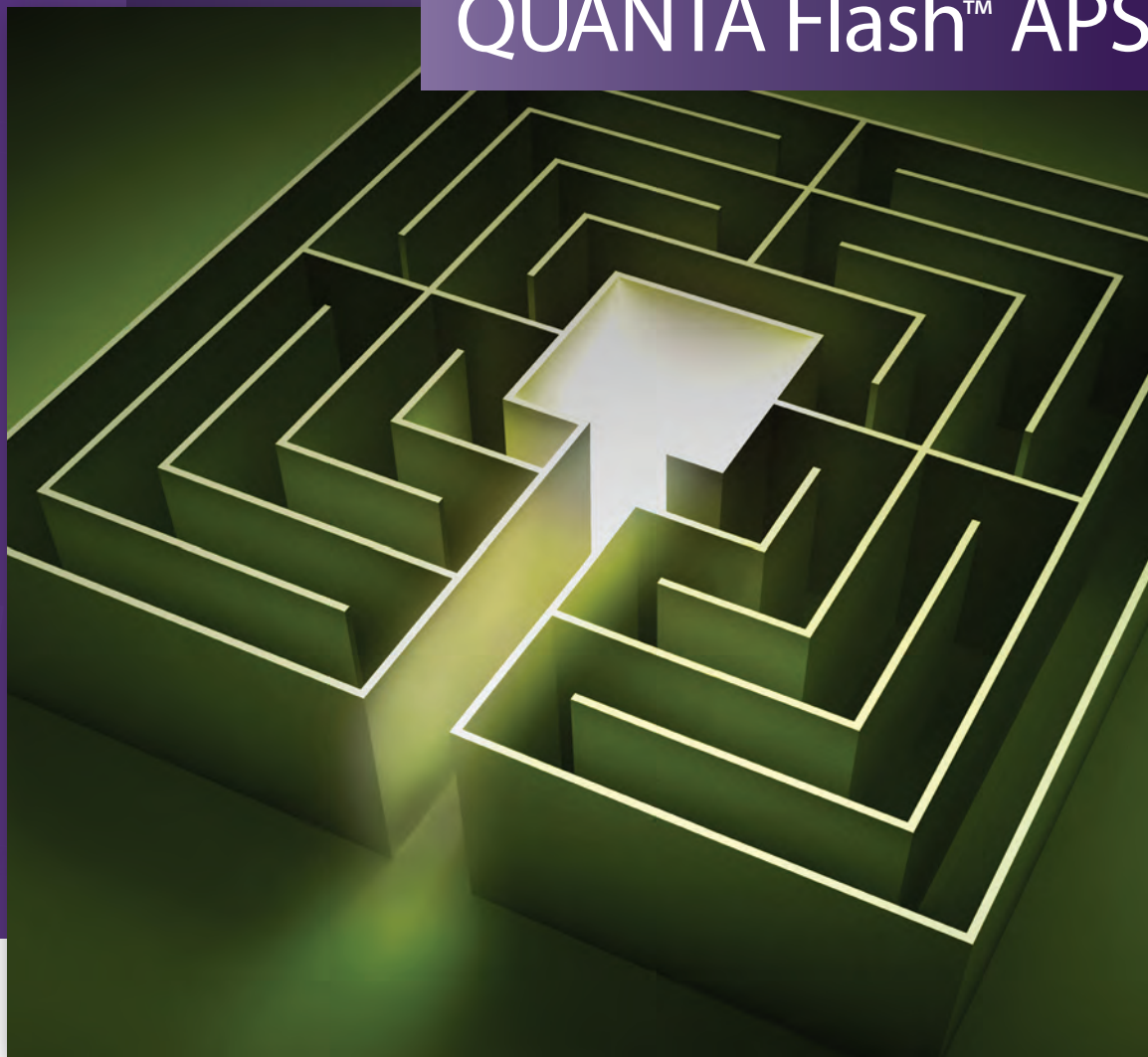
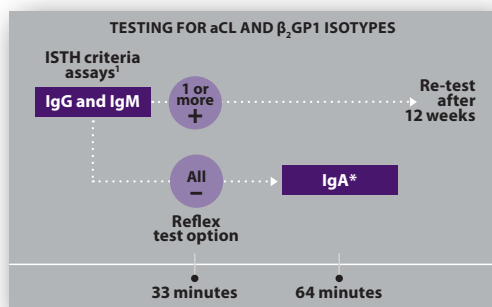


# QUANTA Flash™ APS



## Clarity

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



- Simultaneous processing for multiple assays and isotypes allows for timely follow-up testing
- Anticardiolipin (aCL) and anti- $\beta_2$  Glycoprotein I ( $\beta_2$ GP1) 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

# QUANTA Flash™ APS

## Criteria for definite APS diagnosis<sup>1</sup>

Clinical Criteria	Laboratory Criteria <i>On two or more occasions at least 12 weeks apart</i>
<b>1.</b> Vascular thrombosis (arterial, venous) <b>and/or</b> <b>2.</b> Pregnancy morbidity <ul style="list-style-type: none"> <li>• Unexplained fetal death beyond week 10</li> <li>• Premature birth before week 34</li> <li>• Three or more unexplained spontaneous abortions before week 10</li> </ul>	<b>1.</b> aCL (IgG, IgM) at medium/high titre <b>2.</b> $\beta_2$ GP1 (IgG, IgM) at levels >99 th percentile <b>3.</b> Lupus anticoagulant
	<b>Non-criteria assays are important when<sup>2</sup></b> <ul style="list-style-type: none"> <li>• Above criteria markers are all negative and APS is suspected</li> <li>• Managing certain populations including African-American<sup>3</sup></li> </ul>

## Clinical performance characteristics

### Sensitive

- The combination of QUANTA Flash aCL IgG/M and  $\beta_2$ GP1 IgG/M detected 71.7% of confirmed APS patient samples

### Specific

- Assay specificity is excellent ranging from 91 – 96%
- Disease control groups included SLE, SLE-like, and cardiovascular disorders

## Performance characteristics of QUANTA Flash APS assays<sup>4</sup>

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	$\beta_2$ GP1 IgG	64.1% (53.5% to 73.9%)	90.8% (86.3% to 94.2%)	6.1–6400
701253	$\beta_2$ GP1 IgM	29.3% (20.3% to 39.8%)	95.2% (91.6% to 97.6%)	1.1–841
–	aCL IgA*	N/A	N/A	N/A
–	$\beta_2$ GP1 IgA*	N/A	N/A	N/A

## 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

## For more information, visit [www.inovadx.com](http://www.inovadx.com).

\*aCL IgA and  $\beta_2$ GP1 IgA are not available in the United States.

### 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 a $\beta_2$  glycoprotein-I is the most frequent isotype. *Lupus* 1999; 8:263–268.
4. Respective QUANTA Flash Product Directional Inserts.



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San Diego, CA 92131 USA  
 PH: +1-858-586-9900 US Toll Free: 1-800-545-9495 FAX: +1-858-586-9911

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