

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0225848	(X3) Date Survey Completed 11/12/2025
Name of Provider or Supplier Urological Associates, Ltd	Street Address, City, State 155 Riverbend Drive, Charlottesville, VA	
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
D0000	An off-site CLIA proficiency testing (PT) desk review was conducted for Urological Associates, LTD on November 12, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The survey concluded with an interview with the Primary Testing Personnel on November 12, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The facility was found to be out of compliance with the following CONDITION LEVEL DEFICIENCIES: D2016 - 42 CFR. 493.803 Condition: Successful Participation D6000 - 42 CFR. 493.1403 Condition: Laboratories performing moderate complexity testing- Laboratory Director
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by:</p>

Based on a review of the Certification and Survey Provider Enhanced Reporting (CASPER 0155) report, the laboratory's proficiency testing (PT) records and interview, the laboratory failed to successfully participate in the Endocrinology subspecialty and Testosterone analyte for two consecutive PT testing events. The laboratory had unsatisfactory Endocrinology and Testosterone scores for the second and third events of calendar year 2025. Refer to D2107 and D2108.

D2107

ENDOCRINOLOGY
CFR(s): 493.843(f)

(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.

This STANDARD is not met as evidenced by:

Based on a desk review of proficiency testing (PT) records from the Certification and Survey Provider Enhanced Reporting (CASPER) 0155 report, American Proficiency Institute (API) PT records, and interview, the laboratory failed to attain a score of at least eighty percent (80%) of acceptable responses for Testosterone for two consecutive Endocrinology events in calendar year 2025 resulting in an initial unsuccessful PT performance as reviewed on the date of the inquiry on November 12, 2025. The findings include: 1. Review of the CASPER 0155 report revealed the following results: Chemistry 2025 - 2nd Event - unsatisfactory score of 0% for analyte 0570 Testosterone; Chemistry 2025 - 3rd Event - unsatisfactory score of 0% for analyte 0570 Testosterone. 2. Desk review of the API 2025 PT records outlined above revealed unsatisfactory Testosterone scores of less than 80% for the following 2 consecutive Endocrinology events: 2025 API 2nd Event: Testosterone scored 0% 2025 API 3rd Event: Testosterone scored 0% resulting in an initial unsuccessful PT performance noted by API. 3. In a phone interview with the Office Administrator on November 12, 2025, at 9:20 AM, they stated they have not performed Testosterone testing since November 2024 and confirmed the above findings.

D2108

ENDOCRINOLOGY
CFR(s): 493.843(g)

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on a desk review of proficiency testing (PT) records from the Certification and Survey Provider Enhanced Reporting (CASPER) 0155 report, American Proficiency Institute (API) PT records, and interview, the laboratory failed to achieve overall satisfactory performance of at least eighty percent (80%) for the Endocrinology subspecialty for two consecutive Endocrinology events in calendar year 2025 resulting in an initial unsuccessful PT performance as reviewed on the date of the inquiry on November 12, 2025. The findings include: 1. Review of the CASPER 0155 report revealed the following results: Chemistry 2025 - 2nd Event - unsatisfactory score of 0% for subspecialty 0525 Endocrinology; Chemistry 2025 - 3rd Event - unsatisfactory score of 0% for subspecialty 0525 Endocrinology. 2. A review of the PT testing scores from API (2025 Events 2 & 3) confirmed the above findings. 3. In a

phone interview with the Practice Administrator on November 12, 2025, at 9:20 AM, they stated they have not performed Testosterone testing since November 2024 and confirmed the above findings.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

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.

This CONDITION is not met as evidenced by:
Based on an off-site desk review of the Certification and Survey Provider Enhanced Reporting (CASPER 0155) report, the laboratory's 2025 proficiency testing (PT) records and interview, the laboratory director (LD) failed to provide overall management and ensure the overall quality of the laboratory services provided. Refer to D6016.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:
Based on a review of the Certification and Survey Provider Enhanced Reporting (CASPER 0155) report, the laboratory's 2025 proficiency testing (PT) records, and interview, the laboratory director (LD) failed to ensure the overall quality of the laboratory services provided. The LD failed to ensure successful participation in their Health and Human Services (HHS) approved PT program. Refer to D2107 and D2108.