QUIDEL®
CORPORATION

Technical Bulletin

Group A Streptococcal Rapid Diagnostic Tests: Confirmatory Throat Culture Required in Patients with Negative Test Results

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The FDA requires that negative patient Group A Streptococcal Rapid Diagnostic Tests are confirmed with a throat culture. Refer to the excerpt below explaining this point. You may also reference the following link: http://www.fda.gov/medicaldevices/safety/alertsandnotices/tipsandarticlesondevicesafety/ucm109407.htm. This requirement is also reflected in all the QuickVue® Strep A kit package inserts.

"Since no rapid test has been cleared, approved, or waived through the regulatory process as a stand alone test in the face of locally suppurative disease, lack of a backup method for a negative rapid GAS test result constitutes off label use."

Please contact Quidel Technical Support at 800-874-1517 (USA only), 858-552-1100 or technicalsupport@quidel.com if you have any questions regarding the QuickVue Strep A tests or any other Quidel product. Our hours of operation are Monday-Friday, 7:00 a.m.-5:00 p.m., Pacific Time.

You may also visit our website at www.quidel.com for information on Quidel's line of Rapid Diagnostics, Bone Health and Autoimmune & Complement product lines. Other product information available on our website includes: CPT codes, CLSI Procedure Guidelines, MSDS, and package inserts.