

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 47D0683984	(X3) Date Survey Completed 04/27/2021
Name of Provider or Supplier Gifford Medical Center	Street Address, City, State 44 South Main St, Randolph, VT	
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
D6117	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4)</p> <p>The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the Chemistry Technical Supervisor (TS) failed to ensure the established acceptable parameters of the quality control procedure are followed for testing performed on two Dimension EXL 200 analyzers in 2021. Findings include: 1) Review on 4/27/2021 of the laboratory's procedure titled "Quality Control General Chemistry and Special Chemistry" revealed on page 1 that assayed control materials are used for all analytes on the Dimension EXL 200. Further review on page 1 revealed acceptable criteria includes "Instructions for Technologist: ...2. One control reads within +/- 2 SD of established mean and the other control between 2-3 SD (only once, check previous QC records.)" 2) Interview on 4/27/2021 at approximately 12:30 p.m. with the Chemistry TS confirmed the laboratory uses the manufacturer's assayed control ranges and does not establish their own ranges to use the Westgard rule referenced in the control procedure when one control material is within 2 SD and the other is between 2-3 SD. 3) The laboratory could not provide literature references to support the control procedure or their current practices at the time of the survey.</p>