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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>19D0950940   | <b>(X3) Date Survey Completed</b><br><br>04/18/2023 |
| <b>Name of Provider or Supplier</b><br><br>Baldone Reina Dermatology   | <b>Street Address, City, State</b><br><br>150 Lakeview Circle, Covington, LA |   |
| 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>D0000</b>              | A Certification survey was performed on April 18, 2023 at Baldone Reina Dermatology, CLIA ID # 19D0950940. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.   |
| <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 review of the laboratory's CMS 209 (Laboratory Personnel Report) form, policies, personnel records, and interview with personnel, the laboratory failed to establish and perform annual competency assessments as required and per their established policy for three (3) physicians who perform Microbiology testing. Findings: 1. Review of the laboratory's CMS 209 form revealed three (3) physicians perform Microbiology testing, which includes potassium hydroxide (KOH) and wet prep testing utilizing microscopy procedures. 2. Review of the laboratory's "Quality Assessment policy" revealed "Competency of Testing Personnel and all staff members will be reevaluated and documented every 12 months by the Laboratory Director... CLIA regulations for laboratories performing Moderate and High Complexity testing require semiannual performance assessments during the first year and annual assessments thereafter." 3. Review of the laboratory's policies revealed the laboratory did not include a process for competency evaluation for physicians performing microscopy procedures. 4. Review of the laboratory's personnel records revealed the three (3) physicians did not have documentation of an annual competency assessment for 2021 and 2022 for their Microbiology testing. 5. In interview on April 18, 2023 at 10:58 am, the Laboratory Director confirmed the laboratory did not establish a</p> |

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|              | <p>complete competency assessment procedure or perform assessments annually in 2021 and 2022 for the physicians performing Microbiology testing.</p>   |
| <b>D5217</b> | <p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b><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/>Based on review of the laboratory's policies, test menu, records, and interview with personnel, the laboratory failed to verify the accuracy of Microbiology testing at least twice annually in 2021 and 2022. Findings: 1. Review of the laboratory's test menu revealed the laboratory performs Microbiology testing which includes potassium hydroxide (KOH) and wet preps utilizing microscopy procedures. 2. Review of the laboratory's policies and records revealed the laboratory did not have a policy and documentation of verification of the accuracy of Microbiology testing at least twice annually for 2021 and 2022. 3. In interview on April 18, 2023 at 10:58 am, the Laboratory Director stated she discontinued verifying the accuracy of Microbiology testing in 2009 as notated in her discontinued policy as she thought it was no longer required. The Laboratory Director confirmed the laboratory did not verify the accuracy of Microbiology testing at least twice annually in 2021 and 2022.</p> |
| <b>D5301</b> | <p><b>TEST REQUEST</b><br/>CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of patient test records, patient test logs, and interview with personnel, the laboratory failed to have a written test request for one (1) of five (5) patients reviewed for December 2021. Findings: 1. Review of the laboratory's Microbiology patient test log revealed one (1) patient had a wet prep test performed on December 22, 2021. 2. Review of the patient's test records revealed the laboratory did not have a written test request/order for the wet prep performed for the identified patient on December 22, 2021. 3. In interview on April 18, 2023 at 10:18 am, the CMA confirmed the laboratory did not have a written test request for the wet prep performed for the identified patient. .</p>   |
| <b>D5433</b> | <p><b>MAINTENANCE AND FUNCTION CHECKS</b><br/>CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p>  |

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's maintenance records and interview with personnel, the laboratory failed to perform the weekly microscope maintenance per laboratory policy for two (2) of sixty five (65) weeks reviewed. Findings: 1. Review of the laboratory's "Maintenance Record for Microscopes" revealed the following weekly tasks: "stage & oculars cleaned." 2. Review of the laboratory's "Maintenance Record for Microscopes" logs for 2022 and 2023 revealed the laboratory did not perform weekly maintenance for the following two (2) weeks: Week of September 26, 2022 Week of February 20, 2023 3. In interview on April 18, 2023 at 10:37 am, the CMA confirmed the laboratory did not document the weekly microscope maintenance for the identified weeks.

**D5805**

**TEST REPORT**  
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's patient test logs, patient records, and interview with personnel, the laboratory failed to ensure documentation of the test performed and test result were included in the patient's final test report for one (1) of five (5) patients tested in December 2021. Findings: 1. Review of the laboratory's December 2021 patient test logs for Microbiology testing revealed one (1) patient had a wet prep performed on December 22, 2021. The patient's test result was hand written in the log. 2. Review of the identified patient's final test report (visit note) revealed the laboratory did not include documentation of performance of the wet prep test and the test result. 3. In interview on April 18, 2023 at 10:18 am, the CMA confirmed the identified patient's test report from December 22, 2021 did not include documentation of performance of the wet prep test and test result.

**D6014**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(3)(iii)

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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:  
Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1.

The laboratory failed to verify the accuracy of Microbiology testing at least twice annually in 2021 and 2022. Refer to D5217. 2. The laboratory failed to have a written test request for one (1) of five (5) patients reviewed for December 2021. Refer to D5301.

**D6023**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(6)

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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

This STANDARD is not met as evidenced by:  
Based on record review and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance. Refer to D5433.

**D6026**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(8)

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)(8) Ensure that reports of test results include pertinent information required for interpretation.

This STANDARD is not met as evidenced by:  
Based on record review and interview with personnel, the Laboratory Director failed to ensure patient final test reports included required pertinent information. Refer to D5805.

**D6030**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(12)

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)(12) 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;

This STANDARD is not met as evidenced by:  
Based on record review and interview with personnel, the Laboratory Director failed

to ensure complete policies and procedures for assessing personnel competency were established. Refer to D5209.