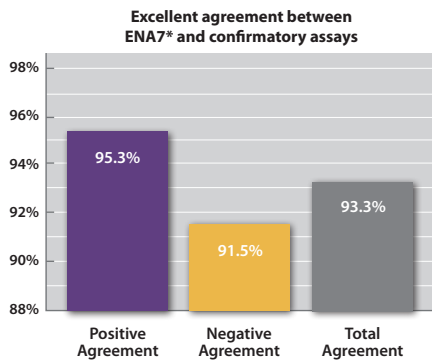


QUANTA Flash[®] CTD



Targeted

QUANTA Flash CTD assays are designed to give you optimal accuracy and efficiency



*ENA7 includes Sm, RNP, Ro60, Ro52, SSB, Scl-70, and Jo-1

- Reflex capabilities allow custom workorders based on results of ENA7 screen, or HEp-2
- Broad range of assays are available including CTD Screen Plus[‡] and ENA7 screen as well as clinically relevant analytes such as Ro52, Ro60¹, and dsDNA
- ENA panel can be completed in under 40 minutes

[‡]CTD Screen Plus can detect antibodies towards dsDNA, Sm/RNP, Ro52, Ro60, SS-B, Scl-70, centromere, Mi-2, Ku, ThTo, RNA Pol III, Pm/Scl, PCNA, Jo-1 and ribosomal-P protein

QUANTA Flash® CTD

Clinical performance characteristics

Sensitive

- Very good correlation to solid phase assays with positive agreement ranging from 83.3% – 100.0%^{1,3}
- Enhanced antigen reactivity from both native and recombinant sources²
- Screen assay are well aligned with detection levels of the individual assays to minimize discordant results³

Specific

- Excellent specificity ranging from 87.1% - 99.9%¹
- Reflex capabilities allow for custom algorithms based on clinical presentation of patients, which can further minimize the occurrence of false positive results

Performance characteristics of QUANTA Flash CTD assays¹

Reference # (50 tests/kit)	QUANTA Flash Assay	Disease State	Antigen	Sensitivity (95% CI)	Specificity (95% CI)	Measuring range (CU)
701198	Centromere	SSc	recombinant, baculovirus	23.4% (16.6% to 31.3%)	99.0% (98.1% to 99.6%)	3.4 - 708.9
701163	Jo-1	PM	recombinant, baculovirus	13.9% (8.0% to 21.9%)	99.9% (99.3% to 100%)	2.2 - 1147.2
701118	RNP	SLE	native purified (calf thymus)	30.7% (23.4% to 38.7%)	95.7% (91.3% to 98.2%)	3.5 - 643.8
701148	Ro60	SS	recombinant, E.coli	66.7% (49.8% to 80.9%)	97.9% (94.7% to 99.4%)	4.9 - 1374.8
		SLE		26.0% (17.7% to 35.7%)		
701263	Ro52	SLE	recombinant, baculovirus	28.2% (19.7% to 37.9%)	96.0% (91.6% to 98.5%)	2.3 - 1685.3
		SS		61.5% (40.6% to 79.8%)		
		SSc		12.3% (5.8% to 22.1%)		
		AIM		31.4% (25.2% to 38.2%)		
701153	SSB	SS	recombinant, baculovirus	35.0% (20.6% to 51.7%)	97.4% (94.8% to 99.0%)	3.3 - 1706.8
		SLE		13.8% (9.7% to 18.8%)		
701158	Scl-70	SSc	recombinant, baculovirus	35.8% (24.5% to 48.5%)	98.7% (97.5% to 95.5%)	3.8 - 969.8
701123	Sm	SLE	native purified (calf thymus)	14.4% (9.1% to 21.1%)	96.9% (93.3% to 98.8%)	3.3 - 693.5
701258	ENA7 screen	CTD	recombinant and native	62.3% (56.7% to 67.8%)	94.9% (90.8% to 97.5%)	3.6 - 429.4
701268	DFS70*	Non-CTD	recombinant, E.coli	8.5% (6.2% to 11.3%)	98.7% (97.6% to 99.4%)	302 - 450.8
701178 701175	dsDNA	SLE	synthetic oligonucleotides	42.7% ⁺⁺ (38.9-46.6%) 49.1% ⁺ (45.2-52.9%)	94.4% ⁺⁺ (91.9-96.3%) 87.5% ⁺ (84.2-90.2%)	9.8-666.9 [†]
701193	Ribo-P*	SLE	synthetic peptide	11.9% (9.1% to 15.1%)	98.9% (97.7% to 99.6%)	1.6 - 362
701220	CTD Screen Plus*	SARD	recombinant, native purified, and peptides	85.0% (81.7 to 87.9%)	87.1% (83.7% to 90.0%)	NA

⁺ Equivocal samples considered positive ⁺⁺ Equivocal samples considered negative [†] Units are IU/mL

* Not available for sale in the US

References:

1. Respective QUANTA Flash CTD assay Directional Inserts.
2. Schulte-Pelkum J, Fritzler M, Mahler M. Latest update on the Ro/SS-A autoantibody system. Autoimmun Rev. 2009 Jun; 8(7):632-7.
3. Bentow C, Swart A, Wu J, et al. Clinical performance evaluation of a novel rapid response chemiluminescent immunoassay for the detection of autoantibodies to extractable nuclear antigens, Clinica Chimica Acta 2013 Sept; 424, 141-147.

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