

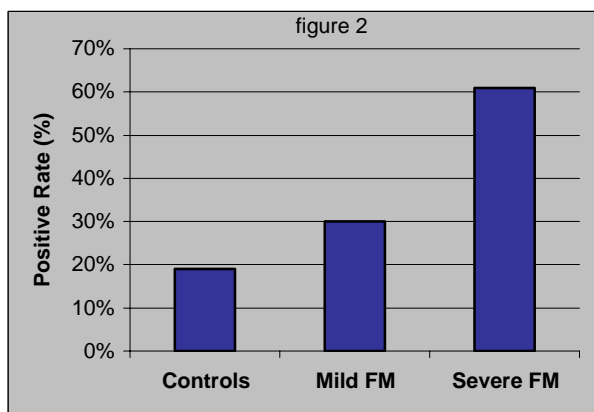
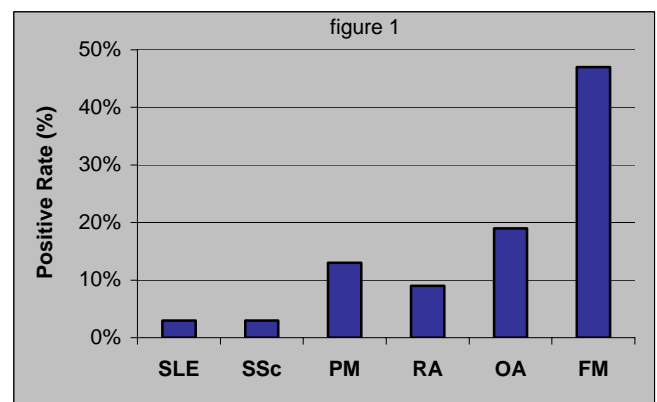
The patented APA ELISA is a semi-quantitative ELISA, which detects IgG anti-polymer antibodies (APA) and identifies certain fibromyalgia patients. Current data suggests that APA-positive fibromyalgia patients comprise the majority of fibromyalgia patients. The APA ELISA is intended for use: 1) as an aid in the diagnosis of patients presenting with the symptoms and signs of fibromyalgia syndrome, 2) as an aid in differentiating fibromyalgia patients from patients with other autoimmune diseases and 3) as an aid in identifying a subgroup of fibromyalgia patients having a unique characteristic immune response.



- The APA ELISA detects IgG anti-polymer antibodies (APA) in human serum
- The presence of the antibodies distinguishes fibromyalgia patients from other autoimmune disease patients
- The O.D. correlates closely with various clinical measures of fibromyalgia symptom severity
- Results are reported in semi-quantitative units
- The easy-to-use test can readily be automated

Published Clinical Specificity and Sensitivity Data

Published data concerning the clinical specificity and sensitivity of detecting anti-polymer antibodies was obtained with an immuno-blot assay². Serum samples from 30 systemic lupus erythematosus (SLE), 30 systemic sclerosis (SSc), 15 poly/dermatomyositis (PM), 43 rheumatoid arthritis (RA) and 47 fibromyalgia (FM) patients were analyzed for the presence of APA. The prevalence of APA in each patient population was as follows: SLE=3%, SSc=3%, PM=13%, RA=9%, OA=19% and FM=47%. As shown in Figure 1, the prevalence of APA in the FM patients was significantly higher compared to the other sample populations. All of the populations were statistically different compared to FM ($p < 0.05$), except the OA group ($p < 0.1$; approaching statistical significance), distinguishing FM from other autoimmune diseases.



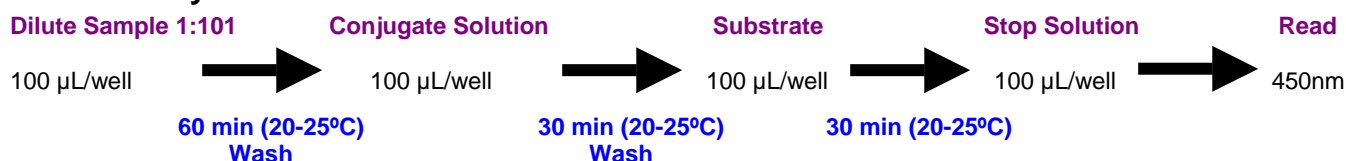
Published Data Associates APA with FM Severity

To determine the association between the presence of APA and symptom severity, samples from patients with mild ($n=37$) and severe ($n=28$) manifestations of FM were tested on an immuno-blot APA assay². Sera samples from normal donors ($n=21$) were also tested as a control population. The prevalence of APA in the control group was 19% (4/21) and 30% (11/37) in the mild FM patients. The prevalence of APA in the severe FM patient population was 61% (17/28). These results are presented in Figure 2. The prevalence of APA observed in the severe FM patients was significantly higher than that found in the mild FM patients ($p < 0.05$) and in the normal donor group (< 0.01), demonstrating that the presence of APA identifies a subgroup of FM patients by disease severity.

Fibromyalgia Syndrome (FMS) is a common chronic disorder of widespread pain that afflicts millions of individuals³. Associated signs and symptoms include tender points, fatigue, morning stiffness, sleep disorder, headache and cognitive problems⁴. Not all of the signs and symptoms are present in every patient, and each individual patient may have different signs and symptoms at different times. The American College of Rheumatology (ACR) criteria require that a patient manifest localized tenderness in at least 11 of 18 specific sites on the body (known as tender points) and have a history of chronic wide-spread pain of greater than 3 months' duration in order to receive a diagnosis of FMS.

The APA ELISA is an objective tool for identifying fibromyalgia patients. The APA ELISA detects antibodies in human serum which bind to partially polymerized polyacrylamide. These antibodies have been detected in the majority of fibromyalgia patients tested, and antibody titers correlated with the severity of symptoms in these patients^{1,2}. Studies have also shown that the presence of the antibodies can be used to help differentiate fibromyalgia from other autoimmune diseases².

ELISA Assay Procedure



References

1. Xiao YM, Russell IJ, Michalek JE, Wilson RB. Anti-Polymer Antibodies Identify a Large Subgroup of Fibromyalgia Syndrome Patients. Presentation; Myopain 2004.
2. Wilson RB, Gluck OS, Tesser JR, Rice JC, Meyer A, Bridges AJ. Antipolymer Antibody Reactivity in a Subset of Patients with Fibromyalgia Correlates With Severity. J Rheumatol 1999;26(2):402-407.
3. Bennett RM. Fibromyalgia and the Disability Dilemma. A New Era in Understanding a Complex, Multidimensional Pain Syndrome. Arthritis Rheum 1996;39(10):1627-1634.
4. Wolfe F, Smythe HA, Yunus MB, Bennett RM, Bombardier C, Goldenberg DL, et al. The American College of Rheumatology 1990 Criteria for the Classification of Fibromyalgia. Report of the Multicenter Criteria Committee. Arthritis Rheum 1990;33(2):160-172.

ELISA Test Kit Contents

96 antigen coated microwells in frame	12 x 8 strips
Calibrator Serum (human)	0.25 mL
Positive Control Serum (human)	0.25 mL
Negative Control Serum (human)	0.25 mL
Conjugate Antibody Solution (anti-human IgG)	15 mL
Sample Diluent	60 mL
Wash Concentrate (33x)	2 x 30 mL
One Component Substrate (TMB/H ₂ O ₂)	15 mL
Stop Solution (0.36 N sulfuric acid)	15 mL

APA ELISA

Product # 11440
Quantity: 96 wells
Tests: 44 in duplicate
Storage: 2-8°C

The Anti-Polymer Antibody ELISA is covered by U.S. Patent No. 5,620,859, European Patent No. 0873518, Australian Patent No. 710252, and other patents and pending patents. The test is manufactured under license from Autoimmune Technologies, LLC, 144 Elks Place New Orleans Louisiana 70112 USA

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