

## MEMORANDUM

**To:** All Regional Medical Laboratory, Inc. Clients  
**From:** Regional Medical Laboratory, Inc  
Cindi R Starkey, MD, PhD, Medical Director  
Patti Loykasek, BS, HTL(ASCP), QIHC(ASCP), Manager of Molecular Diagnostics  
**Date:** April 14, 2016  
**Subject:** Changes for the current cystic fibrosis genetic test, CYSTIC GEN 1515700

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Regional Medical Laboratory, Inc. (RML) has been informed effective immediately that our current Cystic Fibrosis DNA Analysis test has been recalled and discontinued by the test manufacturer. We are in the process of validating a new test with a more comprehensive mutation screening panel to be performed at RML, with anticipation of completion of the switch by May 15, 2016. In the interim, we will be sending this test out to a reference laboratory. This interim test will be very similar to the new test we are bringing in-house but will include an expanded number of mutations evaluated; thus the reporting format will be somewhat different. Expected turnaround time for reporting will be 7-14 days. Please continue to order the same test as previously, the Cystic Fibrosis, DNA Analysis, order name CYSTIC GEN. The specimen requirement has not changed.

If you have any questions, concerns, or have any problems during this transition, please do not hesitate to contact either Dr. Cindi Starkey, Medical Director of RML and Chief of Molecular Diagnostics, or Patti Loykasek, Manager of Molecular Diagnostics, at 918-744-2553.