AUTOIMMUNE PROFILES

Advancing Patient Care in Rheumatology and Autoimmune Disease

labcorp

Autoimmune disorders can be challenging to diagnose and differentiate from other conditions. Labcorp offers a wide range of autoimmune profiles to help diagnose and characterize disease.

Rheumatoid Arthritis Profiles

Diagnosis and classification of rheumatoid arthritis (RA) have relied heavily on the presence of Rheumatoid Factor (RF) and Anti-CCP (Cyclic Citrullinated Peptide). However, 20–25% of patients with RA (and up to 50% of those with suspected early RA) may be seronegative for both RF and Anti-CCP.[1] Novel markers may be useful in identifying more early RA patients, stratifying patients at risk of joint destruction and monitoring disease activity and treatment response.

Profile Name	Profile Description and Components
RAdx6 Profile	Most comprehensive diagnostic and prognostic profile for RA. Along with RF and Anti-CCP Ab, it includes four novel markers (14-3-3 eta, Anti-CEP-1, Anti-Sa, and Anti-CarP) that enhance the ability to diagnose early or established RA as well as to predict disease severity
	Rheumatoid Factor (RF) by Turbidimetry , Anti-CCP (Cyclic Citrullinated Peptide) Ab, IgG and IgA, 14-3-3 eta, Anti-CEP-1 (citrullinated alpha-enolase 1) Ab, Anti-Sa (citrullinated vimentin) Ab, Anti-CarP (carbamylated protein) Ab
SeroNeg RAdx4 Profile	Diagnostic profile for seronegative patients (who have tested RF-negative and Anti-CCP-negative) designed to enhance the diagnosis of RA and early RA. It is comprised of four novel markers (14-3-3 eta, Anti-CEP-1, Anti-Sa, Anti-CarP) that may also predict RA disease severity
	14-3-3 eta protein; Anti-CEP-1 (citrullinated alpha-enolase 1) Ab; Anti-Sa (citrullinated vimentin) Ab; Anti-CarP (carbamylated protein) Ab
RA Profile with Reflex to SeroNeg RAdx4	Novel reflexive profile for RA that if negative for traditional markers, RF and Anti-CCP, reflexes to four novel markers (14-3-3 eta, Anti-CEP-1, Anti-Sa, Anti-CarP) that comprise SeroNeg RAdx4 which is designed to enhance diagnosis of RA and early RA as well as predict disease severity
	RA Profile (Rheumatoid Factor and Anti-CCP) with Reflex to SeroNeg RAdx4 (14-3-3 eta, Anti-CEP-1, Anti-Sa, Anti-CarP)
RF Isotypes, IgG, IgA, and IgM by EIA (RDL)	Profile for RA that may increase the specificity and predictive value of RF by Turbidimetry (a separate test) when all three RF isotypes are detected. This profile may also help predict joint damage
	RF IgG, IgA and IgM isotypes are determined by individual enzyme immunoassays
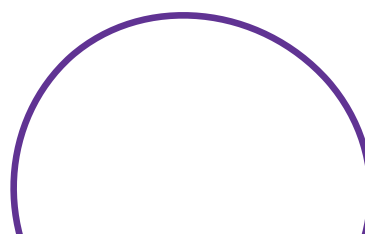
ANA Profiles and Related Tests

Antinuclear antibody (ANA) by indirect immunofluorescence assay (IFA) is the gold standard screening test that detects autoantibodies to the nuclear components of HEp-2 cells.[2] A positive ANA by IFA is reported as titer and pattern. However, IFA patterns are not always specific. Profiles comprised of monospecific assays for individual autoantibodies have diagnostic and potential prognostic utility for several autoimmune diseases.

Profile Name	Profile Description and Components
ANA 12 Plus (RDL) (reflex and Do All options)	Comprehensive diagnostic profile deliberately curated to aid in the differential diagnosis of eight autoimmune disease states: systemic lupus erythematosus (SLE), mixed connective tissue disease (MCTD), Sjögren syndrome (SjS), limited scleroderma, diffuse scleroderma, drug-induced lupus and autoimmune thyroid disease This profile includes unique reflexing strategies designed to detect more true positives and Anti-double stranded DNA by Farr radioimmunoassay which has very high specificity for SLE and is reported as a numeric result with reference range of <8.0 IU/mL
	ANA by IFA is performed and reported with titer and pattern. A lower cutoff 1:40 increases the diagnostic sensitivity This profile is reflexive; if ANA is positive, the following 14 components are performed: Anti-dsDNA Ab by Farr, Anti-Sm, C3 Complement; C4 Complement, Anti-Cardiolipin Ab (IgG, IgA and IgM Isotypes), Anti-U1 RNP, Anti-Ro (SS-A) Ab, Anti-La (SS-B) Ab, RF by Turbidimetry, Anti-CCP (Cyclic Citrullinated Peptide) Ab, Anti-Centromere Ab, Anti-Scl-70 Ab, Anti-Chromatin Ab , Anti-TPO (Thyroid Microsomal Peroxidase) Ab If ANA is negative, an Anti-Ro (SS-A) Ab is performed to catch the small percentage of false negative ANA by IFA. If Anti-Ro is positive, then all profile components are performed Anti-Scl-70 positivity by ELISA is confirmed using a second method to improve its predictive value in identifying diffuse scleroderma
ANA 12 Plus Profile	Do All is not reflexive; it is a separate test code; all components of ANA 12 Plus are always performed and reported
Anti-ENA 6 Plus DFS-70	Unique screening profile with the novel Anti-DFS70 that may help identify SLE, MCTD, SjS, systemic sclerosis, idiopathic myopathy (IIM), and contributes to the inclusion or exclusion of these autoimmune rheumatic diseases. Positive Anti-DFS70, especially when positive in isolation confers a likelihood ratio of 10.9 for the absence of systemic autoimmune rheumatic disease (SARD)[3]
	Anti-DFS70 Ab, Anti-Sm Ab, Anti-U1 RNP Ab, Anti-Ro (SS-A) Ab, Anti-La (SS-B) Ab, Anti-Scl-70 Ab, Anti-Jo-1 Ab
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[4]

Lupus Profiles and Related Tests

SLE, or lupus as it is more commonly known, is a systemic disease that affects hair, skin and internal organs and may cause inflammation and pain in any part of the body. Patients may present with variable clinical systemic manifestations that can imitate other chronic autoimmune diseases, often leading to diagnostic delays or misdiagnosis.

Profile Name	Profile Description and Components
Lupus Diagnostic Profile	Labcorp's Lupus Diagnostic Profile includes highly specific lupus markers to support the diagnosis of SLE
	ANA by IFA with titer and pattern, Anti-dsDNA Ab, Anti-Sm Ab, Anti-U1 RNP Ab, Anti-Ro (SS-A) Ab, Anti-La (SS-B) Ab, Anti-Chromatin Ab, C3 Complement, C4 Complement
Connective Tissue Disease (CTD) Cascade	Labcorp's comprehensive CTD cascade provides testing that differentiates between many acquired autoimmune diseases
	ANA by IFA is performed and reported with titer and pattern. A lower cutoff 1:40 increases the diagnostic sensitivity
	This profile is reflexive; if ANA is positive, the cascade will reflex to additional testing associated with SLE, including complements, antiphospholipid syndrome (APS) and nine monospecific antibodies:
	C3 Complement, C4 Complement, Anti-Beta-2 Glycoprotein I Ab IgG and IgM, Anti-Cardiolipin Ab IgG and IgM, Anti-dsDNA Ab by Farr, Anti-Sm Ab, Anti-U1 RNP Ab, Anti-Ro (SS-A) Ab, Anti-La (SS-B) Ab, Anti-Chromatin Ab, Anti-Centromere Ab, Anti-Scl-70 Ab, Anti-Jo-1 Ab
	If ANA is negative, cascade will reflex to RheumAssure® (RF by Turbidimetry, Anti-CCP Ab, IgG and IgA, 14-3-3 eta protein†) to aid in assessing a possible diagnosis of RA
	If RheumAssure is negative, cascade will reflex to thyroid antibodies (Anti-TPO Ab, Thyroglobulin Ab) to aid in differential diagnosis of hypothyroidism and thyroiditis
	† Positive 14-3-3 eta protein ≥0.2
Lupus Prognostic Profile	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
	Anti-C1q Ab, IgG, Anti-Ribosomal P Ab, Anti-Cardiolipin Ab IgG/IgA/IgM, Anti-Beta-2 Glycoprotein I IgG/IgA/IgM, Anti-PS/PT Ab IgG and IgM
Lupus Monitor Profile	Our Lupus Monitor Profile can help providers observe disease activity while identifying the risk of lupus nephritis
	C3 Complement, C3a Complement, C4 Complement, C4a Complement, Anti-dsDNA Ab by *Crithidia luciliae*, IFA, Anti-C1q Ab, IgG
Anti-dsDNA (Double-stranded) Ab by Farr method (RDL)	The gold standard for DNA antibody testing,[5] 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
Antiphospholid Syndrome (APS), 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
	Anti-Cardiolipin Ab IgG/IgA/IgM, Anti-Beta-2 Glycoprotein I IgG/IgA/IgM, Antiphosphatidylserine IgG and IgM, Activated Partial Thromboplastin Time (aPTT), Dilute Russell's Viper Venom Time (dRVVT), Hexagonal Phospholipid Neutralization, Platelet Neutralization, Lupus Anticoagulant Interpretation

Myositis Profiles and Related Tests

Inflammatory myopathies (or idiopathic inflammatory myopathies), commonly known as myositis, including dermatomyositis, polymyositis, anti-synthetase syndrome and overlap myositis, are systemic diseases that affect multiple organs and can cause severe impairment.

Profile Name	Profile Description and Components
MyoMarker® 3 Plus Profile (RDL)	Most comprehensive diagnostic myositis profile designed to cast the widest net for autoantibodies indicative of dermatomyositis (DM), polymyositis (PM), and anti-synthetase syndrome as well as other diseases that overlap with idiopathic inflammatory myopathies (IIM) This unique profile featuring gold standard RIPA gel radiography aids not only in differential diagnosis but also in characterization of disease pattern, severity and other risks
	Anti-Jo-1 Ab, Anti-PL-7 Ab, Anti-PL-12 Ab, Anti-EJ Ab, Anti-OJ Ab, Anti-MDA5 Ab (CADM-140), Anti-NXP-2 Ab, Anti-TIF-1γ Ab, Anti-SAE1 Ab, Anti-Mi-2 Ab, Anti-SRP Ab, Anti-SS-A 52kD Ab, Anti-Ku Ab, Anti-U1 RNP Ab, Anti-U2 RNP Ab, Anti-U3 RNP (Fibrillarin Ab), Anti-PM/Scl-100 Ab
Anti-HMGCR (RDL)	Marker associated with and specific for necrotizing myopathy most often caused by exposure to statin drugs
Anti-cN1A (RDL)	Marker specific for a distinct form of myositis, sporadic inclusion body myositis (sIBM)

MyoMarker 3 Plus employs RIPA gel radiography. This complex method utilizes immunoprecipitation, gel electrophoresis (SDS-PAGE) and autoradiography to identify radioisotope-labelled proteins from human erythroleukemic cell extracts that are targeted by autoantibodies in patient serum. RIPA gel radiography is a powerful, reliable technology that has been used and refined over more than 30 years to identify many PM/DM autoantibodies with high sensitivity, specificity and reproducibility. It is the original methodology of studies that defined various myositis-specific and myositis-associated antibodies.[8]

Scleroderma Profile and Related Tests

Scleroderma or systemic sclerosis (SS) is a SARD characterized by hardening of the skin and other organs. Testing is centered on diagnosis and differentiation between limited (also known as CREST syndrome with calcinosis, Raynaud's phenomenon, esophageal dysmotility, sclerodactyly and telangiectasia) and diffuse forms.

Profile Name	Profile Description and Components
Scleroderma Comprehensive Plus Profile (RDL)	Most comprehensive scleroderma profile designed to facilitate early diagnosis and intervention as well as differentiation between limited and diffuse forms of scleroderma
	ANA by IFA, Anti-Centromere Ab, Anti-Th/To Ab, Anti-U1 RNP Ab, Anti-U3 RNP (Fibrillarin) Ab, Anti-RNA Polymerase III Ab, Anti-Scl-70 Ab, Anti-PM/Scl-75 Ab, Anti-PM/Scl-100 Ab
Anti-Scl-70 Ab (RDL)	Important marker for scleroderma, incorporating a unique second method that improves positive predictive value

Interstitial Lung Disease Profiles

Interstitial lung disease (ILD) is a frequent manifestation and cause of morbidity and mortality in SARDs including SS, SjS, SLE, RA, idiopathic inflammatory myopathies (IIM) and ANCA-associated vasculitis (AAV). Early detection and diagnosis of ILD and its underlying SARD may offer the opportunity to target management and improve clinical course by suppressing lung inflammation, restricting fibrotic response and limiting irreversible tissue damage.[6]

Profile Name	Profile Description and Components
ILDdx Profile (RDL)	Unique, comprehensive profile to diagnose underlying autoimmune diseases that can cause ILD and to identify rheumatic patients at risk for rapidly progressive ILD
	RF by Turbidimetry, Anti-CCP Ab, Anti-Scl-70 Ab, Anti-PM/Scl-100 Ab, Anti-Jo-1 Ab, Anti-EJ Ab, Anti-OJ Ab , Anti-PL-7 Ab, Anti-PL-12 Ab, Anti-MDA5 Ab, Anti-SRP Ab. Anti-Ku Ab, Anti-SSA 52 kD Ab ANA by IFA, If positive, reflexes to Anti-dsDNA by Farr, Anti-Sm Ab, Anti-U1 RNP Ab, Anti-La (SS-B) Ab, Anti-Ro (SS-A) Ab ANCA by IFA, if positive, reflexes to Anti-MPO Ab and Anti-PR-3 Ab
Interstitial Lung Disease Profile (RDL)	Profile to identify myositis patients at risk for ILD
	Anti-PM/Scl-100 Ab, Anti-Jo-1 Ab, Anti-EJ Ab, Anti-OJ Ab, Anti-PL-7 Ab, Anti-PL-12 Ab, Anti-MDA5 Ab, Anti-SRP Ab, Anti-Ku Ab, Anti-SSA 52 kD Ab

MyoMarker 3 Plus, Scleroderma Comp Plus, ILDdx and Interstitial Lung Profiles employ RIPA gel radiography. RIPA gel radiography is a powerful, reliable technology that has been used and refined for more than 30 years to identify many PM/DM autoantibodies with high sensitivity, specificity and reproducibility. It is the original methodology of studies that defined various myositis-specific and myositis-associated antibodies.[8]

Sjögren's Profile and Related Test

SjS is a SARD characterized by dry eyes, dry mouth and fatigue and can involve multiple organs such as the kidneys, gastrointestinal system, blood vessels, lungs, liver, pancreas and the central nervous system.

Profile Name	Profile Description and Components
Sjögren's Profile Plus (RDL)	Unique Sjögren's profile with Anti-Fodrin Abs to improve early diagnosis
	Anti-Ro (SS-A) Ab; Anti-La (SS-B) Ab; Anti-Fodrin Abs, IgG and IgA
Anti-Fodrin Abs, IgG and IgA (RDL)	Unique markers that may improve the ability to diagnose early stage SjS

ANCA Profile and Other Related Tests

Other autoimmune diseases like ANCA-associated vasculitides (AAV), inflammatory bowel disease (IBD) and autoimmune liver disease may be characterized by the presence of specific autoantibodies.

Profile Name	Profile Description and Components
ANCA Profile (RDL)	Diagnostic profile to identify the AAV, also known as small vessel vasculitides: granulomatosis with polyangiitis (GPA; formerly called Wegener's granulomatosis), microscopic polyangiitis (MPA), and eosinophilic granulomatosis with polyangiitis (EGPA; formerly called Churg-Strauss syndrome)
	ANCA (Anti-Neutrophil Cytoplasmic Ab) by immunofluorescence assay (IFA); Anti-MPO (Myeloperoxidase) Ab and Anti-PR-3 (Proteinase 3) Ab by enzyme immunoassays; Depending on staining patterns on ethanol- and formalin-fixed neutrophils, c-ANCA, p-ANCA or atypical p-ANCA is resulted with titers, if positive. Otherwise, ANCA is reported as negative. ANA by IFA is performed if ANCA-positive to rule out false positive ANCA due to the presence of ANA
Glomerulonephritis (GNP) Profile (RDL)	Diagnostic profile designed to identify underlying autoimmune causes of glomerulonephritis including lupus, AAV, and Anti-GBM (glomerular basement membrane) or Goodpasture's disease
	ANA by IFA, ANCA, Anti-MPO Ab, Anti-PR-3 Ab, Anti-GBM Ab, Anti-dsDNA Ab by Farr, C3 Complement, C4 Complement
Vasculitis Profile (RDL)	Diagnostic profile designed to identify autoimmune causes of vasculitis including lupus, AAV and Anti-GBM disease
	ANA by IFA, ANCA by IFA, Anti-MPO Ab, Anti-PR-3 Ab, Anti-GBM Ab, RF by Turbidimetry, Anti-dsDNA Ab by Farr (RDL), C3 Complement, C4 Complement

Gastroenterology Profiles

Novel serological markers for IBD and autoimmune liver disease improve sensitivity and specificity to aid in differential diagnosis and provide valuable prognostic information about disease behavior.

Profile Name	Profile Description and Components
Inflammatory Bowel Disease (IBD) Expanded Profile	Diagnostic profile including the novel Anti-Glycan Ab designed to help differentiate IBD from non-IBD and Crohn's disease (CD) from ulcerative colitis (UC)[7]
	Anti-Glycan Ab: ASCA (Anti-*Saccharomyces Cerevisiae* Ab, ACCA (Anti-Chitobioside Carbohydrate Ab), ALCA (Anti-Laminaribioside Carbohydrate Ab), AMCA (Anti-Mannobioside Carbohydrate Ab)
Autoimmune Liver Disease Profile (RDL)	Diagnostic profile to identify and differentiate between autoimmune hepatitis types 1 and 2
	ANA by IFA, ANCA by IFA, Anti-Chromatin Ab, Anti-Liver/Kidney Microsomal Ab, Anti-Mitochondrial Ab by IFA, Anti-Mitochondrial M2 Ep (MIT3) Ab, Anti-Smooth Muscle Ab IFA, Anti-Soluble Liver Ag Ab

Autoimmune Test List

Test Name	Test No.
Rheumatoid Arthritis Profiles	
RAdx6 Profile	**520304**
SeroNeg RAdx4 Profile	**520305**
RA Profile (RF, Anti-CCP) With Reflex SeroNeg RAdx4	**520298**
RF Isotypes, IgG, IgA, and IgM by EIA (RDL)	**520178**
ANA and Related Tests	
ANA 12 Plus Profile (RDL)	**520180**
ANA 12 Plus Profile, Do All (RDL)	**520175**
Anti-ENA 6 Plus DFS70 Profile	**520301**
Anti-Dense Fine Speckled Protein 70 kDa (DFS70) Ab	**520313**
Lupus Profiles and Related Tests	
Lupus Diagnostic Profile	**520342**
Connective Tissue Disease (CTD) Cascade	**520340**
Lupus Prognostic Profile	**520555**
Lupus Monitor Profile	**505770**
Anti-dsDNA Ab by Farr, RIA	**520059**
Antiphospholipid Syndrome (APS), Comprehensive	**504400**
Myositis Profile and Related Tests	
MyoMarker® 3 Plus Profile (RDL)	**520085**
Anti-HMGCR Ab (RDL)	**520057**
Anti-cN-1A Ab (NT5c1A) IBM (RDL)	**520061**

Test Name	Test No.
Scleroderma Profile and Related Test	
Scleroderma Comprehensive Plus Profile (RDL)	**520130**
Anti-Scl-70 Ab (RDL)	**520012**
Interstitial Lung Disease Profiles	
ILDdx Profile (RDL)	**520210**
Interstitial Lung Disease Profile (RDL)	**520202**
Sjögren's Profile and Related Test	
Sjögren's Profile Plus (RDL)	**520196**
Anti-Fodrin Antibodies, IgG and IgA (RDL)	**520134**
ANCA Profile and Other Related Tests	
ANCA Profile (RDL)	**520149**
Glomerulonephritis (GNP) Profile (RDL)	**520194**
Vasculitis Profile (RDL)	**520293**
Gastroenterology Profiles	
Inflammatory Bowel Disease (IBD) Expanded Profile	**162045**
Autoimmune Liver Disease Profile (RDL)	**520197**

All individual components are available to order separately.
Please visit **labcorp.com/dos**

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