

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D2014067	(X3) Date Survey Completed 01/10/2023
Name of Provider or Supplier St John's United Diagnostic Laboratory	Street Address, City, State 502 North 30th Street, Billings, MT	
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 observation, review of maintenance documentation, policy and procedures, and interview with technical supervisor (TS) #1 the laboratory failed to follow their procedures and verify the accuracy of two of two multichannel pipettes used in the laboratory from January 1, 2021, to January 10, 2023. Findings: 1. Observed two of two multichannel pipettes (1250 L and 125 L) in the laboratory available for use with no verification labels. 2. A review of laboratory maintenance records lacked documentation of annual verification checks for the multichannel pipettes for years 2021 and 2022. 3. A review of General Maintenance procedure revealed the laboratory failed to follow procedures as stated, "Pipettes accuracy is required to be verified annually or more frequently if required by manufacturer." 4. An interview with the (TS) #1 on January 10, 2023, at 11:20 AM, confirmed the laboratory failed to verify the accuracy of two multichannel pipettes from January 1, 2021, to January 10, 2023.</p>