

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2142606	(X3) Date Survey Completed 12/26/2024
Name of Provider or Supplier Alabama Vascular Solutions, Llc, Dr Steven Taylor	Street Address, City, State 632 2nd Street Northeast, Alabaster, AL	
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>(b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 direct observation, a lack of humidity logs, and an interview with Testing Personnel 1 (TP1), the laboratory failed to record humidity each day patient testing on the i-STAT analyzer. The surveyor noted there was no humidity device at the time of the survey on 12-26-2024 and no humidity readings were recorded from the date of the last survey, 12-19-2022 to the date of the current survey, 12-26-2024. The findings include: 1) During the laboratory tour on 12-26-2024 at approximately 8:44 AM, the surveyor was presented with a device that only monitored temperature. The device did not have the capability to monitor humidity. 2) A review of the i-STAT analyzer manual, Rev. Date February 26,2016, revealed on page 2-2 under Specifications, "Relative Humidity of 90% (maximum) non-condensing". 3) A further review of laboratory records revealed there was no records of humidity monitoring when patient testing was performed on the i-STAT analyzer from 2022-2024. 4) TP1 confirmed the above findings during the exit conference interview on 12-26-2024 at 1:45PM.</p>
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p>

(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on a review of the personnel records and an interview with the Testing Personnel 1 (TP1), the Technical Consultant (TC) failed to ensure all Testing Personnel (TP) listed on the CMS-209 (Laboratory Personnel Report) who performed moderate complexity testing had semi-annual competency assessments during the first year of patient testing. The surveyor noted one of the four TP did not have a semi-annual competency assessment. The findings include: 1. A review of the personnel records revealed TP4 was missing a semi-annual competency assessment in 2023. TP4 had an annual competency assessment completed on 5-30-2024. 2. TP1 confirmed the above findings during the exit conference on 12/26/2024 at 1:45 PM.