

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2199881	(X3) Date Survey Completed 05/12/2026
Name of Provider or Supplier Alabama Men's Clinic	Street Address, City, State 1 Independence Plaza, Suite 130, 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
D2100	<p>ENDOCRINOLOGY CFR(s): 493.843(c)</p> <p>(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with the Technical Consultant (TC), the laboratory failed to ensure PT results were submitted before the due date specified by API. This was noted for one of the three 2024 Chemistry Core Events. The findings include: 1. A review of the API PT records revealed a score of 0 percent due to "Failure to participate" on 2024 Chemistry Core (Testosterone) Event. 2. TC confirmed the above findings during the exit conference on 05-12-2026 at 2:00 PM.</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>(b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to</p>

verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on reviews of the Qualigen Fast Pack analyzer calibration records, the laboratory's Policy and Procedure (P&P) manual and an interview of the Technical Consultant (TC) and Testing Personnel 1 (TP1), the laboratory failed to document the Calibration-Verification (C-V) at least every six months. The surveyor noted two of the two C-Vs due in 2024 had no documentation found. The findings include: 1. A review of the calibration records for the Qualigen Fast Pack analyzer revealed Testosterone was calibrated with less than three calibrators. 2. A further review of the calibration records revealed Testosterone C-V was performed and documented on 04-09-2025 with a retest on 05-21-2025 due to the shipment issue when the specimens arrived. 3. A review of the P&P manual revealed a procedure to perform C-V at least every six months. 4. TC confirmed the above findings during the exit conference on 05-12-2026 at 2:00 PM.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

(b)(9) Thereafter, evaluations must be performed at least annually

This STANDARD is not met as evidenced by:

Based on a review of personnel evaluation records and an interview with the Technical Consultant (TC), the TC failed to assess and document the annual competency for one of two Testing Personnel (TP) responsible for moderate complexity testing in 2023. The findings include: 1. A review of personnel records for TP listed on the CMS-209 Form (Laboratory Personnel Report) revealed the TC failed to perform and document the annual competency assessment for TP1 in 2023. 2. TC confirmed the above findings during the exit conference on 05-12-2026 at 2:00 PM.