

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0698823	(X3) Date Survey Completed 01/24/2023
Name of Provider or Supplier Franklin County Medical Center	Street Address, City, State 44 N 1st E, Preston, ID	
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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on review of Vitros XT 3400 maintenance logs and an interview with the technical supervisor on 01/24/23, the laboratory failed to perform six (6) month maintenance as required by the manufacturer. The findings include: 1. A review of the Vitros XT 3400 monthly maintenance logs identified that the laboratory failed to perform the required six (6) month maintenance which includes performing correction factors and performing pad reflectance test in January 2022. 2. An interview with the technical supervisor on 01/24/23 at 11:37 am confirmed the above findings. 3. The laboratory reports performing 104,000 routine chemistry and endocrinology tests annually.</p>
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>

This STANDARD is not met as evidenced by:

Based on review of pipette calibration reports, a direct observation, and an interview with the technical supervisor on 01/23/23, the laboratory failed to maintain calibrations on four (4) Vista Lab MLA pipettes. The findings include: 1. A review of the pipette calibration reports identified that the laboratory failed to have four (4) of four (4) pipettes calibrated. The pipettes were last calibrated on 06/25/21 with an expiration date of 06/25/22. 2. A direct observation of the four (4) Vista Lab MLA pipettes confirmed that the laboratory failed to have current calibration dates. Pipettes observed: 2 (two) 50/100/200 L adjustable volume pipettes, 1 (one) 50 L fixed pipette, and 1 (one) 250 L fixed pipette. 3. An interview with the technical supervisor on 01/23/23 at 4:16 pm confirmed the above findings. 4. The laboratory reports performing 164,675 tests annually.