

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 14D1043269	<b>(X3) Date Survey Completed</b> 04/24/2018
<b>Name of Provider or Supplier</b> Rockford Dermatology Sc	<b>Street Address, City, State</b> 4338 Morsay Drive, Rockford, IL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3001</b>	<p><b>FACILITIES</b> CFR(s): 493.1101(a)(1)</p> <p>The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process.</p> <p>This STANDARD is not met as evidenced by: Based on observation, review, and interview; the laboratory was not constructed, arranged and maintained to ensure the ventilation and utilities necessary for conducting all phases of the testing process. Findings: 1. Surveyor observation revealed that there was no fume hood in the room where tissue specimens were processed, cut, and stained. 2. Review of laboratory procedures manuals revealed that the laboratory's procedures manuals consisted of a written procedures manual, which was supplemented with 2 American Academy of Dermatology (AAD) CLIA Compliance Manuals. The AAD compliance manual had a section where the laboratory can fill in the blanks to describe its maintenance procedure for its fume hood. The laboratory did not complete the section for maintenance of its fume hood. 3. During survey date 04/24/18, the laboratory director confirmed the surveyor's findings.</p>
<b>D5028</b>	<p><b>HISTOPATHOLOGY</b> CFR(s): 493.1219</p> <p>If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1273, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory procedures manuals and patients test reports; the</p>

laboratory failed to meet the requirements specified in 493.1230 through 493.1256, 493.1273, and 493.1281 through 493.1299. Findings: 1. The laboratory failed to verify its histopathology procedures. See D5217 2. The laboratory failed to have an approved comprehensive procedures manual. See D5403 and D5407 3. The laboratory failed to include pertinent information on its patients' test reports. See D5607 and D5817

**D5217**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**  
CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:  
Based on review and interview, the laboratory failed to verify the accuracy of its histopathology procedures at least annually biannually. Findings: 1. Review of the laboratory's procedures manuals revealed that there were no procedures that described how the laboratory verifies its histopathology procedures. 2. Review of the laboratory's records revealed that there was no documentation to show that the laboratory performed proficiency testing or any other kind of verification procedures for its histopathology tests. 3. During survey date 04/24/18, the laboratory director confirmed the surveyor's findings.

**D5403**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:  
D5403 Based on review of the laboratory's procedures manuals and interview; the procedures manuals did not include the following when applicable to the test procedure: . Findings: 1. The procedures manuals did not include requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. 2. The procedures manuals did not include

	<p>microscopic examination, including the detection of inadequately prepared slides. 3. The procedures manuals did not include control procedures. 4. The procedures manuals did not include corrective action to take when control results fail to meet the laboratory's criteria for acceptability. 5. The procedures manual did not include the laboratory's system for entering results in the patient record and reporting patient results. 6. The procedures manual did not include description of the course of action to take if a test system becomes inoperable. 7. During survey date 04/24/18, the laboratory director confirmed the surveyor's findings.</p>
<p><b>D5407</b></p>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review and interview; the procedures were not approved, signed and dated by the laboratory director. Findings: 1. Review of the laboratory's procedures manuals revealed that the laboratory had a written procedures manual and 2 American Academy of Dermatology (AAD) CLIA Compliance manuals it used as its procedures. There was no documentation to show that the laboratory director approved, signed and dated the procedures. AAD CLIA Compliance manuals even had a signature page for approval of the procedures. However, the approval page was not signed and dated by the laboratory director. 2. During survey date 04/24/18, the laboratory director confirmed the surveyor's findings.</p>
<p><b>D5607</b></p>	<p><b>HISTOPATHOLOGY</b> CFR(s): 493.1273(d)(f)</p> <p>(d) Tissue pathology reports must be signed by an individual qualified as specified in paragraph (b) or, as appropriate, paragraph (c) of this section. If a computer report is generated with an electronic signature, it must be authorized by the individual who performed the examination and made the diagnosis. (f) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on review and interview; Tissue pathology reports were not signed by a qualified individual. Findings: 1. Review of 4 patients' reports revealed that the laboratory director's name was typed at the bottom of 3 of 4 test reports (1 test report had not been entered into the electronic medical records). The surveyor and laboratory director could not determine if the director's typed name constitutes her electronic signature. 2. During survey date 04/24/18, the laboratory director confirmed the surveyor's findings.</p>
<p><b>D5817</b></p>	<p><b>TEST REPORT</b> CFR(s): 493.1291(i)</p> <p>If a laboratory refers patient specimens for testing-- (i)(1) The referring laboratory must not revise results or information directly related to the interpretation of results provided by the testing laboratory; (i)(2) The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially</p>

requested the test. The referring laboratory must retain or be able to produce an exact duplicate of each testing laboratory's report; and (i)(3) The authorized person who orders a test must be notified by the referring laboratory of the name and address of each laboratory location where the test was performed.

This STANDARD is not met as evidenced by:  
Based on review and interview, the referring laboratory failed to notify this laboratory of the name and address of each laboratory location where tests were performed.  
Findings: 1. Review of 4 patients' test reports revealed that the name and address of the laboratory location where the initial tissue was tested and pathology report generated was not included on the Mohs surgical report for 4 of 4 reports reviewed. The laboratory only documented it as "Previous Accession." The surveyor could not determine if the "Previous Accession" was from this laboratory or the referral laboratory. The laboratory made no distinction between its accession #s and their referral labs accession #s. 2. During survey date 04/24/18, the laboratory director confirmed the surveyor's findings.

**D6094**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:  
Based on review and interview, the laboratory director failed to ensure that a quality assessment (QA) program that identifies failures in quality as they occur is established and maintained. Findings: 1. Review of the laboratory's procedures manuals revealed that there were no procedures that described how the laboratory assesses the preanalytic, analytic and post analytic laboratory systems. 2. There was no documentation to show that the laboratory assessed the quality of the preanalytic, analytic and post analytic laboratory systems. 3. During survey date 04/24/18, the laboratory director confirmed the surveyor's findings.

**D6107**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:  
Based on review and interview; the laboratory director failed to specify in writing the responsibilities and duties of each laboratory personnel. Finding: 1. During survey

date 04/24/18, the laboratory director confirmed the he failed to specify the responsibilities and duties of each laboratory personnel as described by the surveyor's findings.