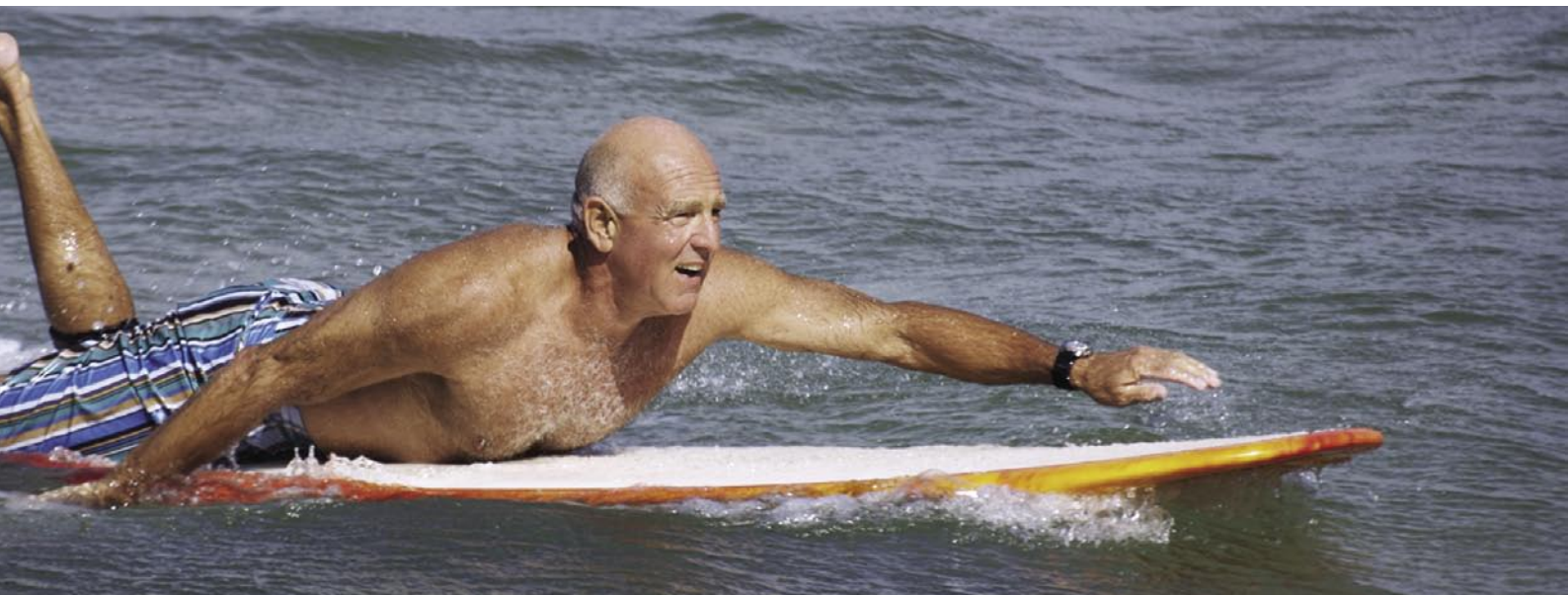


Axis-Shield Anti-CCP

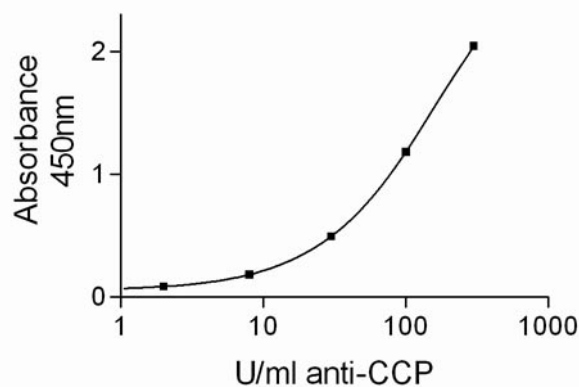
EIA

An aid in the diagnosis of Rheumatoid Arthritis

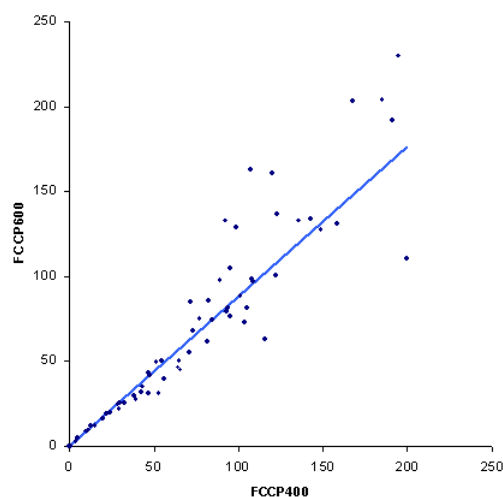


Key Features of new improved Axis-Shield Anti-CCP (FCCP600) assay:

- Increased dynamic range of assay (now up to 300 U/ml)



- Excellent correlation versus current product (FCCP400)



- Improved recovery rate of patient samples above 300 U/ml Calibrator

Samples > 300 U/mL exhibit mean recovery of 100% +/- 15%* of the expected result when diluted into the assay range corrected for dilution.

- Excellent precision/ accuracy

Sample	n	mean (u/mL)	Within run	Between run	Between day	Total
			%CV	%CV	%CV	%CV
Positive Control	80	20.6	2.1	5.8	0.0	6.2
QC 1	80	3.7	8.8	4.5	3.6	10.5
QC 2	80	8.5	3.6	8.3	2.9	9.5
QC 3	80	16.0	2.2	5.8	0.0	6.2
QC 4	80	55.5	4.2	6.0	0.0	7.4
QC 5	80	97.2	2.7	5.7	4.9	8.0
QC 6	80	134.8	3.4	4.3	4.3	7.0
Reference Control	80	5.1	5.1	4.1	4.2	7.7
Sample	80	4.8	3.3	7.9	5.0	9.9

- Excellent agreement with FCCP400 (99%)

All Samples		FCCP400	
		Positive	Negative
FCCP600	Positive	73	0
	Negative	1	24

- Excellent clinical performance

Clinical Sensitivity

Specimen Category	Total (n)	Axis-Shield Anti-CCP Positive (n)	% Sensitivity
All RA	229	179	78
Early RA	43	27	63
Established RA	186	152	82

Clinical Specificity

Specimen Category	Total (n)	Axis-Shield Anti-CCP Positive (n)	% Specificity
Non-RA Specimens in Total	285	4	98.6
Non-RA Healthy Asymptomatic	150	1	99.3
Non-RA Disease Specimens ⁺	135	3	97.8

⁺ The non-RA diseases were Inflammatory polyarthritis, EBV IgG Positive, Hashimoto's thyroiditis, Sjogren Syndrome, Systemic Lupus, Vasculitis, SCL, Osteoarthritis, Crohns disease, Raynaud, Ulcerative colitis positive, Psoriatic arthritis, Reactive arthritis, Ankylosing spondylitis and Polymyositis.

*Representative data; results in individual laboratories may vary from these data.

Shelf Life - Minimum 9 months at 2-8°C

Pack Size - 12 x 8 break apart microtitre wells

Product Code - FCCP600

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