

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2000676	(X3) Date Survey Completed 05/26/2022
Name of Provider or Supplier Southern Blood Services, Inc	Street Address, City, State 1406 Mcfarland Blvd Suite 1-A, Tuscaloosa, 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
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on reviews of AAB (American Association of Bioanalysts) Proficiency Testing (PT) records, the Proficiency Testing Procedure, and an interview with Testing Personnel #1, the laboratory failed to test PT samples the same number of times that it routinely test patient samples. This was noted seven out of seven PT Chemistry Events (Total Protein) in 2020 - 2022. The findings include: 1. A review of AAB PT records revealed the following: a) Q1 Chemistry 2020 attestation listed Testing Personnel #1 performing all five Total Protein samples. Also, two previous employees performed and documented results for all five samples before the due date of 2/19 /2020. b) Q2 Chemistry 2020 attestation listed Testing Personnel #2 performing all five Total Protein samples. Also, one previous employee and Testing Personnel #1 performed and documented results for all five samples before the due date of 5/20 /2020. c) Q3 Chemistry 2020 attestation listed Testing Personnel #1 performing all five Total Protein samples. Also, one previous employee and Testing Personnel #2 performed and documented results for all five samples before the due date of 9/30 /2020. d) Q1 Chemistry 2021 attestation listed Testing Personnel #2 performing all five Total Protein samples. Also, two previous employees and Testing Personnel #1 performed and documented results for all five samples before the due date of 2/17 /2021. e) Q2 Chemistry 2021 attestation listed Testing Personnel #2 performing all five Total Protein samples. Also, two previous employees and Testing Personnel #1 performed and documented results for all five samples before the due date of 5/26 /2021. f) Q3 Chemistry 2021 attestation listed Testing Personnel #3 performing all five Total Protein samples. Also, one previous employee, Testing Personnel #1, and #2 performed and documented results for all five samples before the due date of 9/29</p>

/2021. g) Q1 Chemistry 2022 attestation listed a previous employee performing all five Total Protein samples. Also, Testing Personnel #1, #2, and #3 performed and documented results for all five samples before the due date of 2/16/2022. 2. A review of the Proficiency Testing Procedure revealed "...Proficiency testing specimens are to be analyzed as if they were patient samples..." 3. During an interview on 5/26/2022 at 12:50 PM, Testing Personnel #1 confirmed during each PT event all employees would perform all samples for training purposes before the PT due date. Also, Testing Personnel #1 confirmed patient testing is only performed once by one employee.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(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: (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.

This STANDARD is not met as evidenced by:

Based on a review of temperature records, the AR200 Refractometer User's Guide, and an interview with Testing Personnel #1, the laboratory failed to monitor and document humidity in the area where the AR200 Refractometer is used. This was noted from the previous survey (3/12/2020) to the current survey (5/26/2022). The findings include: 1. A review of environmental records revealed humidity had not been documented for the laboratory. 2. A review of the AR200 Refractometer User's Guide revealed, "...3.0 Environmental Conditions...Max. Relative Humidity: 80% for temperatures to 31 degrees Celsius decreasing linearly to 50% (relative humidity at 40 degrees Celsius)..." 3. During an interview on 5/26/2022 at 12:45 PM, Testing Personnel #1 confirmed the laboratory does not currently monitor and document humidity in the room where the AR200 Refractometer is used.