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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>16D0383517     | <b>(X3) Date Survey Completed</b><br><br>09/29/2020 |
| <b>Name of Provider or Supplier</b><br><br>Harlan & Steinhoff Derm Group   | <b>Street Address, City, State</b><br><br>8131 University Boulevard, Clive, IA |   |
| 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>   |
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| <b>D5217</b>              | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br/>CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:<br/>A. Based on review of the Laboratory Test List and Annual Volume form and confirmed by nursing staff at approximately 1:30 pm on 09/29/2020, the laboratory failed to verify the accuracy for reading MOHS surgery slides twice annually for two out of five time periods from 01/01/2018 - 09/29/2020. The findings include: 1. The laboratory documented the verification of accuracy for reading MOHS surgery slides on 04/18/2018 and 10/31/2018. 2. At the time of the survey, nursing staff confirmed that the laboratory did not have additional accuracy verification documentation for reading MOHS surgery slides from 01/01/2018- 09/29/2020. B. Based on review of the Laboratory Test List and Annual Volume form and confirmed by nursing staff at approximately 1:30 pm on 09/29/2020, the laboratory failed to verify the accuracy for performing potassium hydroxide (KOH) examinations, ectoparasite examinations and reading biopsy slides twice annually for four out of five time periods from 01/01/2018 - 09/29/2020. At the time of the survey, nursing staff confirmed that the laboratory did not perform and document twice annual accuracy verification for KOH examinations, ectoparasite examinations and reading biopsy slides from 01/01/2018- 09/29/2020.</p> |
| <b>D6029</b>              | <p>LABORATORY DIRECTOR RESPONSIBILITIES<br/>CFR(s): 493.1407(e)(11)</p> <p>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</p>  |

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.

This STANDARD is not met as evidenced by:

Based on review of personnel records and confirmed by nursing staff at approximately 1:15 pm on 09/29/2020, 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 #3 and #4) who perform potassium hydroxide (KOH) and ectoparasite examinations. The findings include: 1. Laboratory personnel identifiers #3 and #4 began performing KOH and ectoparasite examinations in August 2019. 2. At the time of the survey, the laboratory did not have documentation of training for personnel identifiers #3 or #4.