



RHEUMATOLOGY SERVICES

Rheumatoid arthritis comprehensive testing capabilities



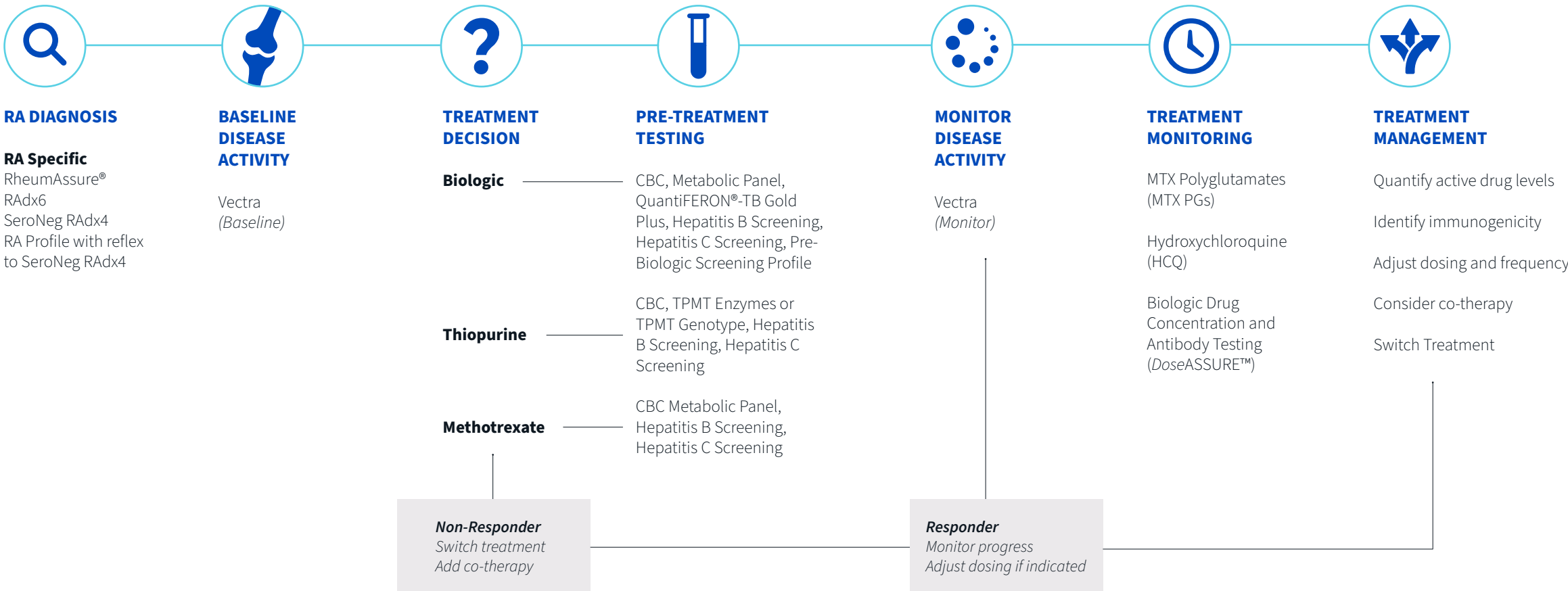
Rheumatoid Arthritis

Rheumatoid arthritis (RA) affects an estimated 1.5 million people in the United States.¹ For most people with RA, early diagnosis and treatment can control joint pain and swelling and lessen joint damage. Labcorp is your single source solution for RA diagnosis, disease activity monitoring and management of treatment.

Trusted Source for the Rheumatology Specialist

Labcorp offers a comprehensive testing menu and numerous service benefits to support the needs of a rheumatology practice:

- Experienced medical affairs professionals are available for consultation and educational programs
- Multiple connectivity options
- Nearly 2,000 patient service centers nationwide
- Extensive network of managed care health plans
- Broad capabilities in autoimmune testing
- Labcorp offers a dedicated Rheumatology Services Hotline 800-338-1918



RA Diagnosis

Early rheumatoid arthritis (RA) diagnosis and initiation of disease-suppressing therapy may improve clinical outcomes and reduce the accrual of joint damage and disability.² Labcorp offers several RA-specific markers that, when used in combination, provide industry-leading sensitivity and help support an early diagnosis of RA.

Prognosis is dependent on early, accurate diagnosis and establishing an effective treatment plan.³ Diagnosis and classification of RA has relied heavily on anti-cyclic citrullinated peptide (Anti-CCP) and rheumatoid factor (RF) IgM.² New markers are available to better identify patients with RA, stratify patients for risk of joint destruction and/or radiographic progression, and to monitor disease activity and effectiveness of treatment.

Profiles

RheumAssure®

Labcorp's RheumAssure panel contains Rheumatoid Factor (RF), Cyclic Citrullinated Peptide (CCP) Antibodies, and 14-3-3 eta protein tests.

- Used together, these three markers are able to diagnose established RA with a sensitivity of 88%-96% and early RA with a sensitivity of 78%- 92%^{3,4}
- Elevation of one or more RheumAssure markers is consistent with an RA diagnosis and if all three markers are negative, a diagnosis is less likely

RAdx6 Profile

The RAdx6 combines four novel markers (14-3-3 eta, Anti-Sa, Anti-CEP-1, and Anti-CarP) with two traditional markers (RF IgM and Anti-CCP) to enhance diagnosis in early or established RA, and help predict disease severity.

- Disappearance or decrease of 14-3-3 eta and/or Anti-Sa with treatment is associated with less radiographic progression
- In pre-clinical RA, Anti-CEP-1 with Anti-CCP antibodies significantly raises the risk of imminently developing clinical RA
- Anti-CarP may predict the development of RA independently of Anti-CCP and may be present years before the onset of symptoms in RA

SeroNeg RAdx4 Profile and RA Profile (RF and Anti-CCP) reflex to SeroNeg RAdx4

Diagnostic and prognostic panels designed to complement traditional RF and Anti-CCP testing. The profile consists of 14-3-3 eta, Anti-Sa, Anti-CEP-1, and Anti-CarP.

- Enhances RA diagnosis and helps predict disease severity
- Helps identify RA in Anti-CCP-negative and IgM-RF-negative patients and in the diagnosis of early RA

Disease activity monitor and prognostic tool

Vectra® by Labcorp

Achieving a state of disease remission in rheumatoid arthritis (RA) is a primary treatment goal. Until the desired treatment target is reached, drug therapy should be adjusted at least every 3 to 6 months. The desired treatment target should be maintained throughout the remaining course of the disease. Vectra provides an objective measure of RA inflammation and can be used to complement other disease activity measures.

Vectra is an advanced blood test that objectively measures inflammation caused by RA. Vectra provides a personalized score by measuring 12 biomarkers and incorporates information on age, gender and adiposity to measure RA inflammation and predict future risk of radiographic progression.⁵

Vectra Cardiovascular Risk provides a personalized assessment of inflammation to predict an RA patient's risk of a cardiovascular event in the next 3 years.⁶

Vectra is intended to be used at therapy initiation, change in drug therapy, and to monitor a patient once they achieve low disease activity.



RA Treatment Monitoring

Although RA treatment is multifaceted, medications play an important role in patient management. Newly developed laboratory assays aid physicians in monitoring use and maximizing effectiveness of both disease-modifying anti-rheumatic drugs (DMARDs) and biologics.

Methotrexate Polyglutamates

Methotrexate (MTX) is subject to wide pharmacokinetic variability. About 30% of patients do not respond to MTX treatment or experience adverse effects.⁷ Testing for MTX PGs can help assess patient compliance and determine correct dosing to achieve therapeutic levels and clinical response.⁸

Hydroxychloroquine, Whole Blood

Hydroxychloroquine (HCQ) concentrations may be useful in achieving maximal clinical benefit while minimizing long-term retinal toxicity in lupus and other chronic autoimmune diseases. Monitoring HCQ may also improve adherence.

Thiopurine Drug

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.⁹ The FDA-approved label recommends testing consideration for the most common TPMT gene mutations (genotype) or TPMT activity (phenotype) before beginning treatment due to potentially severe bone marrow toxicity.



Monitoring Biologics

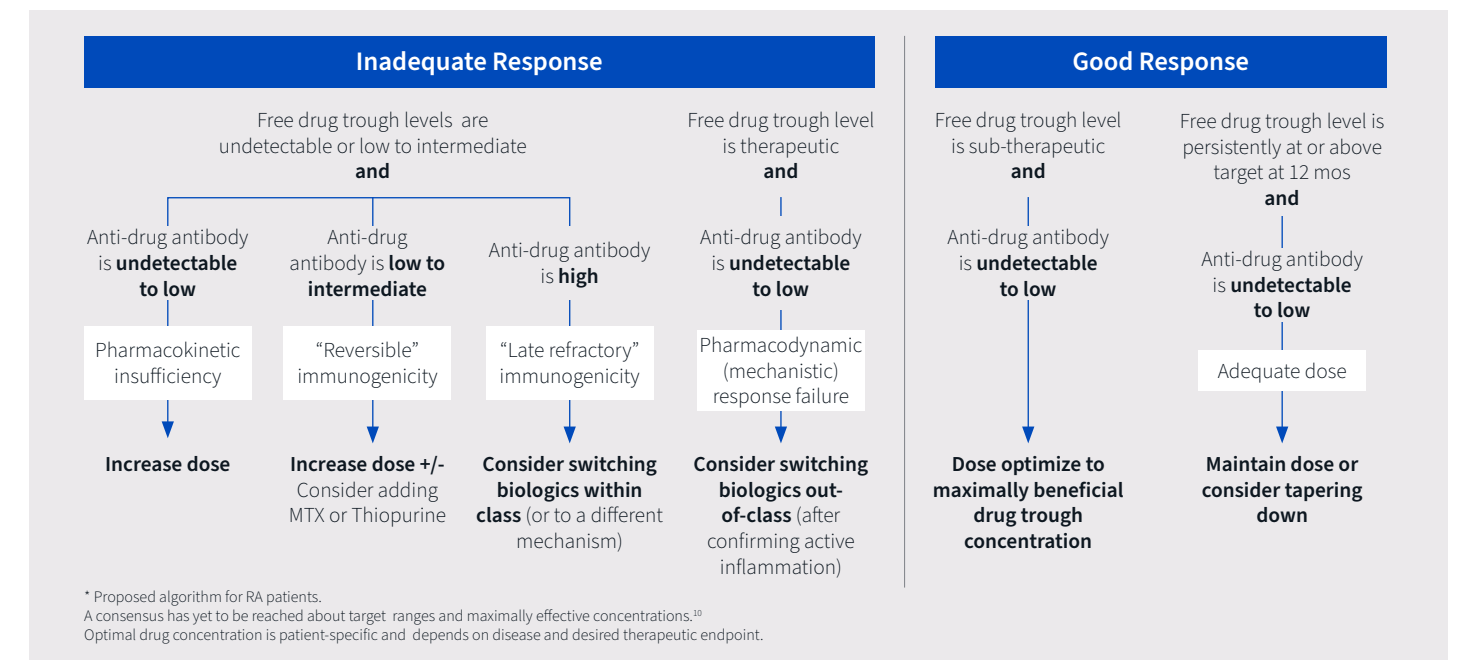
Therapeutic drug monitoring for biologics is a valuable tool to evaluate dose and tailor dose adjustments to your individual patient.¹⁰⁻¹⁴ Dosing by weight and empiric dose adjustment may be inefficient and suboptimal.^{11,14} DoseASSURE™, Labcorp's portfolio of biologics monitoring assays, may help physicians optimize biological therapy using a personalized, patient-specific approach by:

- Aiding in titrating doses and adjusting frequency to maximize effectiveness^{10,11}
- Helping differentiate non-compliance and under-treatment from other causes of lack of response¹²
- Assisting in preventing and managing loss of response due to immunogenicity^{10,13}
- Minimizing cost to patient by avoiding unhelpful dose escalation¹⁴
- Predicting which patients are likely to retain long-term response¹⁵

Biologic Therapy

Labcorp offers serum measurement of drug and anti-drug antibodies for patients on biologic drug therapy. Drug and anti-drug antibody levels provide the pharmacokinetic and immunogenic assessment that discerns the underlying mechanism of an inadequate response to a biologic drug. Testing may be ordered at any time during therapy, though sample collection before the next infusion or injection is recommended.

Patient on Biologic*



Rheumatoid Arthritis and Related Testing

Test Name	Test No.
14-3-3 eta, Rheumatoid Arthritis	504550
Anti-Carbamylated Protein (CarP) Antibody	520311
Anti-CCP (Cyclic Citrullinated Peptide) Antibodies	164914
Anti-CEP-1 Ab, IgG (RDL)	520133
Anti-Sa Ab, IgG (RDL)	520081
Hydroxychloroquine, Whole Blood	504814
Methotrexate polyglutamates	504104
QuantIFERON®-TB Gold Plus	182879
RA Profile with reflex to SeroNeg RAdx4 Profile	520298
RAdx6 Profile	520304
RheumAssure®	504509
Rheumatoid Factor (RF)	006502
SeroNeg RAdx4 Profile	520305
Thiopurine Metabolites	503800
Thiopurine Methyltransferase (TPMT), Enzyme Activity, Erythrocytes	510750
TPMT and NUDT15 Genotyping	512300
Vectra®	504965
Vectra® with CV Risk	504980
DoseASSURE™	
Adalimumab and Anti-Adalimumab Antibody (Serial Monitor), DoseASSURE™ ADL	503890
Certolizumab and Anti-Certolizumab Antibody, DoseASSURE™ CTZ	504627
Etanercept and Anti-Etanercept Antibody (Serial Monitor), DoseASSURE™ ETN	504245
Golimumab and Anti-Golimumab Antibody, DoseASSURE™ GOL	504563
Infliximab and Anti-Infliximab Antibody (Serial Monitor), DoseASSURE™ IFX	503870
Rituximab and Anti-Rituximab Antibody, DoseASSURE™ RTX	504355
Ustekinumab and Anti-Ustekinumab Antibody, DoseASSURE™ UST	504594
Pre-Biologic Screening Profile	144441

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