

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0908217	(X3) Date Survey Completed 04/03/2025
Name of Provider or Supplier North Alabama Urology	Street Address, City, State 825 Adams Street, Huntsville, 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
D2096	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p> <p>(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) testing evaluations and an interview with Testing Personnel (TP) #1, the laboratory failed to satisfactorily perform Testosterone (Chemistry) for two consecutive testing events. These failures resulted in an unsuccessful performance. The findings include: 1. A review of the API testing evaluations revealed the laboratory scored zero percent for the first and third Chemistry event in 2023. 2. During an interview on 4-3-2025 at 10:15 AM, TP #1 confirmed the above findings.</p>
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of the Qualigen FastPack Chemistry analyzer and interviews with Testing Personnel #1, the laboratory failed to ensure: A) Quality Control material was</p>

not expired prior to patient testing. (Refer to D5417). B) Calibration Verification was performed and documented on the Qualigen FastPack analyzer for Prostate-Specific Antigen every six months. (Refer to D5439). C) Two Quality Control materials of different concentration were within manufacturer's specifications for Prostate-Specific Antigen (PSA) and Testosterone (Testo) on both Station 1 and Station 2 prior to patient testing. (Refer to D5447). .

D5417

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

(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
Based on a review of the Qualigen FastPack Quality Control (QC) records and an interview with Testing Personnel #1, the laboratory used expired QC material for Testosterone. This was noted for the month of December 2023 during patient testing; 1 patient was affected. The findings include: 1. A review of the Station 1 Testosterone QC records revealed lot # 22020484 expired December 2023. The expired QC material was utilized for 17 days in December; 1 patient Testosterone test was affected on 12/8/2023. 2. During an interview on 4/3/2025, at 12:26 PM, Testing Personnel #1 confirmed the above findings.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

(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 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 a review of calibration verification (C-V) records and an interview with Testing Personnel (TP) #1, the laboratory failed to ensure C-V was performed and documented on the Qualigen FastPack analyzer for Prostate-Specific Antigen (PSA) for the second half of 2023 (one of three 2023-2024 C-V's missed). The findings include: 1. A review of the PSA C-V records for the Qualigen FastPack analyzer revealed C-V documentation on 3/22/23 and then a year later on 1/5/24. There was no

	<p>evidence of a C-V performed and documented the second half of 2023. 2. During an interview on 4/3/25 at 3:20 PM, TP #1 confirmed PSA C-V's are performed every 6 months and that the second half of 2023 C-V was missed for PSA on analyzer 0444.</p>
<p>D5447</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>(d)(3)(i) Each quantitative procedure, include two control materials of different concentrations;</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Qualigen FastPack Chemistry analyzer Quality Control (QC) records, patient test records, and an interview with Testing Personnel (TP) #1, the laboratory failed to ensure two control materials of different concentration were within manufacturer's specifications for Prostate- Specific Antigen (PSA) and Testosterone (Testo) on both Station 1 and Station 2 prior to patient testing. This was noted for 6 of 12 months reviewed in 2023 and 9 of 12 months reviewed in 2024; 110 patients were affected. The findings include: 1. A review of the PSA and Testo QC records for both Station 1 and Station 2 revealed QC failures for the following months: Station 1 (0444) PSA a. June 2023; 10 patients affected, b. September 2023; 3 patients affected, c. October 2023; 1 patient affected, d. November 2023; 7 patients affected, e. December 2023; 12 patients affected, f. January 2024; 2 patients affected, g. March 2024; 1 patient affected, h. April 2024; 4 patients affected, i. May 2024; 3 patients affected, j. June 2024; 10 patients affected, k. July 2024; 5 patients affected, l. September 2024; 6 patients affected, m. November 2024; 4 patients affected, n. December 2024; 8 patients affected. Station 1 (0366&0748) Testo a. November 2023; 1 patient affected, b. December 2023; 1 patient affected, c. April 2024; 1 patient affected, d. November 2024; 1 patient affected. Station 2 (0110) Testo a. July 2023; 1 patient affected, b. October 2023; 2 patients affected. Station 2 (0147) PSA a. November 2023; 2 patients affected, b. March 2024; 2 patients affected, c. May 2024; 6 patients affected, d. July 2024; 6 patients affected, e. November 2024; 5 patients affected, f. December 2024; 6 patients affected. 2. During an interview on 4/3/2025 at 11:20 AM, TP #1 confirmed PSA and Testo testing was performed on patients when at least one QC level was out of range. TP #1 stated she cannot ensure both levels are in range prior to patient testing when she is not on-site.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on reviews of the Qualigen FastPack Chemistry analyzer and interviews with Testing Personnel #1, the Laboratory Director failed to ensure: 1. Proper oversight of acceptable QC levels over the analytical performance prior to patient testing. (Refer to D6023).</p>
<p>D6023</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6)</p>

(e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

This STANDARD is not met as evidenced by:

Based on reviews of the Qualigen FastPack Chemistry analyzer and interviews with Testing Personnel #1, the Laboratory Director failed to ensure proper oversight of acceptable levels over the analytical performance prior to patient testing. This was noted from the date of the previous survey (3/22/2023) to the date of the current survey (4/3/2025). The findings include: 1. Refer to D5400.

D6033

TECHNICAL CONSULTANT-MODERATE COMPLEXITY

CFR(s): 493.1409

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.

This CONDITION is not met as evidenced by:

Based on reviews of the Quality Control (QC) records and interviews with Testing Personnel #1, the Technical Consultant failed to ensure: 1. The laboratory had two QC materials of different concentration within manufacturer's specifications for Prostate-Specific Antigen (PSA) and Testosterone (Testo) on both Station 1 and Station 2 prior to patient testing. (Refer to D6044).

D6044

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(6)

(b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly;

This STANDARD is not met as evidenced by:

Based on reviews of the Qualigen FastPack Quality Control (QC) records, the Technical Consultant failed to ensure the laboratory had two QC materials of different concentration within manufacturer's specifications for Prostate-Specific Antigen (PSA) and Testosterone (Testo) on both Station 1 and Station 2 prior to patient testing. This was noted from the date of the previous survey (3/22/2023) to the date of the current survey (4/3/2025). The findings include: 1. Refer to D5447.