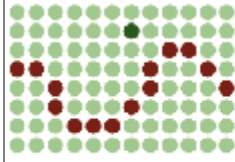


APA Assay FAQs



Autoimmune
Technologies
LLC

Applied Biomedical Science

FREQUENTLY ASKED QUESTIONS ABOUT THE APA ASSAY

Q: Is the APA Assay the first laboratory test for fibromyalgia?

A: Yes. Until now there has not been a lab test that is specific for fibromyalgia. Research studies to date have shown that the APA Assay can identify between one-half and two-thirds of fibromyalgia patients tested.

Q: What does the APA Assay detect?

A: The APA (Anti-Polymer Antibody) Assay detects IgG anti-polymer antibodies in human serum.

Q: What are anti-polymer antibodies?

A: Researchers are still in the process of trying to fully understand the nature of these antibodies. However, published studies have recently reported that fibromyalgia patients with a higher level of anti-polymer antibodies in their blood have more severe fibromyalgia symptoms than patients with lower antibody levels. This makes the APA Assay a valuable fibromyalgia test even though the circumstances surrounding antibody production are not yet completely understood.

Q: Why do anti-polymer antibodies occur in fibromyalgia patients?

A: Why anti-polymer antibodies occur is also not fully understood yet. However, this is not unusual, because it is also not fully understood why other abnormal antibodies occur in diseases like rheumatoid arthritis (RA) and systemic lupus erythematosus (SLE). Nevertheless, detecting the presence of the other antibodies in RA and SLE patients is useful in aiding in the diagnosis, and sometimes the treatment, of those illnesses.

Q: If my physician has already told me that I have fibromyalgia, could this test be of any use for me?

A: Yes it could. The test could objectively confirm your physician's diagnosis, and it might also help in determining your treatment. A positive result on the APA Assay means that a fibromyalgia patient's immune

system is producing anti-polymer antibodies. This is the first evidence that an immune response is associated with fibromyalgia as it is with rheumatoid arthritis and lupus. Immune-modulating drugs have not been thought to be appropriate for fibromyalgia in the past, but now the APA Assay could lend considerable support to a physician's decision to prescribe these drugs for a fibromyalgia patient.

Q: Are there other examples of lab tests for factors that are not completely understood?

A: Yes. One good example is the anti-nuclear antibody test, or ANA test, which is the most commonly used autoimmune screening test. Physicians order the ANA test approximately 25 million times per year worldwide and use the results to help diagnose and monitor their patients, yet researchers still don't fully understand why anti-nuclear antibodies are produced or what their significance is.

Q: What about using other lab tests for fibromyalgia patients?

A: There are dozens of lab tests that physicians can order when they are in the process of examining a patient suspected of having fibromyalgia. However, these tests are not specific for fibromyalgia and they are usually ordered to help rule out other immune disorders. Many fibromyalgia patients have completely normal results on all of these other tests.

Q: Is a lab test useful even if it doesn't detect something in every patient?

A: Yes, both positive and negative test results can supply valuable information, and many diagnostic tests don't operate in the 95% to 100% detection range. For example, the discovery of proteins called rheumatoid factors helped convince physicians that rheumatoid arthritis was a real disease instead of a psychological disorder, yet only about 70% of patients who receive a diagnosis of rheumatoid arthritis test positive for rheumatoid factors.

Q: If I don't have the antibodies that the APA Assay detects, does that mean I don't have fibromyalgia?

A: No, people without anti-polymer antibodies can still have fibromyalgia. In research studies to date, up to two thirds of fibromyalgia patients tested positive on the APA Assay but the other fibromyalgia patients did not. This and other research indicates that there are several distinct subgroups of fibromyalgia patients, and fibromyalgia patients without anti-polymer antibodies probably belong to one of the smaller patient subgroups.

Q: Has the APA Assay been approved by the U.S. Food and Drug Administration for use as a diagnostic test?

A: No, but the test is undergoing the clinical trials necessary to support a

regulatory filing for FDA approval. For diagnostic tests, the FDA requires that tests be produced in kit form, and the kit is what the FDA approves and regulates. An APA Assay kit, in the Enzyme Linked ImmunoSorbent Assay (ELISA) microtiter plate format, has been developed for Autoimmune Technologies by Corgenix, Inc., and this kit is now being used in the U.S. clinical trials. The data obtained from these trials will then be submitted to the FDA in what is called a Pre-Market Approval, or PMA, application.

Q: How long do clinical trials take?

A: Unlike drug trials, clinical trials of a non-invasive blood test like the APA Assay can be done quickly, and the clinical trials of the APA ELISA Kit will probably take between six and nine months to complete. After that, the PMA application to the FDA will be submitted. If the FDA decides to approve the PMA, approval could come within six months to a year after the date of submission.

Q: Can I have my blood tested for anti-polymer antibodies?

A: The APA ELISA Kit is designed to be distributed to the clinical labs which run the test when it is ordered by a physician. FDA regulations prohibit the use of a test kit in the U.S. while it is undergoing clinical trials and approval, but the kit is available to labs in other countries through the Corgenix international sales office in Peterborough, UK. For more information, contact:

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Q: Does my physician know about this test?

A: Your physician may not know about the APA Assay, and you may want to give him or her a printed copy of the APA Assay [Science Summary](#) that is available on the Autoimmune Technologies Web site, www.autoimmune.com. Reprints of published articles are available from Autoimmune Technologies, and representatives are also available to discuss the material with a physician over the telephone.

ADDITIONAL INFORMATION ABOUT THE APA ASSAY

Go to the [Fibromyalgia Syndrome Research Page](#)

Go to the [Autoimmune Technologies Home Page](#)