

Accurate interpretation of antinuclear antibodies test key to confirming autoimmune disease

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The presence of antinuclear antibodies (ANA) indicates the possibility of autoimmunity and the indirect immunofluorescence (IIF) assay on HEp-2 cells is the standard blood test (ANA-HEp-2) used to detect ANA. However, studies have shown that a "false-positive" ANA test occurs in up to 13% of healthy individuals. In such cases the test detects the presence of autoantibodies that apparently are not associated with autoimmunity. Researchers from Brazil have now uncovered distinguishing characteristics of the ANA test in healthy individuals and patients with autoimmune disease, reducing the likelihood of an erroneous autoimmune disorder diagnosis. Their findings are published in the January 2011 issue of *Arthritis & Rheumatism*, a journal of the American College of Rheumatology (ACR).

The immune system is responsible for protecting the body against foreign invaders and infection, but in some individuals the immune system repeatedly attacks healthy cells in the body resulting in an autoimmune disease. According to the Centers for Disease Control and Prevention (CDC) autoimmune diseases—which include rheumatoid [arthritis](#), Sjögren's syndrome, and systemic lupus erythematosus—affect up to 8% (22 million individuals) of the U.S. population.

The Brazilian research team, led by Luis Andrade, MD, PhD, from the Federal University of São Paulo, recruited 918 healthy individuals (634 females and 284 males) between the ages of 18 and 66 years for this

study. In the control group were 153 patients with autoimmune rheumatic diseases that included lupus (87), systemic sclerosis (45), Sjögren's syndrome (11) and idiopathic inflammatory myopathy (10). To determine the concentration of ANA in the blood, ANA-HEp-2 tests were run on all participants and considered positive if a well defined IIF pattern was identified.

"The ANA-HEp-2 test is positive in a sizable portion of the general population and our findings established distinguishing characteristics between healthy individuals and patients with autoimmune disease which is essential to accurately interpret the test results," explained Dr. Andrade. Researchers determined that positive ANA-HEp-2 tests in healthy participants occurred predominantly as a nuclear fine speckled (NFS) pattern (at low to moderate titer) or as a nuclear dense fine speckled (NDFS) pattern (frequently at high titer) in 46% and 33% of ANA-positive healthy individuals, respectively. Healthy participants did not present a nuclear coarse speckled (NCS) or a nuclear homogeneous (Ho) pattern.

In those with autoimmune disease the ANA-HEp-2 showed positive results at a predominantly moderate to high titer. A distinct ANA-HEp-2 pattern profile was observed, characterized by the absence of the NDFS pattern and the exclusive occurrence of the NCS (26%), centromeric (8%), nuclear homogeneous (7%), and cytoplasmic dense fine speckled (3%) patterns. ANA-positive patients with confirmed [autoimmune diseases](#) also showed the presence of the NFS (42%), but at a higher titer than in healthy individuals.

At the end of a 4-year follow-up period 73% of the ANA-positive healthy individuals retained a positive test result, but did not develop any symptoms of autoimmune rheumatic disease. "Our study confirms that the ANA-HEp-2 pattern is critical in properly diagnosing autoimmune disorders and future research should attempt to reproduce the

interpretation of test results among different ANA experts and ANA-HEp-2 slides brands," Dr. Andrade concluded.

More information: "ANA HEp-2 Pattern Is A Critical Parameter For Discriminating ANA-Positive Healthy Individuals And Patients With Autoimmune Rheumatic Diseases." Henrique A Mariz, Emília I Sato, Silvia H Barbosa, Silvia H Rodrigues, Alessandra Dellavance, Luis E Andrade. Arthritis & Rheumatism; Published Online: December 28, 2010 ([DOI: 10.1002/art.30084](https://doi.org/10.1002/art.30084)); Print Issue Date: January 2011.

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