



# Connective Tissue Disorders Panel

## Key Clinical Messages

### What is the Connective Tissue Disorders Panel?

The Vibrant Connective Tissue Disorders Panel is a comprehensive diagnostic blood test for autoimmune-related diseases within the connective tissue disease (CTD) spectrum.

The Connective Tissue Disorders Panel measures 15 autoimmune related markers, and include the following tests:

- Rheumatoid Arthritis test
- ANA IFA panel
- ENA 11 Profile

### What Are Connective Tissue Disorders?

Connective tissue disorders (CTDs) are a subset of genetic and acquired autoimmune diseases that primarily affect connective tissues in multiple organs throughout the body.

#### Specific autoimmune CTDs include:

- Rheumatoid arthritis (RA)
- Systemic sclerosis (SSc)
- Dermatomyositis/polymyositis (DM/PM)
- Mixed connective tissue disease (MCTD)
- Systemic lupus erythematosus (SLE)
- Sjögren's syndrome (SS)
- Relapsing polychondritis
- Ankylosing spondylitis

Connective tissue disorders have unifying characteristics such as immune dysregulation and tissue-specific autoantibody production<sup>1</sup>, as well as genetic, environmental, and biological sex-associated risk factors.<sup>2</sup>

#### Regulatory Statement:

This test has been laboratory developed and their performance characteristics determined by Vibrant America LLC, a CLIA-certified laboratory performing the test CLIA#:05D2078809. The test has not been cleared or approved by the U.S. Food and Drug Administration (FDA). Although FDA does not currently clear or approve laboratory-developed tests in the U.S., certification of the laboratory is required under CLIA to ensure the quality and validity of the tests.

### Why Order the Connective Tissue Disorders Panel?

The Connective Tissue Disorders Panel employs innovative technology for faster patient diagnosis, enabling prompt treatment and enhanced condition management.

Conventional CTD diagnosis often begins with ANA detection by indirect fluorescence assay (IFA) assay. If ANA results are positive, an extractable nuclear antigens (ENA) test is generally performed for further specification.<sup>3</sup>

While ANA IFA assay detects a large number of nuclear and cytoplasm antigens, it lacks sensitivity and specificity due to potential false positives and staining pattern interpretation errors.<sup>4 5</sup>

**The Connective Tissue Disorders panel overcomes these issues by panel automating this first step of ANA testing through a microarray-based assay.**

The Vibrant CTD panel also includes the ENA panel, an extensive 11-biomarker test. **Vibrant internal studies found that concurrent testing of ANA and ENA—rather than reflex ENA—can accelerate connective tissue disorder diagnosis by up to two years.<sup>6</sup>**

Furthermore, the **panel's rheumatoid arthritis section contains three biomarkers for sensitivity and specificity.** When paired with the Disease Activity Score (DAS), it enhances the accuracy of RA diagnosis and management.





## What Markers Are Included in the Connective Tissue Disorders Panel?

Vibrant ANA IFA	ENA Profile-11	Rheumatoid Arthritis Associated Markers
Speckled Nucleolar RIM Cytoplasmic Centromere Homogenous	Anti-dsDNA Jo-1 Sm RNP SSA (Ro) SSB (La) Scl-70 Chromatic Centromere Histone RNA polymerase III	Vibrant RF IgM Anti-CCP3 IgG/IgA hs-CRP

## Which Tests Pair Well with the Connective Tissue Disorders Panel?

- **Wheat Zoomer:** Given the connection between celiac disease and RA,<sup>7</sup> the Wheat Zoomer is crucial. It identifies the full range of wheat and gluten sensitivities. It also checks for intestinal permeability, which may lead to autoimmunity.
- **Gut Zoomer:** Dysbiosis is believed to play a role in the development of RA and other autoimmune diseases.<sup>7</sup>
- **Thyroid Panel:** It's been shown that there is a higher prevalence of thyroid disease in patients with connective tissue disorders.
- **Tickborne 2.0 Test:** Infectious disease from tick-associated organisms can mimic connective tissue disorders such as RA, making this test valuable for differential diagnosis.

## Test Prep for Microtube Blood Collection

There is no fasting, dietary, hydration, medication change, or other test preparation required for the Connective Tissue Disorders Panel. The sample collection is taken from serum.

### Reference Ranges

Adult reference ranges and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines.

### Interpretation Resources

You can find more resources, including the [Connective Tissue Disorders brochure](#) and [Connective Tissue Disorders White Paper](#).

### References

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## Which Patients Benefit from This Test?

Connective tissue disorder symptoms can be broad, affecting both specific organs and the entire body.

### Systemic symptoms can include:

- Fevers
- Rashes
- Weight loss
- Fatigue

Areas rich in connective tissue, like the musculoskeletal, respiratory, and vascular systems, often show specific symptoms such as:

- Arthritis,
- Lung conditions
- Vasculitis

However, many other systems may be impacted, including renal, ocular, cardiac, and GI. The Connective Tissue Disorders Panel may be helpful for patients with unexplained symptoms in these areas, chronic inflammation, potential autoimmune issues, or suspected wheat-related conditions.

## Methodology

### The advantages of our Connective Tissue Disorders Panel include:

- Solid phase bio-chip immunofluorescence assay testing and ELISA technology for superior precision.
- A microarray-based assay that allows simultaneous ANA IFA detection and ENA testing, which has higher sensitivity and specificity than a single test of ANA IFA.
- Simultaneous ANA and ENA testing, which can detect autoimmune diseases significantly earlier.<sup>8</sup>
- Our automated microarray technology places controls on every chip, and tests each analyte multiple times, thus eliminating instrument variation and the need for operator interpretation.

