

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0307528	(X3) Date Survey Completed 06/01/2023
Name of Provider or Supplier Urology Assoc Pc-Skyline Medical Ctr	Street Address, City, State 3443 Dickerson Rd, Suite 160, Nashville, TN	
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
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 review of laboratory policy, proficiency testing (PT) records, and staff interview, the laboratory failed to follow it's own policy for PT record retention in 2021 and 2022 for two of six events reviewed. The findings include: 1. Review of laboratory policy titled "CLINICAL QUALITY ASSURANCE/NOTIFICATION OF LABORATORY CHANGES AND LABORATORY CLOSURE POLICIES" revealed the following: "Urology Associates, P.C. has set the following minimum retention times..." "Proficiency Testing Results and Associated Worksheets" with a minimum retention requirement of two years. 2. Review of the laboratory's American Proficiency Institute (API) PT records revealed the following: Attestation statements provided by the PT program for events 2021 Event 3 and 2022 Event 3 were not retained. Performance evaluation review documentation was not retained for API PT 2022 Event 3. 3. Interview on 06/01/2023 at 11:00 am with the technical consultant confirmed the laboratory failed to follow it's own policy for PT record retention in 2021 and 2022.</p>