

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 08D0691598	(X3) Date Survey Completed 10/04/2023
Name of Provider or Supplier Urology Associates Of Delaware, P A	Street Address, City, State 200 Banning Street, Suite 250, Dover, DE	
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
D5655	<p>CYTOLOGY CFR(s): 493.1274(e)(4)</p> <p>(e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following: (e)(4) Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, cytology slide preparations, corresponding final test reports and interview with the Laboratory Director/Technical Supervisor, the laboratory failed to establish written policies and procedures to ensure unsatisfactory nongynecologic cytology slide preparations were identified and reported as unsatisfactory. The laboratory failed to identify and report one of 28 unsatisfactory nongynecologic cytology slide preparations from January to March 2023 as "Unsatisfactory for Evaluation". The laboratory also failed to identify and report one of 28 "Unsatisfactory for Evaluation" nongynecologic cytology slide preparations from January to March 2023 as being "Negative". Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure unsatisfactory nongynecologic cytology slide preparations were identified and reported as unsatisfactory. 2. The laboratory failed to identify and report one of 28 nongynecologic cytology slide preparations from January to March 2023 as being "Unsatisfactory for Evaluation" due to insufficient cellularity. Refer to D6115. Case includes: - UC23-00068 3. The laboratory failed to identify and report one of 28 "Unsatisfactory for Evaluation" nongynecologic cytology slide preparations as being "Negative". Refer to D6115. Case includes: - UC23-00213 4. During an interview on October 4, 2023 at 10:30 AM these findings were confirmed by the Laboratory Director/Technical Supervisor.</p>
D6115	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2)</p>

The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:
Based on the microscopic review of 287 negative and unsatisfactory nongynecologic cytology cases from January through March 2023, the Technical Supervisor failed to verify the accuracy of two nongynecologic cytology tests. 1. UC23-00068 01/24/2023 CellSolutions preparation LABORATORY DIAGNOSIS: Negative for Malignant Cells SURVEY TEAM DIAGNOSIS: Unsatisfactory, Insufficient Cellularity TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory on Voided Urine 2. UC23-00213 02/28/2023 CellSolutions preparation LABORATORY DIAGNOSIS: Insufficient Cellularity for Diagnosis SURVEY TEAM DIAGNOSIS: Negative for Malignancy TECHNICAL SUPERVISOR DIAGNOSIS: Negative but Obscuring Inflammation

D9999

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