

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0267613	(X3) Date Survey Completed 05/02/2019
Name of Provider or Supplier Halifax Medical Center Blood Gas Lab	Street Address, City, State 303 North Clyde Morris Blvd, Daytona Beach, FL	
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 the Manager, the laboratory failed to document humidity for Blood Gas Analyzer ABL 800 Flex for 2 out of 2 years (2017-2019) reviewed. Findings Included: Review of maintenance records from 05/02/17 through 05/02/19 found no humidity documented for the Blood Gas Analyzer ABL 800 Flex. Review of the manufacturer's instructions showed that the equipment required an environment of humidity from 20% to 80%. During an interview on 05/02/19 at 10:30 AM, the Manager confirmed that there was no humidity documented.</p>