

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 47D0090944	(X3) Date Survey Completed 11/17/2021
Name of Provider or Supplier Grace Cottage Hospital	Street Address, City, State 185 Grafton Rd, Townshend, 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 Hematology Technical Supervisor (TS) failed to ensure the the quality control (QC) procedure included acceptable parameters for QC materials used for complete blood counts performed on the Sysmex XN 550 analyzer in 2021, 2020 and 2019. Findings include: 1. Review on 11 /17/2021 of the laboratory's (lab) procedure titled "Sysmex XN 550 Hematology Analyzer Quality Control," effective 4/10/2019, the lab's procedure failed to define what the acceptable ranges for the QC material are. 2. Interview with the TS on 8/17 /2021 at 11:00 a.m. confirmed the above finding. The TS revealed the lab establishes their own acceptable ranges over time, but will use the manufacturer's ranges if an outlier occurs.</p>