

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D1097101	(X3) Date Survey Completed 09/09/2019
Name of Provider or Supplier St George's Lab	Street Address, City, State 88 Osborne Street, Johnstown, PA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on review of the equipment maintenance records, observation of the laboratory and interview with testing personnel (TP) #1, the laboratory failed to establish and document maintenance protocols for 6 of 6 Thermo Fishers thermometers and 4 of 4 timers from 1/23/2018 to the date of survey. Findings Include: 1. On the day of survey, 09/09/2019, the laboratory could not provide polices regarding how to assess and document maintenance protocols for the Thermo Fishers thermometers and timers. 2. While on tour of the laboratory, 6 of 6 Thermo Fishers thermometers were observed with past due maintenance stickers, that held reagents for all laboratory testing and patient specimens. 3. The Thermo Fishers thermometers listed below, were due for maintenance on the following dates: - 04/22/2009 - 03/25/2012 - 09/09/2012 - 10/21/2012 - 11/14/2012 - 11/26/2015 4. The laboratory could not provide maintenance records for 4 of 4 timers in use. 5. TP#1 confirmed the findings above on 09/09/2019 around 2:30 pm.</p>
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations</p>

Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of quality control (QC) records, and interview with testing personnel (TP) #1, the laboratory failed to perform positive and negative QC each day of patient testing on 69 of 69 Lyme Fluorescent Immunoassay (FIA) tests performed from May 2019 to the date of survey. Findings Include: 1. On the day of survey, 09/09/2019, review of the Quidel Sofia 2, Lyme FIA QC records revealed, the laboratory did not perform positive and negative QC each day of patient testing on 69 of 69 Lyme FIA tests performed from May 2019 to September 9th, 2019. 2. TP#1 confirmed the finding above on 09/09/2019 around 2:00 pm.