Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D1043269	03/07/2023
Name of Provider or Supplier	**Street Address, City, State**	
Rockford Dermatology Sc	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5028	HISTOPATHOLOGY CFR(s): 493.1219 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. This CONDITION is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with Laboratory Director (LD); the laboratory failed to meet the condition level requirements for histopathology. Findings Include: 1. The laboratory failed to perform bi-annual method accuracy evaluations for histopathology testing in 2021 and 2022. See D5217. 2. The laboratory failed to ensure one out of ten patient test reports for Mohs testing was accurately transcribed into the electronic medical record. See D5801. 3. The laboratory failed to follow written policies and procedures to monitor, assess, and when indicated correct problems identified in the post-analytic systems specified in 493.1291. See D5891.
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 of laboratory records, lack of documentation, and interview with Laboratory Director (LD); the laboratory failed to perform bi-annual method accuracy evaluations for histopathology testing in 2021 and 2022. Findings Include: 1. The laboratory's policy and procedure manual and proficiency testing records were

	reviewed for 2021 through 2022. 2. Review of the laboratory's proficiency testing policy failed to include bi-annual method accuracy verifications for Moh's histopathology. 3. Review of proficiency testing documentation found only one Mohs case was sent out in 2021 and one case in 2022 to American Society for Mohs Surgery. 4. Interview with LD on 03-07-2023, at 1:45 pm, confirmed that the laboratory failed to perform bi-annual method accuracy verifications for Moh's histopathology testing in 2021 and 2022.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct observation and interview with the Laboratory Director (LD); the laboratory failed to ensure reagents used for histopathology testing were labeled to ensure accurate and reliable testing. Findings Include: 1. Direct observation of the laboratory facility on 03-07-2023 at 11:00 am identified unlabeled containers of marking ink used for histopathology testing. 2. Interview with the LD on 03-07-2023 at 11:00 am confirmed the containers of marking ink are used for histopathology testing. 3. On survey date 03-07-2023, at 1:45 pm, the LD confirmed the laboratory failed to label the marking ink with the following criteria: (1) Identity (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the Laboratory Director (LD); the laboratory failed to ensure one out of ten patient test reports for MOHs testing was accurately transcribed into the electronic medical record. Findings Include: 1. Review of one of ten patient test reports for Mohs testing found the laboratory failed to accurately transcribe the histopathology results in the laboratory's test report for patient seven (PT7), MRN: MM0000003628. a. The patient test report for the Mohs surgery indicated that margins were free of tumor at stage 1. No stage 2 documented. b. Mohs map indicated two stages were performed to clear the tumor. 2. On survey date 03-07-2023, at 12:45 pm, the LD confirmed the patient test report for

	08-23-2022 was incorrect for Stage I because there was residual tumor found according to the Mohs Map and corresponding slides. Stage II results should have been included on the patient test report based on the Mohs map and patient slides.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation and interview with the Laboratory Director (LD); The laboratory failed to follow written policies and procedures to monitor, assess, and when indicated correct problems identified in the post-analytic systems specified in 493.1291. Findings include: 1. The facility's Quality Control on Documentation Protocol stated the following "quality control is performed on following logs every year by lab technician and medical director will review the log sheet; Mohs log..."Select three cases; Print out selected patient's chart; Check name, site and diagnosis to make sure information matches." 2. Review of quality assessment records found the laboratory failed to document review of three Mohs cases annually in 2021 and 2022. 3. Quality Assessment Procedures also stated "All QA records such as logs of test requisitions, test reports, and receipt and QA of reagents and culture media that have not been reviewed previously will be reviewed by the Laboratory Director or an appropriate, designated staff member every month. The Laboratory Director or an appropriate, designated staff member will conduct meetings with all relevant staff every month to communicate the results of corrective action, QC, and QA reviews and to address any concerns affecting laboratory performance.". 4. Review of quality assessment records found no documentation of monthly meetings for 24 of 24 months reviewed. 5. On survey date 03-07-2023, at 1: 45 pm, the LD confirmed that three Mohs cases have not been reviewed annually for the past 2 years, and monthly meeting had not been held.