| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 16D2037621 | 09/09/2020 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Radiant Complexions Dermatology Clinic | 2913 5th Avenue South, Fort Dodge, IA | |

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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| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Laboratory Test List and Annual volume form, the Quality Assurance procedure and confirmed by laboratory personnel identifier #3 (refer to the Laboratory Personnel Form) at approximately 10:45 am on 9/9/2020, the laboratory failed to verify the accuracy for performing potassium hydroxide (KOH) examination and reading Mohs slides twice annually for two out of three time periods from 1/1 /2019 - 9/9/2020. The findings include: 1. The Quality Assurance procedure stated, "Any test performed in the laboratory for which proficiency testing is not available will be verified at least twice a year and results reviewed by laboratory director." 2. On 11/15/2019, the laboratory documented the verification of accuracy for reading Mohs slides. 3. On 5/4/2020, the laboratory documented the verification of accuracy for performing KOH examinations. 4. At the time of the survey, laboratory personnel identifier #3 confirmed the laboratory only verified the accuracy for KOH examinations and reading Mohs slides on the above dates for the time periods between 1/1/2019 - 9/9/2020. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. |

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| | (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory temperature records and confirmed by laboratory personnel identifier #3 (refer to Laboratory Personnel Report) at approximately 11:00 am on 09/9/2020, the laboratory failed to document the cryostat temperature for one out of two days of patient testing (3/11/2020) in March 2020. The findings include: 1. On 3/11/2020, the laboratory performed Mohs surgery using a cryostat for cutting tissue on Patient identifiers A & B. 2. The laboratory did not document the temperature of the cryostat used for cutting tissue on 3/11/2020. |
| **D5473** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(2)(g)<br><br>(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of quality control records, and confirmed by laboratory personnel identifier #3 (refer to the Laboratory Personnel Report) on 9/9/2020 at approximately 11:00 am, the laboratory failed to document the Hematoxylin and Eosin stain quality each day of patient testing for one out of two days (3/11/2020) in March 2020. The findings include: 1. On 3/11/2020, the laboratory performed Mohs surgery on Patient identifiers A & B. 2. The laboratory did not document the Hematoxylin and Eosin stain quality on 3/11/2020. |
| **D6029** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(11)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of personnel records and confirmed by laboratory personnel identifier #3 (refer to the Laboratory Personnel Report) at approximately 10:30 am on 09/09/2020, the laboratory director failed to ensure that prior to testing patient specimens, all testing personnel performing moderate complexity testing received the appropriate training for two out of two testing personnel (identifiers #1 and #2) who perform potassium hydroxide (KOH) examinations. The findings include: 1. Laboratory personnel identifier #1, started performing KOH examinations in May of |

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| | 2020. 2. Laboratory personnel identifier #2, started performing KOH examinations in August of 2020. 3. At the time of the survey, the laboratory did not have documentation of training for either testing personnel. |