

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0067746	(X3) Date Survey Completed 01/08/2026
Name of Provider or Supplier Pioneer Valley Urology, Pc	Street Address, City, State 100 Wason Ave, Suite 120, Springfield, MA	
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on College of American Pathologists (CAP) proficiency testing (PT) record review and staff interview with Microbiology General Supervisor #1 (MGS1) and the Laboratory Director (LD), the laboratory failed to test PT samples in the same manner as patient samples. Findings include: 1. Record review on 1/8/2026 of the laboratory's 2024, 2025 and 2026 to date CAP Clinical Microscopy (CMP) PT records revealed: A. 2024 Event A, CM-A a. The attestation sheet shows 8 Testing Personnel (TP)'s signatures attesting to the performance of the urine sediment photo portion of the survey in the same manner as patient samples. b. The attestation sheet was signed by the LD attesting to the performance of the urine sediment photo portion of the survey in the same manner as patient samples. c. 6 answer sheets with the initials of 6 different TP. 0 of 6 of these answer sheets had the correct answer for all 3 CM-A photographs. d. A post-it note with the LD's initials on it with answers to the urine sediment photo portion of the survey. e. The results submitted to CAP were the LD's results who is not a routine TP for the microscopic examination of urine sediment. B. 2024 Event B, CM-B a. The attestation sheet shows 3 illegible signatures attesting to the performance of the urine sediment photo portion of the survey in the same manner as patient samples. b. The attestation sheet was signed by the LD attesting to the performance of the urine sediment photo portion of the survey in the same manner as patient samples. c. A post-it note with the LD's initials on it with answers to the urine sediment photo portion of the survey. d. The results submitted to CAP were the LD's results who is not a routine TP for the microscopic examination of urine sediment. C. 2025 Event A, CM-A a. The attestation sheet shows 4 TP's signatures attesting to the</p>

performance of the urine sediment photo portion of the survey in the same manner as patient samples. b. The attestation sheet was signed by the LD attesting to the performance of the urine sediment photo portion of the survey in the same manner as patient samples. c. An answer sheet with the initials of 3 TP all with the same date of 2/11/2025 that was before the due date of 3/4/2025. d. 4 answer sheets with the initials of 4 other TP. 2. During staff interview on 1/8/2026 at 11:45 AM, MGS1 and the LD confirmed the above findings. 3. The laboratory performs 17 microscopic urine sediment examinations annually.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:
Based on record review and confirmed through an interview with Microbiology General Supervisor #1 (MGS1) and the Laboratory Director (LD), the laboratory did not have an ongoing mechanism to evaluate the GS based on their CLIA responsibilities. Findings Include: 1. Record review on 1/8/2026 of the laboratory's 2024, 2025, and 2026 to date personnel competency records revealed the laboratory did not have documented competency evaluation for MGS1 and MGS2 based on their CLIA responsibilities. 2. Record review on 1/8/2026 of the laboratory's, 'Competency' procedure revealed the procedure did not contain any information about GS competency based on their CLIA responsibilities. 3. During staff interview on 1/8/2026 at 1:30 PM with MGS1 and the LD, MGS1 and the LD confirmed the laboratory does not have a procedure in place to document competency assessment of the GS based on their CLIA responsibilities and they were not assessed. 4. The laboratory performs 560 tests annually in the specialty of Microbiology.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

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.

This STANDARD is not met as evidenced by:
Based on College of American Pathologists (CAP) proficiency testing (PT) record review and staff interview with Microbiology General Supervisor #1 (MGS1) and the Laboratory Director (LD), the laboratory failed to verify at least twice annually the accuracy of the microscopic examination of urine sediment in the subspecialty of Urinalysis. Findings include: 1. Record review on 1/8/2026 of the laboratory's 2024, 2025 and 2026 to date CAP Clinical Microscopy (CMP) PT records revealed: a. The laboratory did not have PT results for 2025 Event 2. b. Code 33 (Specimen unsatisfactory) was entered in the test result column. 2. During staff interview with MGS1 on 1/8/2026 at 11:34 AM: a. The LD and MGS1 Confirmed the above findings. b. MGS1 Stated, "We had to temporarily move the lab and we did not receive the shipment. When we called for replacement specimens, we were told that we should put in code 33 and we would get a mulligan. We were unable to get replacement specimens." c. MGS1 also Stated, "We did not use an alternate method to

	<p>verify the accuracy of the microscopic examination of urine sediment." 3. During a telephone call on 1/8/2026 at 11:45 AM with CAP customer service representative #1 (CSR1), CSR1 stated: a. "The call was given a case number 02582360." b. "We were unable to provide replacement specimens, so we told the lab to enter code 33 unsatisfactory specimen." c. "We advised the caller to use an alternate method to verify the accuracy of the test." 4. The laboratory performs 17 microscopic urine sediment examinations annually.</p>
<p>D5401</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with Microbiology General Supervisor #1 (MGS1) and the Laboratory Director (LD), the laboratory failed to have a written procedure for the microscopic examination of urine sediment. Findings Include: 1. Record review on 1/8/2026 of the laboratory's procedure manual revealed the procedure manual did not include a procedure for the microscopic examination of urine sediment. 2. Staff interview on 1/8/2026 at 11:00 AM with MGS1 and the LD confirmed the above findings. 3. The laboratory performs 17 microscopic urine sediment examinations annually.</p>
<p>D5429</p>	<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 surveyor observation and staff interview with Microbiology General Supervisor #1 (MGS1) and the Laboratory Director (LD), the laboratory failed to ensure instrument maintenance and function checks were performed on the fume hood. Findings include: 1 Surveyor observation on 1/8/2026 at 1:00 PM of a sticker attached to the fume hood located in the laboratory revealed: a. The last time the hood was checked for proper function was March 2022. b. The due date for the next function check was listed as March 2023. 2. Staff interview with MGS1 and the LD on 1/8/2026 at 1:10 PM confirmed the above findings. GS1 stated, "I am having a hard time getting someone in to do the function check, but I did vapor monitoring." 3. The laboratory performs 10,209 tests annually in the Specialty of Pathology.</p>
<p>D6054</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>(b)(9) Thereafter, evaluations must be performed at least annually</p> <p>This STANDARD is not met as evidenced by:</p>

Based on record review and staff interview with Microbiology General Supervisor #1 (MGS1) and the Laboratory Director (LD) who is also the Technical Consultant (TC), the TC failed to evaluate Testing Personnel (TP) performance annually to confirm TP ability to perform microscopic analysis of urine sediment in the subspecialty of Urinalysis. Findings include: 1. Record review on 1/8/2026 of the laboratory's CMS form 209 revealed 11 TP listed as performing microscopic analysis of urine sediment. 2. Record review on 1/8/2026 of the laboratory's 2024, 2025 and 2026 to date TP competency records revealed 11 of 11 TP who perform microscopic analysis of urine sediment did not have documented competency assessment. 3. Record review on 1/8/2026 of the laboratory's College of American Pathologists (CAP) Clinical Microscopy (CMP) 2024 event A proficiency testing (PT) records revealed: a. 6 answer sheets with the initials of 6 different TP. 0 of 6 of these answer sheets had the correct answer for all 3 CM-A photographs. b. The answer sheets were not graded. c. Continuing education was not documented for the incorrect answers. 4. Staff interview on 1/8/2026 at 10:30 AM with MGS1 and the TC confirmed the above findings. 5. The laboratory performs 17 microscopic urine sediment examinations annually.