

Autoimmunity

Setting the standard

EliA™ autoimmune rheumatic disease testing:

Primary care considerations

Autoimmune rheumatic diseases (ARDs) are chronic inflammatory autoimmune disorders which include rheumatoid arthritis (RA), systemic lupus erythematosus (SLE), Sjögren's syndrome (SS), systemic sclerosis (SSc), idiopathic inflammatory myopathies (IIM), and mixed connective tissue disease (MCTD).¹ Rheumatologic conditions necessitate prompt diagnosis and early treatment to help avoid permanent end-organ damage.^{2,3}

Optimized blood testing in primary care can help:^{1,3-5}



Promote timely and accurate diagnosis



Ensure better patient outcomes

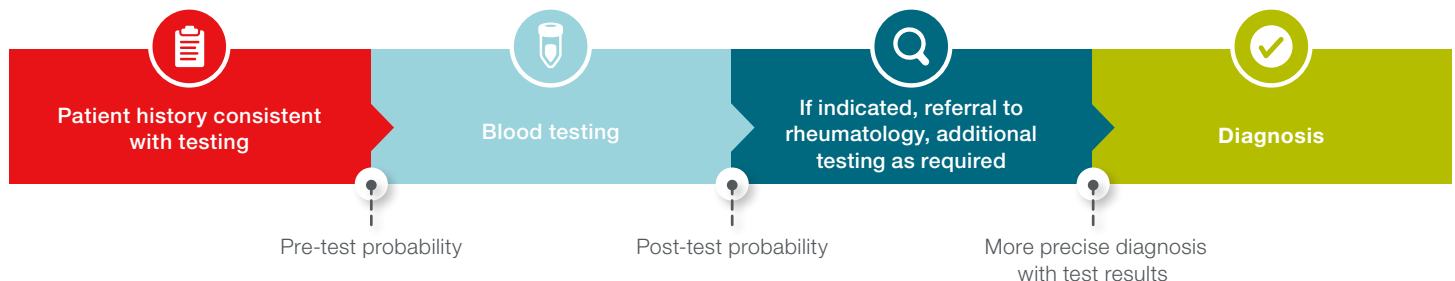


Generate appropriate referrals

Did you know?

Autoimmune related testing cascades have been shown in one study, to **reduce rheumatologist referral wait times by as much as 50%.**³

Steps to a diagnosis^{1,3,5}



Consider rheumatic disease serology profiles:

Depending on a patient's symptoms, one of the following **primary care algorithms** may be appropriate.

Connective tissue disease ^{4,6-8**}	Rheumatoid arthritis ^{9†}	Autoimmune rheumatic diseases ^{4,6-8,10†}
Defined ANA screen + Double stranded DNA (dsDNA)	Rheumatoid Factor (RF) IgM + Cyclic citrullinated peptide (CCP)	Defined ANA screen + Double stranded DNA (dsDNA) + Cyclic citrullinated peptide (CCP)
If positive, reflex to* - SS-B/La - Smith (Sm) - Ribonucleoprotein (RNP) - SS-A/Ro - Scl-70 - Jo-1 - Centromere (CENP)		If positive, reflex to* - SS-B/La - Smith (Sm) - Ribonucleoprotein (RNP) - SS-A/Ro - Scl-70 - Jo-1 - Centromere (CENP)

*The Connective Tissue Disease or ARDs profile can be run without or alongside an ANA-Screen (IFA Hep-2).⁵ Reflex testing should be specific to the tests covered within the defined ANA screen.

†Official Well product names for tests mentioned within this document are EliA Symphony® Well (Defined ANA screen), EliA dsDNA Well, EliA RF IgM Well, EliA CCP Well, EliA U1RNP Well, EliA Jo-1 Well, EliA Smd²-S Well, EliA Ro Well (52kDa, 60kDa), EliA La Well, EliA CENP Well, EliA Scl-70° Well

Testing profile interpretation considerations:

CCP and/or RF IgM	+	- Supportive of the diagnosis of rheumatoid arthritis^{2,9} - Consider referral to rheumatologist, as early intervention is essential for proper patient management^{2,9}
	—	Negative serology does not eliminate the possibility of RA, but does decrease the likelihood of having RA²
Defined ANA screen and/or dsDNA	+	- Autoimmune disease more likely, consider referral to rheumatologist^{1,7} - Individual autoantibodies have increased prevalence in certain connective tissue diseases and most are included in certain classification criterias as follows: dsDNA: Systemic lupus erythematosus^{1,11} SS-A/Ro: Systemic lupus erythematosus, Sjögren's syndrome, idiopathic inflammatory myopathies^{1,12} SS-B/La: Systemic lupus erythematosus and Sjögren's syndrome¹ RNP: Systemic lupus erythematosus, idiopathic inflammatory myositis, systemic sclerosis, mixed connective tissue disease^{1,13} Scl-70: Systemic sclerosis^{1,13} Jo-1: Idiopathic inflammatory myopathies^{1,14} CENP: Systemic sclerosis^{1,13} Sm: Systemic lupus erythematosus^{1,11}
	—	- Negative serology does not eliminate the possibility of autoimmunity, but does decrease the likelihood⁷ If there is a high suspicion of autoimmunity, consider ANA-IIF testing⁷ If there is a low suspicion of autoimmunity, consider alternative diagnoses⁷

EliA™ assays help provide diagnostic clarity for patients with autoimmune rheumatic disorders^{7,8,15} and, in the case of EliA CCP IgG, can even support the prediction of disease prior to symptom onset.¹⁵

References

1. Goldblatt F, O'Neill SG. Clinical aspects of autoimmune rheumatic diseases. *Lancet*. 2013 Aug 31;382(9894):797-808. doi: 10.1016/S0140-6736(13)61499-3. PMID: 23993190. 2. Cush JJ. Rheumatoid Arthritis: Early Diagnosis and Treatment. *Med Clin North Am*. 2021 Mar;105(2):355-365. doi: 10.1016/j.mcna.2020.10.006. PMID: 33589108. 3. Chen, Lei et al. "Algorithmic Approach With Clinical Pathology Consultation Improves Access to Specialty Care for Patients With Systemic Lupus Erythematosus." *American journal of clinical pathology* vol. 146,3 (2016): 312-8. doi:10.1093/ajcp/aqw122 4. Bizzaro N, et al. The association of solid-phase assays to immunofluorescence increases the diagnostic accuracy for ANA screening in patients with autoimmune rheumatic diseases. *Autoimmun Rev*. 2018 Jun;17(6):541-547. doi: 10.1016/j.autrev.2017.12.007. Epub 2018 Apr 7. PMID: 29631063. 5. Littlejohn EA, Monrad SU. Early Diagnosis and Treatment of Rheumatoid Arthritis. *Prim Care*. 2018 Jun;45(2):237-255. doi: 10.1016/j.pcp.2018.02.010. PMID: 29759122. 6. Tebo AE. Recent Approaches To Optimize Laboratory Assessment of Antinuclear Antibodies. *Clin Vaccine Immunol*. 2017 Dec 5;24(12):e00270-17. doi: 10.1128/CVI.00270-17. PMID: 29021301; PMCID: PMC5717181. 7. Van Praet JT, et al. Validation of a new screening strategy for anti-extractable nuclear antigen antibodies. *Clin Exp Rheumatol*. 2009 Nov-Dec;27(6):971-6. PMID: 20149314. 8. González C, et al. Laboratory screening of connective tissue diseases by a new automated ENA screening assay (EIA Symphony) in clinically defined patients. *Clin Chim Acta*. 2005 Sep;359(1-2):109-14. doi: 10.1016/j.cccn.2005.03.042. PMID: 15894301. 9. Aletaha D, et al. 2010 Rheumatoid arthritis classification criteria: an American College of Rheumatology/European League Against Rheumatism collaborative initiative. *Arthritis Rheum*. 2010 Sep;62(9):2569-81. doi: 10.1002/art.27584. PMID: 20872595. 10. Mayo Clinic Laboratories. Connective Tissue Disease Cascade. Rochester, MN. 2020. www.mayocliniclabs.com/tt-mmfiles/Connective_Tissue_Disease_Cascade_CTDC_.pdf. Accessed 13 October 2022. 11. Aringer M, et al. 2019 European League Against Rheumatism/American College of Rheumatology classification criteria for systemic lupus erythematosus. *Ann Rheum Dis*. 2019 Sep;78(9):1151-1159. doi: 10.1136/annrheumdis-2018-214819. Epub 2019 Aug 5. PMID: 31383717. 12. Shiboski CH, et al; International Sjögren's Syndrome Criteria Working Group. 2016 American College of Rheumatology/European League Against Rheumatism classification criteria for primary Sjögren's syndrome: A consensus and data-driven methodology involving three international patient cohorts. *Ann Rheum Dis*. 2017 Jan;76(1):9-16. doi: 10.1136/annrheumdis-2016-210571. Epub 2016 Oct 26. PMID: 27789466. 13. van den Hoogen F, et al. 2013 classification criteria for systemic sclerosis: an American college of rheumatology/European league against rheumatism collaborative initiative. *Ann Rheum Dis*. 2013 Nov;72(11):1747-55. doi: 10.1136/annrheumdis-2013-204424. PMID: 24092682. 14. Lundberg IE, et al; International Myositis Classification Criteria Project Consortium, the Euromyositis Register, and the Juvenile Dermatomyositis Cohort Biomarker Study and Repository (UK and Ireland). 2017 European League Against Rheumatism/American College of Rheumatology Classification Criteria for Adult and Juvenile Idiopathic Inflammatory Myopathies and Their Major Subgroups. *Arthritis Rheumatol*. 2017 Dec;69(12):2271-2282. doi: 10.1002/art.40320. Epub 2017 Oct 27. 15. Kokkonen H, et al. Antibodies of IgG, IgA and IgM isotypes against cyclic citrullinated peptide precede the development of rheumatoid arthritis. *Arthritis Res Ther*. 2011 Feb 3;13(1):R13. doi: 10.1186/ar3237. PMID: 21291540; PMCID: PMC3241357.

Learn more at thermofisher.com/EliA

© 2023 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified. 317102.AI.US.EN.v1.23

thermo scientific