

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0421529	(X3) Date Survey Completed 11/20/2025
Name of Provider or Supplier York Urologic Uropartners	Street Address, City, State 950 N York Rd, Hinsdale, IL	
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
D5024	<p>HEMATOLOGY CFR(s): 493.1215</p> <p>If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on review laboratory policies and procedures, laboratory records, patient testing records, lack of documentation, laboratory test volume worksheet and interview with laboratory representative, the laboratory failed to perform bi-annual method accuracy evaluations for qualitative semen analysis testing in 2023 through the survey date of 11/20/2025 (See D5217), the laboratory failed to outline all components of a test procedure for qualitative semen analysis (See D5403), the laboratory failed to establish quality control procedures to monitor quality performance of qualitative semen analysis for 46 of 46 patients tested in 2024 and 2025 (See D5441),</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation, and interview with the laboratory representative; the laboratory failed to perform bi-annual method accuracy evaluations for qualitative semen analysis testing in 2023 through the survey date of 11/20/2025. Findings include: 1. Review of laboratory records found no documented bi-annual method accuracy evaluations for qualitative semen analysis testing in 2023 through the survey</p>

date of 11/20/2025. 2. Interview with the laboratory representative on 11/20/2025, at 10:32 am, confirmed that the laboratory failed to perform bi-annual method accuracy evaluations for qualitative semen analysis testing.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on review of laboratory's policy and procedure manual and interview with the laboratory representative, the laboratory failed to outline all components of a test procedure for qualitative semen analysis. Findings Include: 1. Review of the laboratory policy and procedure manual identified the procedure, "Semen analysis" which failed to include the following required test procedure components for qualitative semen analysis. A.Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection. B.Control procedures. C.Corrective actions to take when control results fail. D.Pertinent literature references. E.The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminent life threatening results, or panic, or alert values. 2. During survey date 11-20-2025, at 12: 15 pm, interview with laboratory representative confirmed the laboratory failed to have the required components of a test procedure for qualitative semen analysis.

D5441

CONTROL PROCEDURES
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and

precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policy and procedure manual, patient testing records, the laboratory test volume worksheet and interview with the laboratory representative, the laboratory failed to establish quality control procedures to monitor quality performance of qualitative semen analysis for 46 of 46 patients tested in 2024 and 2025. Findings include: 1. Review of the laboratory policy and procedure manual identified the procedure, "Semen Analysis" which failed to have a quality control process for qualitative semen analysis. See D5403. 2. Review of three of three laboratory patient testing reports revealed the laboratory failed to document quality control for post vasectomy semen analysis testing. MRN Date of testing A.7095420 09/26/25 B.7476730 09/26/25 C.7322970 08/08/25 3. During survey date 11-20-2025, at 12:15 pm, interview with laboratory representative confirmed the laboratory failed to establish and perform quality controls for qualitative semen analysis. 4. Review of laboratory document titled "Non-waived CLIA test volumes worksheet" revealed that the laboratory performed 46 post vasectomy semen analysis tests from October 1st of 2024 to September 30th of 2025.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies, patient testing records and quality control records, the laboratory director (LD) failed to ensure the quality control programs were established and maintained to assure the quality of laboratory services provided for hematology and microbiology testing. Findings Include: 1. Review of the laboratory policy manual identified the procedure, "Semen analysis" which failed to have quality control procedures. See 5403 2. Review of the laboratory's patient testing records revealed the laboratory failed to have quality control testing completed for semen analysis. See 5441. 3. Review of laboratory quality control records titled "Quality Control Log - Mueller Hinton Medium & Antibiotics Discs" revealed that testing personnel A lacked the educational requirements to qualify as a high complexity testing personnel and performed quality control testing for microbiology susceptibility from 3-28-24 to 11-4-25. See D6102

D6102

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(12)

(e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

This STANDARD is not met as evidenced by:

Based on review of laboratory quality control records, laboratory personnel records, lack of documentation and interview with laboratory representative, the laboratory director failed to ensure one of one laboratory personnel performing quality control testing had the appropriate education for high complexity microbiology susceptibility testing using Muller Hinton Medium & Antibiotic Discs. Findings include: 1. Review of laboratory quality control records titled "Quality Control Log - Mueller Hinton Medium & Antibiotics Discs" revealed that testing personnel A performed microbiology susceptibility quality control testing and was not listed on the CMS-209 form. 2. Review of laboratory personnel records revealed testing personnel A lacked the educational qualifications to perform high complexity microbiology susceptibility testing. See D6171. 3. Interview with laboratory representative on 11/20/25, at 11:31 am, confirmed that the laboratory failed to have qualifying educational documents for testing personnel A for microbiology susceptibility testing.

D6168

TESTING PERSONNEL
CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:
Based on review of personnel records, lack of academic records and interview with the laboratory representative, the laboratory failed to have qualifying academic records for one of one testing personnel performing microbiology testing. See D6171.

D6171

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) (A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or

(b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on review of personnel records, lack of academic records and interview with the laboratory representative, the laboratory failed to have qualifying academic records for one of one laboratory personnel performing microbiology susceptibility testing. Findings include: 1. Review of laboratory personnel records found the laboratory lacked education documents to qualify testing personnel A for microbiology susceptibility testing. 2. Interview with laboratory representative on 11/20/2025 at 11:31 am confirmed the laboratory failed to have the required qualifying academic records for testing personnel A for microbiology susceptibility testing.