

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2104515	(X3) Date Survey Completed 05/02/2024
Name of Provider or Supplier Dba Alabama Oncology	Street Address, City, State 3670 Grandview Pkwy Suite 200, Birmingham, 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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the API (American Proficiency Institute) proficiency testing (PT) records and an interview with Testing Personnel #8, the laboratory failed to enroll in an approved Proficiency Testing program for iStat Chemistry 8 panel cartridge, a moderate complexity test. This was noted for three of three events starting from the date of implementation, 4/11/2023, to the date of the current survey, 5/2/2024. The findings include: Refer to D2001. Refer to D6041.</p>
D2001	<p>ENROLLMENT CFR(s): 493.801(a)(1)(2)(i)</p> <p>The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS;</p>

This STANDARD is not met as evidenced by:
Based on a review of the API (American Proficiency Institute) proficiency testing (PT) records and an interview with Testing Personnel #8, the laboratory failed to enroll in an approved Proficiency Testing program for the i-STAT Chemistry 8 panel cartridge. This was noted for three of three events starting from the i-STAT implementation date, 4/11/2023, to date of survey, 5/2/2024. The findings include: 1. A review of the API PT records revealed no evidence of enrollment in a proficiency testing program for 2023 Event 2, 2023 Event 3, and 2024 Event 1 for the i-STAT Chemistry 8 panel cartridge. No evidence of alternative accuracy verification procedures were available for review. 2. During an interview at 1:00 PM on 5/2/2024, Testing Personnel #8 confirmed the above findings.

D5215

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:
Based on a review of the API (American Proficiency Institute) proficiency testing (PT) records, corrective action documentation, and an interview with Testing Personnel #8, the laboratory failed to ensure PT results were submitted before the postmark due date. This was noted for one of two events reviewed in 2022. The findings include: 1. A review of the API PT records revealed a score of 0% and "Failure to participate" on 2022 Complete Blood Count (CBC) Hematology Event 2 with a deadline date of 8/3/2022. 2. A further review of the corrective action documentation revealed the PT results were submitted after the deadline due to clerical error with dates. Upon receipt of the Hematology Event 2 testing results, a self grade was performed and found all analytes to be successful. 3. During an interview on 5/1/2024 at 11:45 AM, Testing Personnel #8 confirmed the above findings.

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 the temperature records, the i-STAT user manual, and an interview with Testing Personnel #8, the Laboratory failed to document humidity for the room in which the i-STAT was stored. This was noted from the date of i-STAT implementation on 4/11/2023 to the current survey on 5/2/2024. The findings include: 1. A review of the temperature records revealed no evidence of documentation of

	<p>room humidity where the i-Stat was stored. 2. A further review of the i-STAT user manual on page 3 under "Specifications" reveals, "Relative Humidity: 90% maximum." 3. During an interview on 5/2/2024, at 11:58 AM, Testing Personnel #8 confirmed the above findings.</p>
<p>D5431</p>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the i-STAT monthly cartridge checks, policy and procedures, and an interview with Testing Personnel #8, the Laboratory failed to ensure the monthly cartridge check was performed per the laboratory policy. This was noted for one of four months reviewed in 2024. The findings include: 1. A review of the i-STAT records revealed the monthly cartridge check was not performed in February 2024. 2. A review of the i-STAT policy and procedure manual revealed the following, "...Logs and Maintenance requirements with frequency... b. Monthly Cartridge Check: Monthly." 3. During an interview on 5/2/2024, at 12:25 PM, Testing Personnel #8 confirmed February 2024 monthly cartridge check was overlooked.</p>
<p>D6033</p>	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on reviews of the American Proficiency Institute (API) proficiency testing (PT) records and testing personnel semi annual and annual competencies, the Technical Consultant failed to provide adequate technical and scientific oversight of the laboratory. The findings include: 1. A review of the laboratory records revealed the Technical Consultant failed to: (A) Ensure the laboratory was enrolled in an approved Proficiency Testing program for i-STAT Chemistry 8 panel cartridges. (Refer to D6041) (B) Evaluate semi-annual competencies for testing personnel performing moderate complexity testing. (Refer to D6053) (C) Evaluate annual competencies for testing personnel performing moderate complexity testing. (Refer to D6054) (D) Ensure the laboratory documented humidity for the room in which the i-STAT was stored since the date of implementation on 4/11/2023. (Refer to D5413)</p>
<p>D6041</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3)</p> <p>(b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;</p>

	<p>This STANDARD is not met as evidenced by: Based on a review of the API (American Proficiency Institute) proficiency testing (PT) records and an interview with Testing Personnel #8, the Technical Consultant failed to ensure the laboratory was enrolled in an approved Proficiency Testing program for i-STAT Chemistry 8 panel cartridges, a moderate complexity test. This was noted for three of three proficiency events reviewed from the date of implementation, 4/11/2023, to the date of the current survey, 5/2/2024. The findings include: 1. Refer to D2001.</p>
<p>D6053</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the personnel records and an interview with Testing Personnel #8, the Technical Consultant failed to evaluate semi-annual competencies for testing personnel performing moderate complexity testing. This was noted for 6 of 17 new testing personnel listed on the CMS-209 (Laboratory Personnel Report) in 2023 and 2024. The findings include: 1. A review of the personnel records revealed no evidence of evaluation by the Technical Consultant for the semi-annual competencies of the following testing personnel: a) 2023: Testing Personnel #13, #14, #16, and #17. b) 2024: Testing Personnel #2 and #3. 2. During an interview on 5/1/2024, at 11:03 AM, Testing Personnel #8 confirmed the above findings.</p>
<p>D6054</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the personnel records and an interview with Testing Personnel #8, the Technical Consultant failed to evaluate annual competencies for Testing Personnel performing moderate complexity testing. This was noted for 4 of 17 Testing Personnel listed on the CMS-209 (Laboratory Personnel Report) in 2023 and 2024. The findings include: 1. A review of the personnel records revealed no evidence of evaluation by the Technical Consultant for annual competency assessments of Testing Personnel #1, #8, #9 and #11 for 2023 and 2024. 2. During an interview on 5/1/2024, at 11:03 AM, Testing Personnel #8 confirmed the above findings.</p>
<p>D6072</p>	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3)</p> <p>Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.</p>

This STANDARD is not met as evidenced by:

Based on a review of Flow Cytometry QC (Quality Control) records, policy and procedures, and an interview with Testing Personnel #8, the laboratory failed to retain documentation of monthly Single Antibody QC. This was noted for 12 of 23 months reviewed in 2022 and 2023. The findings include: 1. A review of the Flow Cytometry QC records revealed no evidence of monthly Single Antibody QC from May 2022 to April 2023. 2. A further review of the policy and procedure under "Monthly Antibody Positivity QC" revealed, "The antibody positivity analysis is printed each month and filed in the binder or stored online." 2. During an interview on 5/1/2024 at 11:48, Testing Personnel #7 confirmed the above findings.