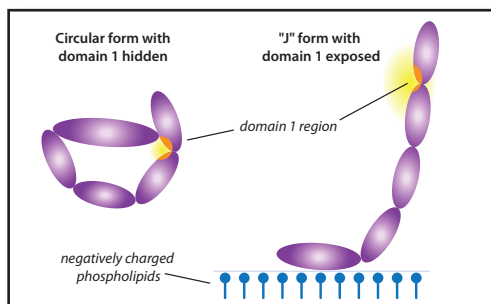




Specificity

QUANTA Flash β_2 GP1-Domain 1 is highly specific for the diagnosis of antiphospholipid syndrome and may help support therapeutic decision making

The domain 1 region of beta 2 glycoprotein1 (β_2 GP1)



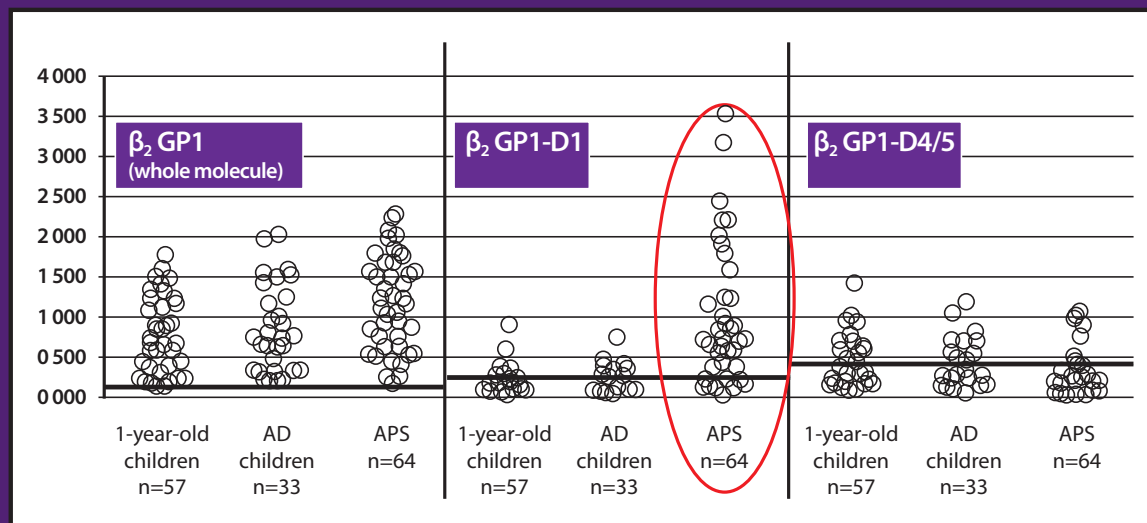
- Domain 1, the immunodominant epitope in APS, becomes exposed when bound to negatively charged phospholipids¹
- Antibodies to β_2 GP1 domain 1 are more specific for APS compared with other parts of the molecule such as domain 4/5²
- The higher the titer of anti- β_2 GP1 domain 1 antibodies the greater the likelihood of APS and of thrombosis^{3,4}
- Detection of anti- β_2 GP1 domain 1 antibodies may serve as an aid to confirm suspected APS and provide insight into risk for thrombosis⁴

QUANTA Flash β_2 GP1-Domain 1

The need for more specific markers in APS diagnosis

- Current diagnostic criteria rely on both clinical and serologic measures to confirm presence of APS⁵
- Single serologic markers can be elevated for reasons other than APS⁵
- Antibodies to domain 1 of β_2 GP1 yielded 99.5% specificity for APS in a population of 662 disease control subjects⁶

The domain 1 region of β_2 GP1 does a better job differentiating APS from other diseases compared to the whole molecule or domain 4/5.²



Adapted from Andreoli, et al. Ann Rheum Dis (2010)

1-year-old children: one year-old children born to mothers with systemic autoimmune diseases; AD children: children with atopic dermatitis; APS: patients with antiphospholipid syndrome.

QUANTA Flash β_2 GP1-Domain 1 is a highly specific and reproducible assay for APS^{6,7}

Reference #	Description	Determinations	Sensitivity (95% CI)	Specificity (95% CI)	Between run variability	Measuring range (CU) (cut-off is 20)
701188	QUANTA Flash β_2 GP1-Domain 1	50	49.8% (43.7-55.9%)	99.5% (98.7-99.9%)	0.0% - 5.3%	3.6 to 1380.4

References:

1. Agar C, van Os GM, Mörgelin M, et al. Beta2-glycoprotein I can exist in 2 conformations: implications for our understanding of the antiphospholipid syndrome. Blood 2010; 116:1336–1343.
2. Andreoli L, Nalli C, Motta M, et al. Anti-b2-glycoprotein I IgG antibodies from 1-year-old healthy children born to mothers with systemic autoimmune diseases preferentially target domain 4/5: might it be the reason for their 'innocent' profile? Ann Rheum Dis (2010). doi:10.1136/ard.2010.137281
3. Banzato A, Pozzi N, Frasson R, De Filippis V, Ruffatti A, Bison E, et al. Antibodies to Domain I of beta(2) Glycoprotein I are in close relation to patients risk categories in Antiphospholipid Syndrome (APS). Thromb Res 2011; 128:583–6.
4. de Laat B, Pengo V, Pabinger I, Musial J, Voskuyl AE, Bultink IE, et al. The association between circulating antibodies against domain I of beta2-glycoprotein I and thrombosis: an international multicenter study. J Thromb Haemost 2009; 7:1767–73.
5. Miyakis S, M. D. Lockshin, T. Atsumi, et al. International consensus statement on an update of the classification criteria for definite antiphospholipid syndrome (APS). J. Thromb. Haemost 2006; 4:295–306.
6. QUANTA Flash β_2 GP1-Domain 1 Directional Insert
7. Mahler, M., G. L. Norman, et al. (2012). Autoantibodies to domain 1 of beta 2 glycoprotein 1: a promising candidate biomarker for risk management in antiphospholipid syndrome. Autoimmun Rev 12(2): 313-317

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