

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0431110	(X3) Date Survey Completed 11/18/2020
Name of Provider or Supplier Illinois Urologic Health Surgeons	Street Address, City, State 2937 State Route 178, Utica, IL	
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
D5032	<p>CYTOLOGY CFR(s): 493.1221</p> <p>If the laboratory provides services in the subspecialty of Cytology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1274, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews it was determined the laboratory failed to reassess and document a workload limit for the Laboratory Director/Technical Supervisor (refer to D5637 and D5647); failed to establish policies and procedures to ensure that the laboratory would maintain records of the total hours spent examining slides (refer to D5645); and failed to establish policies and procedures to ensure test reports contained narrative descriptive nomenclature (refer to D5657). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results in the subspecialty of Cytology.</p>
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, laboratory records and interviews it was determined that the laboratory failed to follow a written policy and procedure to reassess a maximum workload limit at least every six months for one of</p>

one Laboratory Director/Technical Supervisors in 2019 and to the date of the survey 2020. Findings include: 1. The laboratory failed to follow the written policy and procedure WORKLOAD LIMITS which stated: "The workload limit will be reassessed at least every six months and any changes implemented." 2. The Survey Team requested and the laboratory failed to provide documentation of a workload reassessment for the Laboratory Director/Technical Supervisor in 2019 and 2020. 3. During interviews on November 16, 2020 at 10:15 AM and November 18, 2020 at 10:20 AM the Laboratory Director/Technical Supervisor confirmed these findings.

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, laboratory records and interviews it was determined that the laboratory failed to establish written policies and procedures to ensure that the laboratory would maintain records of the total number of hours one of one Laboratory Director/Technical Supervisors spent examining slides irrespective of site, during each 24-hour period in 2019 and 2020 to the date of the survey. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how records would be maintained of the total number of hours the Laboratory Director/Technical Supervisor spent examining slides during each 24-hour period, irrespective of site. 2. The Survey Team requested and the Laboratory Director/Technical Supervisor failed to provide records to document the total number of hours spent examining slides at FACILITY A (CLIA #12D0431110) from January through December 2019. a. Laboratory records titled DAILY DIAGNOSIS LOG 2019 failed to include the time spent examining slides on 71 of 71 days from January through December 2019. Dates include: -January 8, 10, 13, 15, 21, 27, 31 -February 4, 10, 17, 19, 24, 25 -March 3, 10, 11, 13, 17, 22, 31 -April 7, 8, 14, 21, 25, 28 -May 12, 13, 16, 22, 26, 27 -June 2, 10, 13, 16, 18, 23, 24, 30 -July 7, 15, 22, 29, 31 -August 6, 10, 15, 20, 25, 26, 31 -September 9, 15, 23, 28, 29, 30 -October 6, 13, 19, 22, 31 -November 3, 9, 17, 24, 30 -December 9, 15, 26 b. Laboratory records titled DAILY DIAGNOSIS LOG 2020 failed to include the time spent examining slides on 63 of 63 days from January through October 2020. Dates include: -January 1, 5, 6, 13, 15, 20, 27, 30 -February 3, 9, 15, 23, 29 -March 8, 15, 21, 22, 29 -April 6, 8, 11, 15, 19, 20, 26 -May 10, 15, 16, 25, 31 -June 7, 14, 15, 19, 28, 31 -July 5, 12, 15, 20, 26, 31 -August 9, 11, 16, 19, 23, 30, 31 -September 6, 7, 13, 17, 20, 23, 25 -October 4, 5, 11, 12, 18, 25, 28 c. During an interview on November 16, 2020 at 10:15 AM the Laboratory Director/Technical Supervisor stated "I used to record the hours but I stopped." 3. The Survey Team requested and the Laboratory Director/Technical Supervisor failed to provide records to document the total number of hours spent examining slides at Facility B (CLIA #14D2030411) from January through September 2020. a. Laboratory records titled CYTOTECHNOLOGISTS MONTHLY WORKLOAD LOG and DAILY DIAGNOSIS LOG failed to include the time spent examining slides on 113 of 113 days from January through September 2020. Dates include: -January 2, 3, 6, 8, 9, 13, 14, 15, 16, 17, 20, 21, 22, 23, 24, 27, 29, 30, 31 -February 4, 5, 6, 10, 11, 12, 14, 17, 18, 20, 21, 24, 26, 27 -March 3, 4, 6, 9,

10, 11, 12, 13, 17, 20, 26 -April 0 -May 1, 7, 11, 12, 13, 14, 19, 26, 27, 28 -June 1, 2, 3, 8, 11, 12, 16, 17, 18, 19, 24, 25, 26, 30 -July 1, 6, 7, 8, 9, 10, 13, 15, 17, 20, 21, 22, 24, 27, 28, 29, 30 -August 4, 5, 6, 7, 12, 14, 18, 19, 20, 21, 24, 25, 28 -September 1, 2, 4, 8, 9, 14, 15, 16, 17, 18, 21, 23, 28, 29, 30 4. The Survey Team requested and the Laboratory Director/Technical Supervisor failed to provide records to document the total number of hours spent examining slides at Facility C (CLIA #14D0705475) on January through October 2020. a. Laboratory records titled DAILY DIAGNOSIS LOG 2020 failed to include the time spent evaluating slides on 33 of 33 days from January through October 2020. Dates include: -January 15, 16, 21, 26 -February 13 - March 5, 18, 19, 22, 24 -April 0 -May 0 -June 1, 10, 18, 19, 30 -July 12, 20, 26 - August 4, 10, 11, 17, 31 -September 9, 10, 13, 16, 22, 25 -October 15, 16, 20, 25 5. During an interview on November 16, 2020 at 1:15 PM the Laboratory Director /Technical Supervisor stated that the Laboratory Director/Technical Supervisor "evaluates slides at two other locations." When asked by the Survey Team if slides were examined at Facility B or Facility C on the same day slides were examined at FACILITY A the Laboratory Director/Technical Supervisor replied "sometimes, but not often." 6. During interviews on November 16, 2020 at 1:15 PM and November 18, 2020 at 10:20 AM the Laboratory Director/Technical Supervisor confirmed these findings.

D5647

CYTOLOGY
CFR(s): 493.1274(d)(4)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(4) Records are available to document the workload limit for each individual.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, lack of laboratory records and interviews it was determined that the laboratory failed to establish written policies and procedures to ensure records to document the workload limit for one of one Laboratory Director/Technical Supervisors in 2019 and to the date of the survey in 2020 were available. Cross refer to D5637 Findings include: 1. The Survey Team requested and the laboratory failed to provide records of an established workload limit for the one of one Laboratory Director/Technical Supervisor in 2019 and to the date of the survey in 2020. 2. During interviews on November 16, 2020 at 10:15 AM and November 18, 2020 at 10:20 AM the Laboratory Director/Technical Supervisor confirmed these findings.

D5657

CYTOLOGY
CFR(s): 493.1274(e)(5)

(e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(5) The report contains narrative descriptive nomenclature for all results.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures and interviews it was determined that the laboratory failed to establish written policies and procedures to ensure nongynecologic urine cytology test reports contained narrative descriptive nomenclature. Findings include: 1. The Survey Team requested and the laboratory

	<p>failed to provide written policies and procedures to describe the laboratory's nomenclature system for reporting nongynecologic urine cytology test results. 2. During interviews on November 16, 2020 at 3:45 PM and November 18, 2020 at 10:20 AM the Laboratory Director/Technical Supervisor confirmed these findings.</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 interviews it was determined that the laboratory failed to establish written policies and procedures to ensure that corrected reports indicated the basis for the correction on the report. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure corrected reports indicated the basis for the correction on the report. 2. During interviews on November 16, 2020 at 3:45 PM and November 18, 2020 at 10:20 AM the Laboratory Director/Technical Supervisor confirmed these findings.</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 review of laboratory records and interviews it was determined that the Technical Supervisor failed to reassess workload limits at least every six months for one of one Laboratory Director/Technical Supervisors in 2019 and to the date of the survey in 2020. Cross 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 laboratory records and interviews it was determined that one of one Technical Supervisors failed to document the number of hours devoted to screening slides during each 24-hour period in 2019 and to the date of survey in 2020. Cross refer to D5645</p>

D9999

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