

ESOTERIX UPDATE

A NEWSLETTER FOR CLIENTS

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Holiday Closure

In observance of Independence Day, all Esoterix facilities will be closed on Tuesday, July 4, 2017. For questions regarding specimen handling, please contact Esoterix client services at 800-444-9111.

New Procedures

RheumAssure804509

Methodology

RA Factor: Immunoturbidimetry

CCP Antibodies: ELISA

14-3-3 eta protein: ELISA

Turnaround Time See individual assays

CPT 83520; 86200; 86431

Performing Location Endocrine Sciences

Specimen Serum

Volume 2 mL

Pediatric Minimum Volume 0.8 mL (**Note:** This volume does **not** allow for repeat testing.)

Container Red-top or gel-barrier tube

Collection Serum must be separated from cells within 45 minutes of venipuncture. Transfer into plastic transport tube.

Storage Instructions Frozen preferred, refrigerated acceptable

Reference Interval

RA Factor: <14 IU/mL

CCP Antibodies IgG, IgA: Units

Negative: <20

Weak positive: 20 - 39

Moderate positive: 40 - 59

Strong positive: >59

14-3-3 eta protein: <0.2 ng/mL

Use Aid in the diagnosis of rheumatoid arthritis (RA)^{1,2}

Limitations Results of this panel should be used in conjunction with clinical findings and other laboratory tests.

"It is acknowledged that an individual patient may meet the definition of RA without requiring that all tests be performed. For example, patients with a sufficient number of joints involved and longer duration of symptoms will meet criteria regardless of their serologic or acute-phase response status. The classification criteria can be applied to any patient or otherwise healthy individual, as long as 2 mandatory requirements are met: First, there must be evidence of currently active clinical synovitis (i.e., swelling) in at least 1 joint as determined by an expert assessor. Second, the criteria may be applied only to those patients in whom the observed synovitis is not better explained by another diagnosis."⁶

Additional Information This RheumAssure panel is comprised of three tests: RA Factor, CCP Antibodies, and 14-3-3 eta protein.

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%.^{1,2}

RA factor (also called RF) is elevated in established RA (sensitivity 72-85%)^{2,3} and in early RA (sensitivity 44-63%).^{1,4} Its specificity for RA is 80%.³

CCP Antibodies have similar sensitivities for established RA (66-79%) and early RA (59%)^{2,3} but higher specificity (90-96%).^{3,5}

Serum 14-3-3 eta protein is elevated in both established RA (sensitivity 77%) and early RA (sensitivity 59-64%).^{1,2} It may provide a 15-20% incremental benefit in identifying early RA.^{1,4}

Therefore, elevation of one or more markers of RheumAssure is consistent with a diagnosis of rheumatoid arthritis. When all three markers are negative, an RA diagnosis is less likely.

Footnotes

1. Maksymowych WP, Boire G, van Schaardenburg D, et al. 14-3-3η Autoantibodies: Diagnostic Use in Early Rheumatoid Arthritis. *J Rheumatol* 2015;42(9):1587-1594. PubMed 26178283
2. Maksymowych WP, Naides SJ, Bykerk V, et al. Serum 14-3-3η is a novel marker that complements current serological measurements to enhance detection of patients with rheumatoid arthritis. *J Rheumatol* 2014;41(11):2104-2113. PubMed 25128504
3. Lee DM, Schur PH. Clinical utility of the anti-CCP assay in patients with rheumatic diseases. *Ann Rheum Dis* 2003 Sep;62(9):870-874. PubMed 12922961
4. Carrier N, Marotta A, de-Brum-Fernandes AJ, et al. Serum levels of 14-3-3η protein supplement C-reactive protein and rheumatoid arthritis-associated antibodies to predict clinical and radiographic outcomes in a prospective cohort of patients with recent-onset inflammatory polyarthritis. *Arthritis Res Ther* 2016 Feb 1;18:37. PubMed 26832367
5. Dubucquoi S, Solau-Gervais E, Lefranc D, et al. Evaluation of anti-citrullinated filaggrin antibodies as hallmarks for the diagnosis of rheumatic diseases. *Ann Rheum Dis* 2004 Apr;63(4):415-419. PubMed 15020336
6. American College of Rheumatology. The 2010 ACR-EULAR Classification Criteria for Rheumatoid Arthritis. http://www.rheumatology.org/practice/clinical/classification/ra/ra_2010.asp. Accessed June 20, 2014.

Updates to the Esoterix Test Menu

Test Name	Test No.	Change (Only fields that change are included here.)
Plasminogen Activator Inhibitor-1 (PAI-1) Activity	300126	This assay has been reinstated and now is available for testing.
Platelet HPA-1a/1b Antibody Identification	300524	Effective August 15, 2017, this test will no longer be available. No alternative testing is planned at this time due to test kit being discontinued by manufacturer.
Thrombotic Marker Profile	300907	Effective June 26, 2017, this profile is no longer available. As an alternative, Esoterix offers Markers of Coagulation Activation (300939) . Visit the Test Menu at www.esoterix.com for more details.

For up-to-date test information, please consult the Esoterix Test Menu at www.esoterix.com. For additional information, call Esoterix client services at 800-444-9111.



The CPT codes included in this publication are in accordance with *Current Procedural Terminology*, a publication of the American Medical Association. CPT codes are provided here for the convenience of our clients; however, correct coding often varies from one carrier to another, and specific carriers may be billed using codes other than those shown. Clients who bill for services should verify the codes with the applicable payer to confirm that their use is appropriate in each case.