

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D0522746	(X3) Date Survey Completed 04/12/2023
Name of Provider or Supplier Tanner Clinic - Layton	Street Address, City, State 2121 N 1700 W, Layton, UT	
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
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</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: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, record review, and interview with the technical supervisor (TS), pipette calibration check was not performed per protocol for the Group B Strep PCR assay performed on the BD Max instrumentation. The laboratory performs approximately 900 Group B Strep tests per year. Findings include: 1. Direct observation on 4/12/23 at approximately 3:10 PM, revealed a calibration check sticker on Fisherbrand Elite 10-100 L pipette with serial number Q419087 which stated calibration was due on 03/2022. 2. Review of the Fisherbrand Elite Pipette Manual revealed that the pipette should be checked every three months. 3. Record review did not include pipette calibration checks for pipette Q419087. 4. In an interview on 4/12/23 at approximately 3:15 PM, TS1 confirmed pipette Q419087 was utilized for patient testing for the Group B Strep PCR assay when the pipette was past its calibration check due date.</p>