

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0067746	(X3) Date Survey Completed 11/17/2023
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
D0000	A CLIA recertification survey was conducted for the Pioneer Valley Urology, PC laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. Please refer to Conditions of Participation for Clinical Laboratories 42 CFR Part 493. .
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing review and interview, the laboratory failed to maintain a copy of all proficiency testing records as evidenced by the following: a) A review of proficiency testing records for calendar years 2022 and 2023 (6 testing events) revealed the fact that a copy of the attestation statement provided by the PT program, signed by the analyst and the laboratory director were not available for the College of American Pathologist (CAP) reports for the clinical microscopy (CM series sent two times per year) and semen analysis (SM series sent two times per year)reports for the first and second testing event of 2022 and 2023. b) The clinical manager confirmed in</p>

an interview on 11/17/23 at 12:10 PM that the attestation forms for the CAP proficiency were not being printed out and signed by the laboratory director and the personnel performing the testing.

D5787

TEST RECORDS
CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:
Based on record review and confirmed through an interview with one laboratory histotechnician, the laboratory failed to have a record system which included the identity of the personnel who performed the test(s) as evidenced by the following: a) A review of 20 patient charts for laboratory testing performed between 1/3/23 and 11/13/23 revealed the fact that the identity of the person performing the testing was not available for 2 out of the 20 charts reviewed for tissue grossing performed on 1/20/23 (medical record number 213118 - prostate needle biopsy) and 8/24/23 medical record number 90498 - bladder biopsy). b) Histotechnician number one confirmed in an interview on 11/17/23 at 12:22 PM that they were not documenting the identification of who performed the tissue grossing on the request forms as they previously had. The laboratory performs approximately 2,042 histology tissue grossing annually.