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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>10D2066545      | <b>(X3) Date Survey Completed</b><br><br>06/04/2019 |
| <b>Name of Provider or Supplier</b><br><br>Blue Ocean Dermatology Llc  | <b>Street Address, City, State</b><br><br>3951 S Nova Rd Ste 3, Port Orange, FL |   |
| 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>D5209</b>              | <p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b><br/>CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on record review and staff interview, the laboratory failed to have competency evaluations performed by someone who qualified as a Technical Supervisor for 2 of 3 testing personnel. Findings Included: Review of competency evaluations for testing person #2 and testing person #3 found the competency evaluations completed in 2018 and 2019 were completed by a staff member that did not qualify as a Technical Supervisor. During an interview on 06/04/19 at 11:30am, the office manager confirmed the staff member that performed the competency evaluations did not meet the CMS requirements for Technical Supervisor.</p> |
| <b>D5609</b>              | <p><b>HISTOPATHOLOGY</b><br/>CFR(s): 493.1273(e)(f)</p> <p>(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on record review and staff interview, the laboratory failed to maintain complete Histopathology quality control documentation of reagent expiration dates for 2018 and 2019. Findings Included: Record review of quality control documentation showed there was no record of expiration dates for the Immunohistochemistry (IHC) staining</p>   |

reagents. Interview with the laboratory supervisor on 6/4/19 at 11:30am confirmed that the laboratory had not kept any quality control reagent logs showing documentation of the expiration dates for the IHC staining reagents.

**D5781**

**CORRECTIVE ACTIONS**

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the facility failed to document corrective action when the water bath temperature was out of range for 1 of 31 days in April 2019, room temperature was out of range for 2 of 31 days in May 2019, and embedding temperature was out of range for 1 of 31 days in March 2019. Findings included: 1. Record review of the Blue Ocean Dermatology - Lab Maintenance Logs showed the acceptable water bath temperature is " 43-50 degrees C . The temperature on April 3, 2019 was documented as 91 degrees C. There was no corrective action documented. 2. Record review of the Blue Ocean Dermatology - Lab Maintenance Logs showed the acceptable room temperature is " 60-82 degrees F. The temperature on May 15, 2019 was documented as 83 F and on May 17, 2019 the temperature was documented as 85 F. There was no corrective action documented. 3. Record review of the Blue Ocean Dermatology - Lab Maintenance Logs showed the acceptable embedding temperature is " 57-64 degrees C . The temperature on March 18, 2019 was documented as 65 degrees C. There was no corrective action documented. Interview with the laboratory supervisor at 11:30 AM confirmed no corrective action was documented for the out of range temperatures.