

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0430238	(X3) Date Survey Completed 07/28/2021
Name of Provider or Supplier Rockford Urological Associates	Street Address, City, State 351 Executive Pkwy, Rockford, 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, nongynecologic specimen slides and interviews it was determined the laboratory failed to establish written policies and procedures to assess the competency for one of one Technical Supervisor (refer to D5209); failed to establish written policies and procedures for the evaluation of three of three annual statistics (refer to D5629); failed to establish written policies and procedures to ensure individual workload limits were established and reassessed for one of one Technical Supervisor (refer to D5633 and D5637); failed to establish written policies and procedures to ensure the workload limit, when examining slides in less than 8-hours and with duties other than slide examination, would be prorated to determine the number of slides that may be examined (refer to D5641); and failed to establish written policies and procedures to ensure that unsatisfactory nongynecologic slide preparations were identified and reported as unsatisfactory (refer to D5655).</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p>

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, lack of laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to assess the competency of one of one Technical Supervisor in 2019, 2020 and to the date of the survey in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process for assessing the competency of one of one Technical Supervisor. 2. The Survey Team requested and the laboratory failed to provide records of competency assessment for the one of one Technical Supervisor in 2019, 2020 and to the date of the survey in 2021. Technical Supervisor includes: - Laboratory Director/Technical Supervisor 3. During an interview on July 27, 2021 at 1:15 PM the Laboratory Director/Technical Supervisor confirmed these findings.

D5629

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

(c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c) (5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures for the evaluation of three of three annual laboratory statistics. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual statistical evaluation of three statistics that were provided for the nongynecologic specimens. Nongynecologic specimens include: a) Cytology cases examined; b) Specimens processed by specimen type; c) Patient cases reported by diagnosis to include unsatisfactory. 2. During an interview on July 28, 2021 at 9:00 AM the Medical Technologist confirmed these findings.

D5633

CYTOLOGY
CFR(s): 493.1274(d)(1)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, lack of laboratory records and interview it was determined that the laboratory failed to follow written policies and procedures to ensure that maximum workload limits were established for one of one

Technical Supervisor in 2019, 2020 and to the date of the survey in 2021. Findings include: 1. The laboratory failed to follow the procedure WORKLOAD LIMITS which stated: "Slide examination performance will be evaluated and documented at least twice a year to establish a maximum workload for that individual based on the capability and documented performance evaluation." 2. The Survey Team requested and the laboratory failed to provide individual maximum workload limits for one of one Technical Supervisor in 2019, 2020, and to the date of the survey in 2021. Technical Supervisor includes: -Laboratory Director/Technical Supervisor 3. During an interview on July 27, 2021 at 1:15 PM the Laboratory Director/Technical Supervisor confirmed these findings.

D5637

CYTOLOGY
CFR(s): 493.1274(d)(1)(ii)

(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.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, lack of laboratory records and interview it was determined that the laboratory failed to follow written policies and procedures to reassess a maximum workload limit at least every six months for one of one Technical Supervisor in 2019, 2020 and to the date of the survey in 2021. Cross refer to D5633 Findings include: 1. The laboratory failed to follow the procedure WORKLOAD LIMITS which stated: "Slide examination performance will be evaluated through our bi-annual peer review process." 2. The Survey Team requested and the laboratory failed to provide records of a workload reassessment at least every six months for one of one Technical Supervisor in 2019, 2020 and to the date of the survey in 2021. Technical Supervisor includes: -Laboratory Director/Technical Supervisor 3. During an interview on July 27, 2021 at 1:15 PM the Laboratory Director/Technical Supervisor confirmed these findings.

D5641

CYTOLOGY
CFR(s): 493.1274(d)(2)(ii)

(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 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 and laboratory records it was determined that the laboratory failed to follow written policies and procedures to ensure that the Laboratory Director/Technical Supervisor did not exceed the prorated workload limit when examining slides in less than an 8-hour workday during 27 of 27 days in 2021. Findings include: 1. The laboratory failed to follow the procedure WORKLOAD LIMITS which stated: "The maximum number of slides examined by an individual in each 24-hour period must not exceed 100 slides" the procedure

further stated "Non-gynecologic slide preparations made using liquid-based slide preparatory techniques that result in a cell dispersion over one-half or less of the total available slide may be counted as one-half slide; therefore, under CLIA guidelines, the maximum workload limits for Urine Cytology slides at Rockford Urological Associates is 200 slides." 2. The Survey Team reviewed "Daily Specimen Log (R.U. A. Cytology Lab/CLIA #14D0430238)" records from January through July 2021. The Laboratory Director/Technical Supervisor exceeded the prorated workload limit of 25 slides per hour during 27 of 27 days in 2021. 2021 days include: -January 7 Slide Review Time: 13 minutes Number slides evaluated: 9 Number slides allowed: 5 - January 11 Slide Review Time: 12 minutes Number slides evaluated: 6 Number slides allowed: 5 -January 25 Slide Review Time: 22 minutes Number slides evaluated: 16 Number slides allowed: 9 -February 2 Slide Review Time: 41 minutes Number slides evaluated: 19 Number slides allowed: 17 -February 8 Slide Review Time: 23 minutes Number slides evaluated: 16 Number slides allowed: 10 -February 15 Slide Review Time: 14 minutes Number slides evaluated: 9 Number slides allowed: 6 -February 23 Slide Review Time: 24 minutes Number slides evaluated: 15 Number slides allowed: 10 -March 9 Slide Review Time: 20 minutes Number slides evaluated: 14 Number slides allowed: 8 -March 15 Slide Review Time: 23 minutes Number slides evaluated: 13 Number slides allowed: 10 -March 23 Slide Review Time: 30 minutes Number slides evaluated: 17 Number slides allowed: 13 -March 30 Slide Review Time: 10 minutes Number slides evaluated: 5 Number slides allowed: 4 -April 6 Slide Review Time: 18 minutes Number slides evaluated: 13 Number slides allowed: 8 -April 15 Slide Review Time: 8 minutes Number slides evaluated: 5 Number slides allowed: 3 - April 21 Slide Review Time: 10 minutes Number slides evaluated: 5 Number slides allowed: 4 -April 27 Slide Review Time: 35 minutes Number slides evaluated: 24 Number slides allowed: 15 -May 3 Slide Review Time: 16 minutes Number slides evaluated: 10 Number slides allowed: 7 -May 11 Slide Review Time: 22 minutes Number slides evaluated: 16 Number slides allowed: 9 -May 18 Slide Review Time: 20 minutes Number slides evaluated: 16 Number slides allowed: 8 -June 2 Slide Review Time: 20 minutes Number slides evaluated: 14 Number slides allowed: 8 - June 15 Slide Review Time: 13 minutes Number slides evaluated: 10 Number slides allowed: 5 -June 21 Slide Review Time: 13 minutes Number slides evaluated: 10 Number slides allowed: 5 -June 24 Slide Review Time: 13 minutes Number slides evaluated: 7 Number slides allowed: 5 -June 29 Slide Review Time: 28 minutes Number slides evaluated: 18 Number slides allowed: 12 -July 8 Slide Review Time: 13 minutes Number slides evaluated: 9 Number slides allowed: 5 -July 13 Slide Review Time: 7 minutes Number slides evaluated: 6 Number slides allowed: 3 -July 20 Slide Review Time: 22 minutes Number slides evaluated: 16 Number slides allowed: 9 -July 25 Slide Review Time: 27 minutes Number slides evaluated: 14 Number slides allowed: 11

D5655

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

(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.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that unsatisfactory nongynecologic slide preparations were identified and

	<p>reported as unsatisfactory. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that unsatisfactory nongynecologic slide preparations were identified and reported as unsatisfactory. 2. During an interview on July 27, 2021 at 1:15 PM 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 policies and procedures, lack of laboratory records and interview it was determined that Laboratory Director/Technical Supervisor failed to establish individual workload limits and failed to reassess and adjust when necessary workload limits at least every six months, for one of one Technical Supervisor in 2019, 2020 and to the date of the survey in 2021. Cross Refer to D5633 and D5637.</p>
<p>D9999</p>	<p>By agreement between ASCT Services, Inc. and CMS, information provided for CMS's completion of CMS Form 670 are ASCT Services, Inc. averages only. This information is confidential and proprietary to ASCT Services, Inc., is exempt under the Freedom of Information Act (5 U.S.C. 552 et seq.), and shall be used for federal government purposes only.</p>