| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 14D1037339 | 03/10/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Premier Dermatology | 1520 Bond St, Naperville, 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 |
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| **D5203** | SPECIMEN IDENTIFICATION AND INTEGRITY<br>CFR(s): 493.1232<br><br>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's procedure manual; patients' testing logs; and interview with the practice manager, the laboratory failed to establish and following written policies and procedures that ensure positive and optimum integrity of patients' specimens from the time of collection or receipt of specimen through completion and reporting of results. 1. Review of the laboratory's procedure manual revealed that there were no procedures that describes the requirements for patient specimen processing. 2. Review of patients' testing logs revealed that the same patients' Case numbers (SA026, SA027, SA028, SA029, SA030, SA031, SA032, SA033, SA034, and SA035) are assigned to 2 different patients for each number for 2 separate years (2019 and 2020). The surveyor could not differentiate case numbers written on the specimen log in 2019 from ones written on specimen logs in 2020. 3. On March 10, 2021 at 3:30 PM, the practice manager confirmed the surveyor's findings. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>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 |

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| | 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's procedures manual; patients' testing logs; and interview with the practice manager, the procedures failed to include pertinent information applicable to its histology procedures (micrographic surgery). Findings: 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. Review of patients' testing logs revealed that there is no consistency in how MOHs surgeons enter Case numbers of patients' specimens on testing logs. One MOHs surgeon uses the letters "SA" followed by a number, while the other MOHs surgeon uses the letters "EM" followed by a number. 3. On March 10, 2021 at 3:30 PM, the practice manager confirmed the surveyor's findings. |
| **D6103** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(13)<br><br>The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's procedure manual; Laboratory Personnel Report - CLIA (FORM 209); personnel records and interview with the practice manager, the laboratory director failed to be responsibel for ensuring that policies and procedures are established for monitoring testsing personnel to assure that the are competent and maintain their competency to perform test procedures and report test results. Findings: 1. Review of the laboratory's policy and procedure revealed that there is a policey titled, "Personnel Competency Testing." On teh last page of the policy, it reads as follows: "The Competecny Testing and Assessment can be reviewed by another Forefront physician, nurse practioner or physician assistant. The policy also says, "The director is responsible for ensuring that the testing personnel have completed proper training and that the training is documented and reviewed by him/her." 2. Review of FORM 209 revealed that the laboratory director is listed as the person who fulfills the following positions in the laboratory: a. Laboratory Director b. Clinical Consultant c. Technical Supervisor d. General Supervisor e. High Complexity Testing |

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| | Person Also, there were 11 Moderate Complexity Testing persons and 1 other High Complexity Testing Person. 3. Review of personnel records revealed that the laboratory director was not the person responsible for assessing the competency of 11 of 11 Moderate Complexity Testing Perons and 1 of 2 High Complexity Testing Persons. 4. On March 10, 2021 at 3:00 PM, the practice manager confirmed the surveyor's findings. |