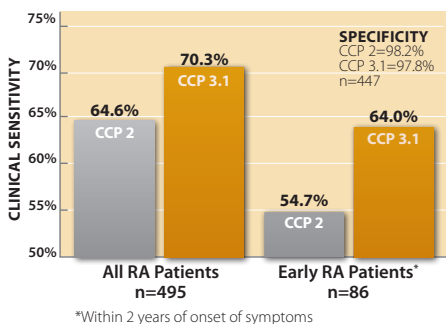


QUANTA Lite[®] CCP 3.1



Certainty

QUANTA Lite CCP 3.1 is the first anti-citrullinated protein antibody (ACPA) test indicated for early detection of rheumatoid arthritis (RA)¹



CCP 3.1 adds certainty to the diagnosis of early RA with superior sensitivity compared to CCP2 for all RA patients and early RA patients.

- Unique peptide epitopes preferentially detect auto-antibodies present during the first two years of RA symptoms
- Semiquantitative method allows for distinction between high and low positive results
- Ideal serology marker for use with 2010 RA classification criteria²

QUANTA Lite[®] CCP 3.1

Clinical performance characteristics¹

Sensitive

CCP 3.1 uniquely provides combined IgG/IgA detection of auto-antibodies to peptide epitopes to outperform CCP 2:

- 5.7% greater sensitivity overall (70.3% vs 64.6%)
- 9.3% greater sensitivity for early RA group (64.0% vs 54.7%)

Specific

CCP 3.1 achieves 97.8% specificity in group of 447 controls, including:

- Other rheumatic disease (74)
- Infectious disease (98)

N=942	CCP 3.1		CCP 2	
	+	-	+	-
RA (n=495)	348	147	320	175
Early RA – within 2 years (n=86)	55	31	47	39
Controls (n=447)	10	437	8	439
Blood Donors (n=275)	2	273	3	272
Other Rheumatic Diseases (n=74)	6	68	4	70
Infectious Disease (n=98)	2	96	1	97
Clinical Sensitivity (95% CI)	70.3% (66-74%)		64.6% (60-69%)	
In RA within 2 years of onset of symptoms	64.0% (52-74%)		54.7% (43-65%)	
Clinical Specificity (95% CI)	97.8% (96-99%)		98.2% (97-99%)	
Overall Accuracy	83.2%		80.6%	

All ACPA tests are not the same. CCP 3.1 offers:

- Certainty with the first ACPA test indicated as an aid in diagnosis of RA within two years of the onset of symptoms
- Superior overall accuracy for RA detection compared to CCP 2

A full range of tests for rheumatoid arthritis

QUANTA Lite CCP 3.1 IgG/IgA is ideally used in combination with other QUANTA Lite RA products.

Product Ordering Information	IgA	IgG	IgM	IgG/IgA
QUANTA Lite CCP 3.1				704550
QUANTA Lite CCP 3		704535		
QUANTA Lite RF	708695	708685	708690	

References

1. Source: Quanta Lite CCP 3.1 IgG/IgA ELISA Directional Insert.
2. Aletaha D, Neogi T, Silman AJ, et al. 2010 rheumatoid arthritis classification criteria: an American College of Rheumatology/European League Against Rheumatism collaborative initiative. *Ann Rheum Dis*. 2010;69(9):1580-1588.

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