

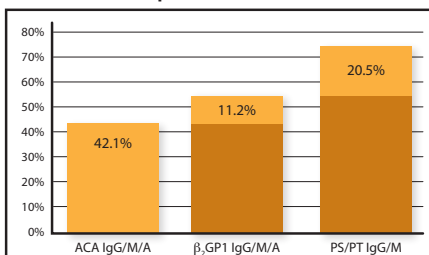
QUANTA Lite® PS/PT



Complementary

When used in combination with other APS tests, provides the best diagnostic accuracy

Incremental detection rates for aPL serological markers in primary APS patients (N=107)¹



Sensitivity increase as assays are added

Accurately identifies APS patients without the need to interrupt anti-coagulation therapy.

- PS/PT IgG & IgM may serve as a confirmatory test for lupus anticoagulant (LAC)²
- Superior clinical performance is delivered by targeting the entire PS/PT complex rather than just PS or PT alone^{3,4}
- PS/PT positivity has been found to be an independent risk factor for thrombosis, and may aid in patient stratification^{5,6}

QUANTA Lite® PS/PT

Clinical performance characteristics

Sensitive

- The combination of PS/PT IgG and IgM assays successfully detected:
 - 70.8% (92 of 130) of suspected APS patients positive for lupus anticoagulant²
 - 67.6% (48 of 71) of confirmed APS patients⁷

Specific

- The combination of PS/PT IgG and IgM assays correctly identified 97.2% (240 of 247) of normal controls⁷
- Specificity among disease controls including known syphilis patients was 98.1%⁷

Detection Rates ⁶	# Samples	PS/PT IgG	PS/PT IgM	PS/PT IgG and/or IgM
Antiphospholipid Syndrome (APS)	71	33 (46.5%)	34 (47.9%)	48 (67.6%)
Normal Controls	247	3 (1.2%)	4 (1.6%)	7 (2.8%)
Disease Controls	52	0	1 (1.9%)	1 (1.9%)

A full range of tests for Antiphospholipid Syndrome

QUANTA Lite PS/PT assays deliver optimal results when used in combination with other QUANTA Lite APS products.

Product Ordering Information	IgG	IgM	IgA	Screen (IgG/IgM/IgA)
QUANTA Lite® ACA III	708625	708630	708635	708620
QUANTA Lite® β ₂ GPI	708665	708670	708675	708660
QUANTA Lite® anti-PS/PT	708835	708845	NA	NA

References:

1. Data on file.
2. Viagea A, et al. Antiphosphatidylserine/Prothrombin Antibodies (aPS/PT) as Potential Markers of Antiphospholipid Syndrome. Clin Appl Thromb Hemost. 2 March 2012.
3. Miyaskis S, et al., International consensus statement on an update of the classification criteria for definite antiphospholipid syndrome (APS). J Thromb Haemost 2006; 4:295-306.
4. Atsumi T, et al., Association of autoantibodies against the phosphatidylserine-prothrombin complex with manifestations of the antiphospholipid syndrome and with the presence of lupus anticoagulant. Arthritis Rheum 2000; 43: 1982-1993.
5. Hoxha A, et al. Antiphosphatidylserine/prothrombin antibodies in primary antiphospholipid syndrome. Lupus 2012; 21: 787-789.
6. Sciascia S, et al. Clinical accuracy for diagnosis of Antiphospholipid Syndrome in SLE: evaluation of 23 possible combinations of antiphospholipid antibody specificities. J Thromb Haemost 2012; Accepted Article, doi:10.1111/jth.12014.
7. QUANTA Lite PS/PT IgG/IgM directional inserts.

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