

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D1107817	<b>(X3) Date Survey Completed</b>  02/26/2026
<b>Name of Provider or Supplier</b>  Clinical Urology Associates Pc	<b>Street Address, City, State</b>  713 Goodyear Ave, Gadsden, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5213</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>(b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with the Laboratory Director (LD), the LD or designee failed to document review and evaluation of PT performance in the following specialties, Chemistry and Microbiology. The surveyor noted two of the three events in Chemistry and one of the three events in Microbiology were not reviewed in 2025. The findings include: 1. A review of the API PT records revealed no documentation of review on the returned evaluations by the Laboratory Director, or designee, for the following events: a) 2025 Chemistry Core, 1st and 3rd Events b) 2025 Microbiology, 3rd Event. 2. The LD confirmed the above findings during the exit conference on 02-26-2026 at 4:45 PM.</p>
<b>D5429</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on reviews of the Water Purification maintenance records, Aqua Solutions Operating Manual and an interview with the Laboratory Director (LD), the laboratory failed to perform and document the manufacturer's required annual maintenance for</p>

the water system. The surveyor noted three of the three annual maintenances required in 2023-2025 were not performed. The findings include: 1. A review of the Water Purification maintenance records revealed no annual maintenance documentation from 2023 through 2025. 2. A review of the Aqua Solutions Operating Manual revealed on page 41 the following manufacturer's maintenance instructions: A) Activated Carbon Cartridge... "replaced at least every 12 months..." B) Reverse Osmosis Cartridge... "changed every 2 to 3 years..." C) DI Module... "replaced at least every 12 months..." D) Final Filter... " replaced at least every 12 months..." 3. The LD confirmed the above findings during the exit conference on 02-26-2026 at 4:45 PM.

**D5435**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(b)(2)

(b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:  
Based on a review of the pipette maintenance records and an interview with the Laboratory Director (LD), the laboratory failed to perform and document the annual pipette calibration in 2024. This was noted for seven of the seven pipette volumes available for use in the laboratory. The findings include: 1. A review of the 2024 pipette maintenance records revealed Model 3120 pipette was not calibrated in 2024. The following volumes were available for use; 5, 10, 50, 100, 200, 500 and 1000 microliters. 2. A further review of the pipette maintenance records revealed all pipettes were calibrated in 2025. 3. The LD confirmed the above findings during the exit conference on 02-26-2026 at 4:45 PM.

**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 lack of the Qualigen FastPack analyzer Calibration-Verification (C-V) records, the Qualigen FastPack analyzer calibration records and an interview with the Laboratory Director, the laboratory failed to fulfill CLIA C-V regulatory requirements by implementing C-V procedures at least every six months when less than three levels of calibrators were performed with testing. The surveyor noted missing C-V documentation for six of the six C-Vs due in 2024-2025. The findings include: 1. A lack of C-V records for the Qualigen FastPack analyzer revealed no C-V was performed for the Prostatic Specific Antigen (PSA) and Testosterone testing. 2. A review of the calibration records for PSA and Testosterone revealed both analytes were calibrated with less than three calibrators. 3. The LD confirmed the above findings during the exit conference on 02-26-2026 at 4:45 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 Laboratory Director (LD), the LD failed to assess and document the 2024 annual competency for two of the eight Testing Personnel (TP) responsible for moderate complexity testing. The findings include: 1. A review of personnel records for TP listed on the CMS-209 Form (Laboratory Personnel Report) revealed the LD failed to perform and document the annual competency assessment for TP4 and TP6 in 2024. 2. The LD confirmed the above findings during the exit conference on 02-26-2026 at 4:45 PM.