

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0932353	(X3) Date Survey Completed 12/22/2021
Name of Provider or Supplier Amit H Sheth Md Pc	Street Address, City, State 22878 Three Notch Road, California, MD	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with laboratory staff, the laboratory did not take corrective action during the month of December 2021 when 8 of 16 humidity readings did not meet the laboratory's criteria for acceptability. Findings: 1. The December 2021 humidity readings that did not meet the laboratory's written criteria for acceptability were reading lower than acceptable but no recheck was made and there was no recheck documented for the humidity readings; and 2. This was confirmed during interview with laboratory staff on the afternoon of the day of the survey.</p>