Technical Bulletin

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

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The FDA states, "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." Quidel's Solana® GAS and Solana Strep Complete molecular assays have been cleared by the FDA and do NOT require culture confirmation of a negative test result, and therefore can be used to confirm QuickVue® and Sofia® Group A Strep tests. Refer to the following link for more information:

https://wayback.archive-it.org/7993/20170112085448/http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm109407.htm

Follow-up culture or molecular testing of negative results is recommended in the following kits:

QuickVue Dipstick Strep A
QuickVue+® Strep A
QuickVue In-Line® Strep A
Sofia Strep A FIA
Sofia Strep A+ FIA

Please contact Quidel Technical Support at 800.874.1517 (in the U.S.), 858.552.1100 (outside the U.S.) or technicalsupport@quidel.com if you have any questions regarding Quidel's Group A Strep tests or any Quidel product. Our hours of operation are Monday through Friday, 7:00 a.m. to 5:00 p.m. Pacific Time.

You may also visit our website at **quidel.com** for information on Quidel's line of Rapid Diagnostics, Molecular Diagnostics, Cell Culture and Specialty Products (Bone Health and Autoimmune & Complement). Other product information available on our website includes: CPT codes, CLSI procedure guides, SDS, and Package Inserts.

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