Technical Bulletin

October 12, 2015

Automatic Reflex of Negative Group A Strep Rapid Tests to Culture (Test Code 1731)

Dear Client,

Effective immediately, Southeast Clinical Laboratories will begin to automatically reflex all negative Rapid Direct tests for Group A Streptococcus Culture.

Rapid tests for the detection of Group A Strep may provide valuable, time sensitive adjunctive diagnostic information. However, although the sensitivity and specificity of rapid test for Group A Strep have improved to 97% and 95%, respectively, multiple specialty societies, including the American Academy of Pediatrics, the American Heart Association, and the Infectious Disease Society of America, recommend additional testing by throat culture in children that initially test negative by rapid Strep test methods. (1,2)

In addition, the FDA has enforced these recommendations since no rapid streptococcal test has been cleared, approved, or waived through the regulatory process as a standalone test in the face of locally suppurative disease and has determined that the lack of a backup method for a negative rapid Group A Strep test result constitutes off label use. (2)

In accordance with published consensus guidelines and product labeling, Southeast Clinical Laboratories will begin to automatically reflex all Negative Group A Rapid Screens (Test Code 1731) to Group A Streptococcus Culture (Test Code 4006) at an additional charge (CPT 87081). The test name will be updated to Group A Streptococcus Rapid Screen Reflex Culture to reflect this change. All Positive results will result out as Positive. All Negative results will result out as Negative with a note that the specimen has been reflexed to culture.

We recommend the use of the eSwab for the pharyngeal swab, since this specimen type can easily be reflexed to culture if there is a negative rapid Strep test. However, non-gel 2 swab systems will also be accepted as an acceptable specimen type.

If you have any questions, please contact Customer Service at 205-918-7156. As always, thank you for your continued business.

References:

1. Package insert, Cardinal Health Strep A Dipstick – Rapid Test.
2. FDA, Use of Backup Testing for Negative Rapid Group A Strep Tests, <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm109407.htm>