

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 30D0712579	(X3) Date Survey Completed 02/02/2024
Name of Provider or Supplier Valley Regional Hospital	Street Address, City, State 243 Elm Street, Claremont, NH	
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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory (lab) failed to demonstrate that it can obtain performance specifications for accuracy, precision and reportable range before performing routine chemistry, toxicology and hematology testing on patient samples in May 2023. Findings include: 1. Review on 2/2/2024 of the lab's test list revealed a new instrument (Nova Prime Plus) used for hydrogen concentration (pH), partial pressure of carbon dioxide (pCO2), partial pressure of oxygen (pO2), total hemoglobin, oxygenated hemoglobin (HbO2), carboxyhemoglobin (HbCO2), and methemoglobin (MetHb). The test list showed a combined annual test volume of 1,205. 2. Review on 2/2/2024 of verification procedures for a new blood gas analyzer revealed the manufacturer's representative performed the verification procedures beginning in March 2023. The Lab Director (LD) signed in approval of the manufacturer's verification of performance specifications on May 5/18/2023, after which the lab began testing patient samples. 3. Interview on 2/2/2024 at 9:00 a.m. with the Technical Consultant (TC) confirmed the above findings and revealed the lab performed a correlation study with the previous instrument but did not perform testing to verify performance specifications for accuracy, precision and reportable range.</p>