DIAGNOSTIC LABORATORY SERVICES, INC.

Technical Memorandum

TO: Physicians, Staff

From: Wesley Kim, MD, Medical Director

Date: December 8, 2011

Subject: Anti-cyclic citrullinated peptide (anti-CCP)

Antibody to cyclic citrullinated peptide (anti-CCP), is a test used to help diagnose, and aid in prognosis, in patients with rheumatoid arthritis. Beginning 12/20/11, DLS will be changing anti-CCP testing from the current manual immunoassay method (DIASTAT anti-CCP) to an automated immunoassay method (ROCHE anti-CCP). Extensive in-house correlation between the two methods shows greater than 95% qualitative agreement between the two methods on multiple patient samples. Based on manufacturer normal and disease population studies, the two methods also show comparable clinical performance (DIASTAT: sensitivity 75%, specificity 95%; ROCHE: sensitivity 73%, specificity 97%). In addition, the use of the new automated method will help reduce test variability, improve precision, improve turn-around-time and efficiency, and reduce error.

The reference range for the new assay will be slightly different from the current assay. It is important to note, anti-CCP values determined on patient samples by different testing methods cannot be directly compared with one another. Therefore, a comment to anti-CCP report will be added:
"The following results were obtained with the Elecsys Anti-CCP assay. Results from assays of other manufacturers cannot be used interchangeably."

Test Information:

TEST	ORDER CODE	OLD REFERENCE RANGE	NEW REFERENCE RANGE	UNITS
Anti-CCP	4349	<5	<17	U/mL

DLS will monitor the new method very closely and make adjustments to ensure optimal performance. Because of this, it is important that any feedback, questions, or concerns that you may have in regards to laboratory performance, be immediately communicated to our client services, your marketing representative, or a DLS Laboratory Director, so that they may be addressed to ensure the quality and safety of laboratory results.

You may contact DLS Client Services at 589-5101, or Dr. Wesley J. Kim at 589-5131.