



RHEUMATOLOGY TESTING

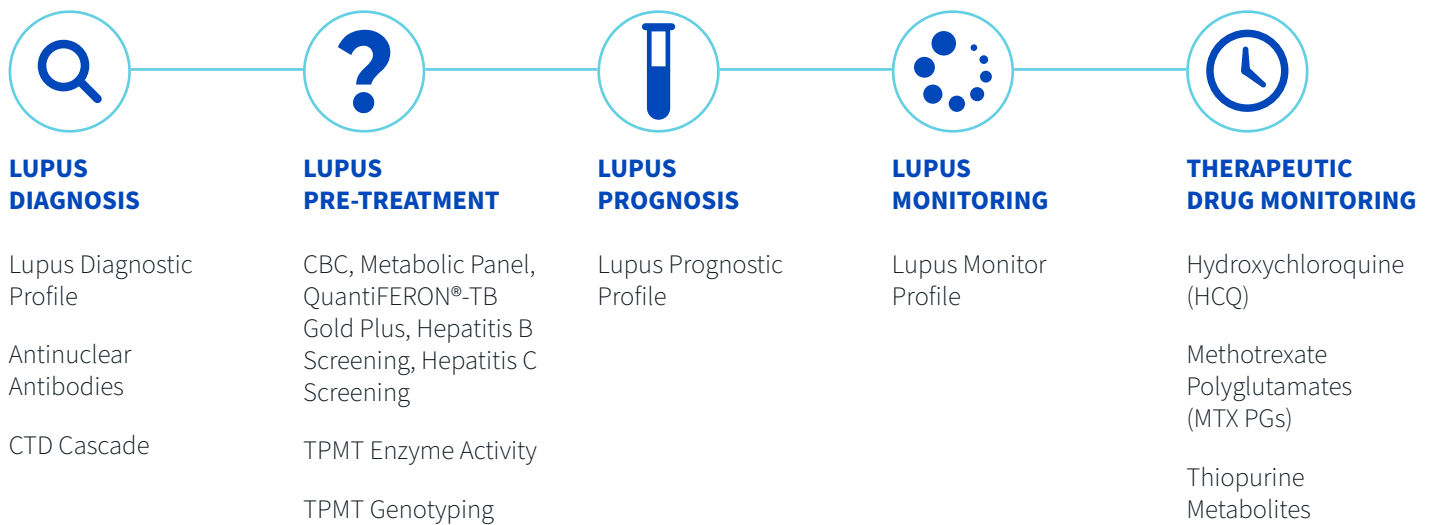
Comprehensive testing for lupus and related autoimmune syndromes



Systemic lupus erythematosus (SLE), commonly known as lupus

Lupus affects an estimated 1.5 million people in the United States.¹ Patients may present with variable clinical systemic manifestations that can imitate other chronic autoimmune diseases, often leading to diagnostic delays or misdiagnosis.

Labcorp can deliver an accurate and early diagnosis to inform treatment decisions, manage symptoms and improve patient outcomes. Our comprehensive tests and services help distinguish between SLE and other complex autoimmune disorders across all stages of the patient journey.







Lupus Diagnosis

Lupus can be difficult to recognize, as various clinical symptoms may develop at different disease stages and may not occur simultaneously.² Reducing the delay from symptom onset to diagnosis and treatment of lupus can help suppress inflammation and prevent irreversible organ damage.³

Labcorp's profiles combine multiple autoantibodies, utilizing various methodologies to help with the diagnosis of lupus.

Lupus Diagnostic Profile

Labcorp's Lupus Diagnostic Profile includes highly specific lupus markers to support the diagnosis of SLE:

- ANA by IFA
- Anti-dsDNA Ab by Farr
- Anti-Sm Ab
- Anti-U1 RNP Ab
- Anti-Chromatin Ab
- Anti-Ro (SS-A) Ab
- Anti-La (SS-B) Ab
- C3 Complement
- C4 Complement

Antinuclear Antibody (ANA) by Immunofluorescence Assay (IFA) Testing

ANA testing can aid in the differential diagnosis of various autoimmune disease states: SLE, drug-induced SLE, mixed connective tissue disease (MCTD), Sjögren syndrome, limited scleroderma (CREST), diffuse scleroderma, rheumatoid arthritis (RA) and autoimmune thyroid disease.

Labcorp offers ANA testing options for initial screening with titer results reported at a 1:80 dilution, and for the rheumatology specialist with titer results reported at a 1:40 dilution.

Connective Tissue Disease (CTD) Cascade

Labcorp's comprehensive CTD cascade provides testing that differentiates between many acquired autoimmune diseases.

- If ANA is positive, cascade will reflex to additional testing associated with SLE, including complements, antiphospholipid syndrome (APS) and nine other monospecific autoantibodies
- If ANA is negative, cascade will reflex to RheumAssure® to aid in assessing a possible diagnosis of RA
- If RheumAssure is negative, cascade will reflex to thyroid antibodies to aid in differential diagnosis of hypothyroidism and thyroiditis

Lupus Prognosis

The prognosis of lupus can be variable, depending on disease severity and organ involvement.

As part of Labcorp's comprehensive portfolio, our Lupus Prognostic Profile can help you assess prognosis for nephritis, neuropsychiatric, thrombotic and other cardiovascular risks. Our profile includes the following components:

- Anti-C1q Ab, IgG
- Anti-Ribosomal P Ab
- Anti-Cardiolipin Ab IgG
- Anti-Cardiolipin Ab IgA
- Anti-Cardiolipin Ab IgM
- Anti-Beta-2 Glycoprotein I IgG
- Anti-Beta-2 Glycoprotein I IgA
- Anti-Beta-2 Glycoprotein I IgM
- Anti-PS/PT Ab IgG
- Anti-PS/PT Ab IgM

Lupus Monitoring

Labcorp offers a Lupus Monitor Profile that can help providers observe disease activity while identifying the risk of lupus nephritis.

Our profile includes the following components:

- C3 Complement
- C3a Complement
- C4 Complement
- C4a Complement
- Anti-dsDNA Ab by *Crithidia luciliae*, IFA
- Anti-C1q Ab, IgG



Lupus Therapeutic Drug Monitoring

Treatment options for lupus are limited and often include azathioprine, hydroxychloroquine and methotrexate. Therapeutic drug monitoring can not only support ongoing lupus patient management and identify compliance, but it can also help identify targets for clinical benefit.⁴

Hydroxychloroquine (HCQ)

To evaluate lupus and other autoimmune patients on daily HCQ, Labcorp offers whole blood HCQ testing to help assess daily dosage, improve adherence and reach the maximal clinical benefit.

Methotrexate Polyglutamates (MTX PGs)

MTX is subject to wide pharmacokinetic variability. About 30% of patients do not respond to MTX treatment or experience adverse effects.⁵ Testing for MTX PGs can help assess patient compliance and determine correct dosing to achieve therapeutic levels and clinical response.⁶

Thiopurine Therapy

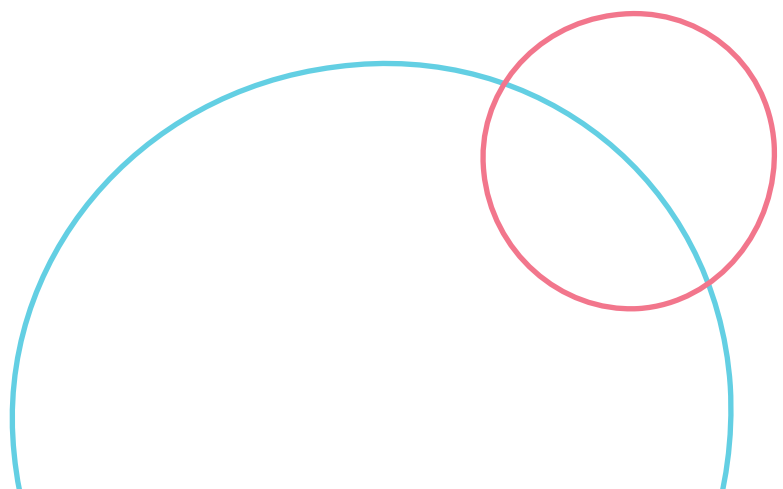
Once thiopurine therapy (e.g., azathioprine, 6-mercaptopurine, 6-thioguanine) has been undertaken and an equilibrated drug level is achieved (usually three to six months), thiopurine-related testing may be used to assess dosing before and during treatment, as well as to identify patients who may be at risk for drug toxicity.⁷

The FDA-approved label recommends testing consideration for the most common TPMT gene mutations (genotype) or TPMT enzyme activity (phenotype) before beginning treatment due to potentially severe bone marrow toxicity.



Other Related Tests

Test Name	Test Description
Anti-dsDNA (Double-stranded) Ab by Farr method (RDL)	The gold standard for DNA antibody testing, ⁸ detects high avidity Anti-dsDNA antibodies. The Farr assay is the most specific method for detecting dsDNA autoantibodies. Significant elevations in dsDNA autoantibody concentrations confirm the diagnosis of SLE.
Anti-Dense Fine Speckled Protein 70 kDa (DFS70) Ab	Anti-DFS70 antibodies may help identify individuals who do not have an ANA-associated autoimmune rheumatic disease (AARD) especially in the absence of significant clinical findings. ⁹
Anti-ENA6 Plus DFS70Ab Profile	Unique screening profile with the novel Anti-DFS70 that may help identify SLE, MCTD, Sjögren syndrome, systemic sclerosis, idiopathic myopathy (IIM) and contributes to the inclusion or exclusion of these AARD. Positive Anti-DFS70, especially when positive in isolation confers a likelihood ratio of 10.9 for the absence of systemic autoimmune rheumatic disease (SARD). ¹⁰
APS Profile, Comprehensive	This profile is used to determine the presence of antiphospholipid antibodies, using either clot-based or ELISA technology, that may be associated with an increased risk for arterial or venous thrombosis or obstetric complications.
Vasculitis Profile (RDL)	Diagnostic profile designed to identify autoimmune causes of vasculitis including lupus, ANCA-associated vasculitides (AAV) and Anti-GBM (glomerular basement membrane) disease.



Testing for Lupus and Related Autoimmune Syndromes

Test Name	Test No.
Lupus Diagnostic Profile	520342
ANA 12 Profile (RDL)	520188
ANA 12 Profile, Do All (RDL)	520299
ANA 12 Plus Profile (RDL)	520180
ANA 12 Plus Profile, Do All (RDL)	520175
ANA by IFA, Reflex to Titer and Pattern	164947
ANA by IFA, Reflex to 9-biomarker Profile by Multiplex Immunoassay	340897
ANA by IFA, Reflex to 11-biomarker Profile by Multiplex Immunoassay	382965
Connective Tissue Disease (CTD) Cascade	520340
Lupus Prognostic Profile	520555
Lupus Monitor Profile	505770
Hydroxychloroquine, Whole Blood	504814
Methotrexate Polyglutamates	504104
Thiopurine Metabolites	503800
TPMT and NUDT15 Genotyping	512300
Thiopurine Methyltransferase (TPMT), Enzyme Activity, Erythrocytes	510750
Other Related Tests	
Anti-dsDNA (Double-stranded) Ab by Farr method (RDL)	520059
Anti-Dense Fine Speckled Protein 70 kDa (DFS70) Ab	520313
Anti-ENA6 Plus DFS70Ab Profile	520301
APS Profile, Comprehensive	504400
Vasculitis Profile (RDL)	520293
Complement Options	
Complement C2	161414
Complement C3	006452
Complement C3a	004220
Complement C4	001834
Complement C4a	004330
Complement, Total (CH50)	001941

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