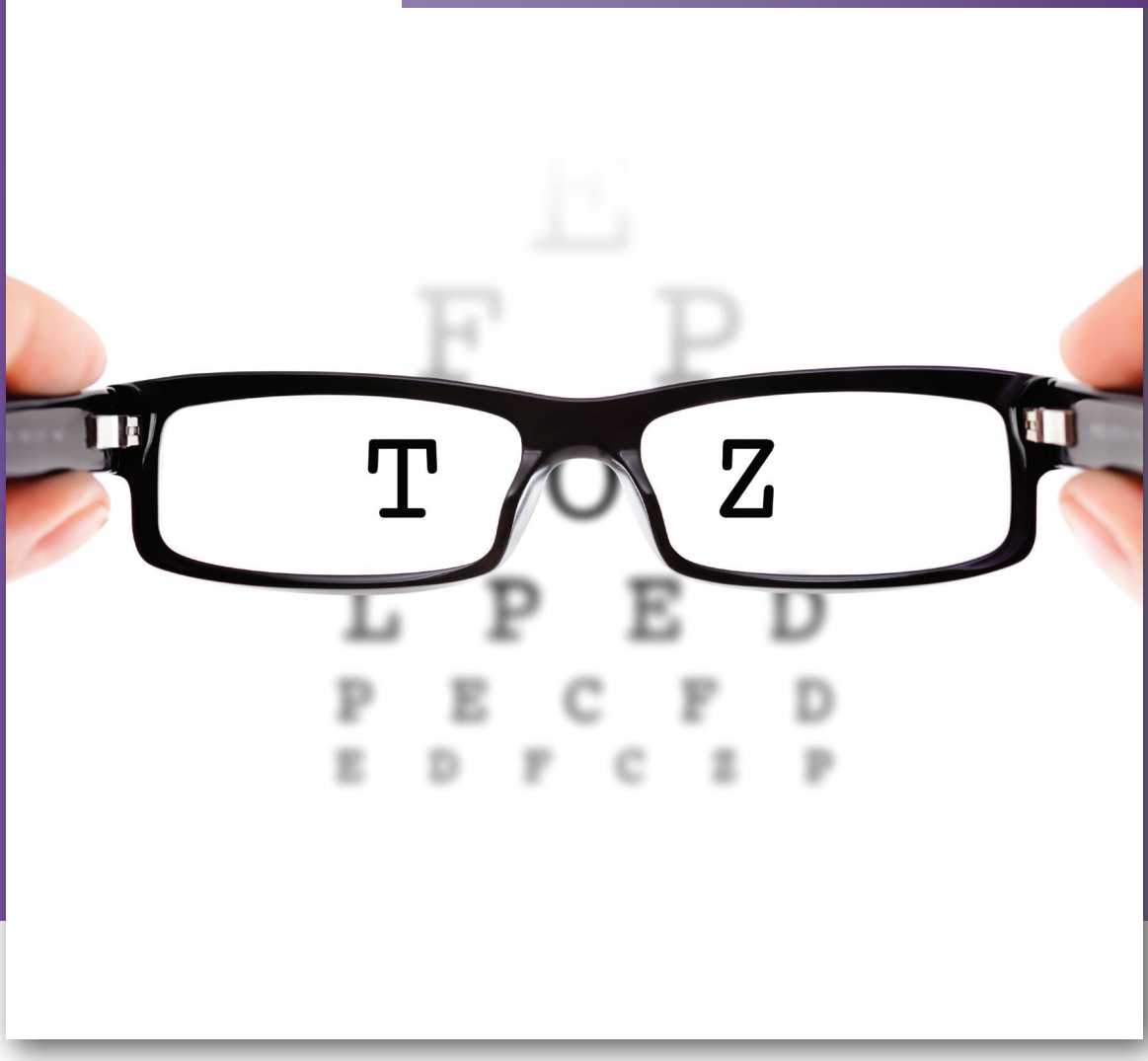
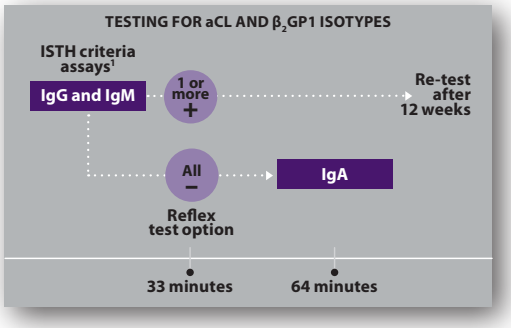
QUANTA Flash® APS



Clarity

QUANTA Flash APS assays can bring clarity to the complicated diagnosis of Antiphospolipid Syndrome



- Simultaneous processing for multiple assays and isotypes allows for timely follow-up testing
- Anticardiolipin (aCL) and anti-β_2 Glycoprotein I (β_2GP1) combine to offer excellent clinical correlation
- Fully automated, random access processing with results in as little as 30 minutes
- Serum or plasma samples can be quickly processed without interrupting anticoagulant therapy

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QUANTA Flash® APS

Criteria for definite APS diagnosis[1]

Clinical Criteria	Laboratory Criteria *On two or more occasions at least 12 weeks apart*
1. Vascular thrombosis (arterial, venous) **and/or** **2.** Pregnancy morbidity • Unexplained fetal death beyond week 10 • Premature birth before week 34 • Three or more unexplained spontaneous abortions before week 10	**1.** aCL (IgG, IgM) at medium/high titre **2.** β_2GP1 (IgG, IgM) at levels >99 th percentile **3.** Lupus anticogulant **Non-criteria assays are important when[2]** • Above criteria markers are all negative and APS is suspected • Managing certain populations including African-American[3]

Clinical performance characteristics

Sensitive

- The combination of QUANTA Flash aCL IgG/M and β_2GP1 IgG/M detected 71.7% of confirmed APS patient samples

Specific

- Assay specificity is excellent ranging from 91 – 97%
- Disease control groups included SLE, SLE-like, and cardiovascular disorders

Performance characteristics of QUANTA Flash APS assays[4]

Reference # (50 tests/kit)	QUANTA Flash assay	Sensitivity (95% CI)	Specificity (95% CI)	Measuring range (CU) (Cut-off is 20)
701233	aCL IgG	54.3% (43.6% to 64.8%)	95.6% (92.1% to 97.9%)	2.6–2024
701238	aCL IgM	33.7% (24.2% to 44.3%)	94.8% (91.0% to 97.3%)	1.0–774
701248	β_2GP1 IgG	64.1% (53.5% to 73.9%)	90.8% (86.3% to 94.2%)	6.1–6400
701253	β_2GP1 IgM	29.3% (20.3% to 39.8%)	95.2% (91.6% to 97.6%)	1.1–841
701228	aCL IgA	31.5% (26.2% to 37.2%)	96.8% (94.3% to 98.4%)	1.4-351
701243	β_2GP1 IgA	33.6% (28.1% to 39.3%)	96.2% (93.6% to 98.0%)	4-512
701188	β_2GP1 domain 1	49.8% (43.7% to 55.9%)	99.5% (98.7% to 99.9%)	3.6-1380

QUANTA Flash APS assays for use on the BIO-FLASH® rapid-response chemiluminescent analyzer

- Full-menu, random-access processing eliminates batching
- On-board reagents and calibration curves make even the most specialized autoimmune tests efficient to perform
- Offers precise quantification and a broad dynamic range using chemiluminescent technology

References:

1. Miyakis S, Lockshin MD, Atsumi T, et al. International consensus statement on an update of the classification criteria for definite antiphospholipid syndrome (APS). *J Thromb Haemost.* 2006;4(2):295-306.
2. Bertolaccini ML, Amengual O, Atsumi T, et al. 'Non-criteria' aPL tests: report of a task force and preconference workshop at the 13th International Congress on Antiphospholipid Antibodies, Galveston, TX, USA, April 2010. *Lupus.* 2011;20:191-205.
3. Diri E, Cucurull E, Gharavi AE, et al. Antiphospholipid (Hughes') syndrome in African-Americans: IgA aCL and aβ_2 glycoprotein-I is the most frequent isotype. *Lupus* 1999; 8:263–268.
4. Respective QUANTA Flash Product Directional Inserts.

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