

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0861767	(X3) Date Survey Completed 11/20/2024
Name of Provider or Supplier Urologic Health Center Of Nj, Pc	Street Address, City, State 67 Route 37 West, Toms River, NJ	
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
D5637	<p>CYTOLOGY CFR(s): 493.1274(d)(1)(ii)</p> <p>(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of workload limit reassessment records and interview with the Laboratory Director/Technical Supervisor the laboratory failed to establish and follow written policies and procedures to reassess a maximum workload limit at least every six months for the Technical Supervisors. The Technical Supervisor failed to reassess a maximum workload limit for one of one Technical Supervisors in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The laboratory failed to follow the procedure CYTOLOGY WORKLOAD LIMITS, which stated: "* Evaluate every 6 months" 2. The laboratory failed to establish a written policy and procedure to describe the criteria to be used to reassess and adjust as needed the workload limit. 3. The Survey Team requested and the laboratory failed to provide documentation the Technical Supervisor reassessed a maximum workload limit for one of one Technical Supervisors in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Technical Supervisor includes: -Laboratory Director/Technical Supervisor 4. During an interview on November 18, 2024 at 10:00 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor.</p>
D5641	<p>CYTOLOGY CFR(s): 493.1274(d)(2)(ii)</p> <p>(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(2)(ii) For the purposes of establishing</p>

workload limits for individuals examining slides in less than an 8-hour workday (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours is used to prorate the number of slides that may be examined. The formula-- Number of hours examining slides X 100 / 8 is used to determine maximum slide volume to be examined;

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, workload records and interview with the Laboratory Director/Technical Supervisor the laboratory failed to follow written policies and procedures to ensure that workload limits for the Technical Supervisor would be prorated when examining slides in less than an eight hour work day. Findings include: 1. The laboratory failed to follow the written procedure CYTOLOGY WORKLOAD LIMITS, which stated: "Screening of Nongynecological Cytology Specimens Federal regulations require that the individual examining a cytology specimen be a qualified cytotechnologist or pathologist in a certified laboratory. These individuals may examine up to 100 slides (gynecologic and nongynecologic) per 24 hours (average 12.5 slides/hour) and in not less that eight hours." 2. The Survey Team requested and the laboratory failed to provide documentation of prorated workload limits for one of one Technical Supervisors who performed primary screening of cytology specimens in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. 3. The laboratory failed to document the number of hours spent examining slides so a proration of the number of slides allowed to be examined was not performed. Refer to D5645. Technical Supervisor includes: - Laboratory Director/Technical Supervisor 4. During an interview on November 18, 2024 at 10:00 AM, these findings were confirmed with the Laboratory Director /Technical Supervisor.

D5645

CYTOLOGY

CFR(s): 493.1274(d)(3)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, workload limit records and interview with the Laboratory Director/Technical Supervisor the laboratory failed to establish written policies and procedures to ensure records were available to document the number of hours spent examining slides for one of one Technical Supervisors in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure records would be maintained of the number of hours Technical Supervisors spent examining slides during each 24-hour period. 2. The Survey Team requested and the laboratory failed to provide records of the time spent examining slides for one of one Technical Supervisors who performed primary examination of cytology specimens in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Technical Supervisor includes: -Laboratory Director/Technical Supervisor 3. During an interview on November 18, 2024 at 10:00 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor.

<p>D5655</p>	<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 and interview with the Laboratory Director/Technical Supervisor the laboratory failed to establish and follow written policies and procedures to ensure unsatisfactory nongynecologic cytology slide preparations were identified and reported as unsatisfactory. 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. During an interview on November 20, 2024 at 10:00 AM, these findings were confirmed with the Laboratory Director /Technical Supervisor.</p>
<p>D5659</p>	<p>CYTOLOGY CFR(s): 493.1274(e)(6)</p> <p>(e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(6) Corrected reports issued by the laboratory indicate the basis for correction.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview with the Laboratory Director/Technical Supervisor the laboratory failed to establish written policies and procedures to ensure corrected test reports indicated the basis for correction on the corrected test report. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure corrected test reports indicated the basis for correction on the corrected test report. 2. During an interview on November 20, 2024 at 10:00 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor.</p>
<p>D6108</p>	<p>LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447</p> <p>The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews the laboratory failed to have a Technical Supervisor who meets the qualification requirements of 493.1451 of this subpart. The Technical Supervisor failed to reassess a maximum workload limit at least every 6 month for one of one Technical Supervisors (refer to D6130); and failed to ensure one of one Technical Supervisors documented the hours devoted to screening slides during each 24-hour period (refer to D6133).</p>

<p>D6115</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2)</p> <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.</p> <p>This STANDARD is not met as evidenced by: Based on the microscopic review of 341 random negative nongynecologic cytology cases/slides from January 2023 through November 2024 and confirmation by the Technical Supervisor on November 20, 2024 the Technical Supervisor failed to verify the accuracy of 1 nongynecologic cytology test. 1. CT24-314 04/10/2024 Voided Urine LABORATORY DIAGNOSIS: Negative for Malignant Cells SURVEY TEAM DIAGNOSIS: High Grade Urothelial Carcinoma TECHNICAL SUPERVISOR DIAGNOSIS: Suspicious for Malignant Cells</p>
<p>D6130</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(2)(3)</p> <p>(c) In cytology, the technical supervisor or the individual qualified under 493.1449(k) (2)-- (c)(2) Must establish the workload limit for each individual examining slides and (c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of workload limit reassessment records and interview the Technical Supervisor failed to reassess a maximum workload limit for one of one Technical Supervisors in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The Technical Supervisor failed to provide documentation the Technical Supervisor reassessed a workload limit at least every six months for one of one Technical Supervisors who performed primary cytology slide examinations in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Refer to D5637</p>
<p>D6133</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(6)</p> <p>In cytology, the technical supervisor or the individual qualified under 439.1449(k)(2), if responsible for screening cytology slide preparations, must document the number of cytology slides screened in 24 hours and the number of hours devoted during each 24-hour period to screening cytology slides.</p> <p>This STANDARD is not met as evidenced by: Based on review of workload records and interview the Technical Supervisor failed to provide records documenting the number of hours spent screening cytology slides for one of one Technical Supervisors in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The Technical Supervisor failed to provide records documenting the number of hours spent screening cytology slides for one of one Technical Supervisors who performed primary cytology slide examinations in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Refer to D5645</p>

D9999

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