Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0950940	02/12/2025
Name of Provider or Supplier	**Street Address, City, State**	
Baldone Reina Dermatology	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Recertification survey was performed at Baldone Reina Dermatology, CLIA ID 19D0950940, on February 12, 2025. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5309	TEST REQUEST CFR(s): 493.1241(e) (e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately. This STANDARD is not met as evidenced by: Based on review of the laboratory's patient test log, patient test report, and interview with personnel, the laboratory failed to ensure the correct test ordered was written into the patient test log for one (1) of seven patients reviewed in January 2024. Findings: 1. Review of the laboratory's patient test log book revealed the laboratory hand writes the date, patient name, test to be performed, suspected fungi/parasite, test result, and physician who performed the test. 2. Further review of the laboratory's patient test log book and patient final test report revealed the following patient had an incorrect test order entered into the log book: January 10, 2024: Patient PETBR005. The log book had a written test order of "KOH;" however, the patient's test report indicated a wet mount preparation procedure was performed. 3. In interview on February 12, 2025 at 11:26 am, the Medical Assistant stated the test order entered into the log book for the identified patient was incorrect and should have been a wet prep.
D5393	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(b)(c) (b) The preanalytic systems assessment must include a review of the effectiveness of

	corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all preanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, patient test logs, patient test reports, and interview with personnel, the laboratory failed to ensure their monitors identified issues within the preanalytic system. Findings: 1. Review of the laboratory's "QC for KOH, ectoparasites" policy revealed "Biannually, 5 cases will be randomly selected from the log to verify the order and results are documented correctly in both the patients' charts and the log book. This will be checked by a nurse and verified by the lab director." 2. Review of the laboratory's "Biannual KOH/wet prep/ectoparasite QC" forms revealed the laboratory documents the date of test, patient name, and "Results in chart and log." The nurse and Lab Director both initial and date their review. 3. Review of the laboratory's patient test log and patient test reports revealed the test order was incorrect for one (1) of seven patients reviewed in January 2024. Refer to D5309. 4. In interview on February 12, 2025 at 11:26 am, the Medical Assistant confirmed the laboratory's current quality assessment monitors did not identify the documentation of an incorrect test order.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of the laboratory's temperature logs and interview with personnel, the laboratory failed to perform corrective actions performed when the refrigerator temperature was not maintained within acceptable limits per manufacturer's requirements for 154 of 215 dates reviewed. Findings: 1. Observation by surveyor on February 12, 2024 at 10:03 am revealed the laboratory stored Consult Diagnostics hCG Urine controls in the refrigerator. 2. Review of the Consult Diagnostics hCG Urine Controls package insert revealed the storage requirement as 36-46 degrees Fahrenheit (2-8 degrees Celsius). 3. Review of temperature logs from January 2024 through January 2025 revealed the refrigerator temperatures were documented as outside of acceptable limits without corrective action for the following 154 dates: January 30, 2024: documented temperature of 30 degrees Fahrenheit (F) January 31, 2024: documented temperature of 30 degrees F February 7, 2024: documented temperature of 23 degrees F February 8, 2024: documented temperature of 23 degrees F February 12, 2024: documented temperature of 25 degrees F February 14, 2024: documented temperature of 25 degrees F February 15, 2024: documented temperature of 25 degrees F February 19, 2024: documented temperature of 25 degrees F February 20, 2024: documented temperature of 25 degrees F February 21, 2024: documented temperature of 25 degrees F February 27, 2024: documented temperature of 25 degrees F February 28, 2024: documented temperature of 25 degrees F February 29, 2024: documented temperature of 25 degrees F March 4, 2024: documented temperature of 25 degrees F March 5, 2024: documented temperature of 25 degrees F March 6, 2024: documented temperature of 25 degrees F March 7, 2024: documented temperature of 25 degrees F March 11, 2024: documented temperature of 25 degrees

F March 12, 2024: documented temperature of 25 degrees F March 13, 2024: documented temperature of 25 degrees F March 14, 2024: documented temperature of 25 degrees F March 18, 2024: documented temperature of 25 degrees F March 19, 2024: documented temperature of 25 degrees F March 20, 2024: documented temperature of 25 degrees F March 21, 2024: documented temperature of 25 degrees F March 25, 2024: documented temperature of 25 degrees F March 26, 2024: documented temperature of 25 degrees F March 27, 2024: documented temperature of 25 degrees F March 28, 2024: documented temperature of 25 degrees F April 1, 2024: documented temperature of 25 degrees F April 2, 2024: documented temperature of 25 degrees F April 3, 2024: documented temperature of 25 degrees F April 4, 2024: documented temperature of 25 degrees F April 8, 2024: documented temperature of 25 degrees F April 9, 2024: documented temperature of 25 degrees F April 10, 2024: documented temperature of 25 degrees F April 15, 2024: documented temperature of 25 degrees F April 16, 2024: documented temperature of 25 degrees F April 17, 2024: documented temperature of 25 degrees F April 18, 2024: documented temperature of 25 degrees F April 22, 2024: documented temperature of 25 degrees F April 23, 2024: documented temperature of 25 degrees F April 24, 2024: documented temperature of 25 degrees F April 25, 2024: documented temperature of 25 degrees F April 29, 2024: documented temperature of 25 degrees F April 30, 2024: documented temperature of 25 degrees F May 1, 2024: documented temperature of 28 degrees F May 2, 2024: documented temperature of 28 degrees F May 6, 2024: documented temperature of 28 degrees F May 7, 2024: documented temperature of 28 degrees F May 8, 2024: documented temperature of 28 degrees F May 9, 2024: documented temperature of 28 degrees F May 13, 2024: documented temperature of 28 degrees F May 14, 2024: documented temperature of 28 degrees F May 15, 2024: documented temperature of 28 degrees F May 16, 2024: documented temperature of 28 degrees F May 21, 2024: documented temperature of 28 degrees F May 22, 2024: documented temperature of 28 degrees F May 23, 2024: documented temperature of 28 degrees F May 24, 2024: documented temperature of 28 degrees F May 28, 2024: documented temperature of 28 degrees F May 29, 2024: documented temperature of 28 degrees F May 30, 2024: documented temperature of 28 degrees F May 31, 2024: documented temperature of 28 degrees F June 3, 2024: documented temperature of 28 degrees F June 4, 2024: documented temperature of 28 degrees F June 5, 2024: documented temperature of 28 degrees F June 6, 2024: documented temperature of 28 degrees F June 7, 2024: documented temperature of 28 degrees F June 10, 2024: documented temperature of 28 degrees F June 11, 2024: documented temperature of 28 degrees F June 12, 2024: documented temperature of 28 degrees F June 13, 2024: documented temperature of 28 degrees F June 17, 2024: documented temperature of 28 degrees F June 18, 2024: documented temperature of 28 degrees F June 19, 2024: documented temperature of 28 degrees F June 20, 2024: documented temperature of 28 degrees F June 24, 2024: documented temperature of 28 degrees F June 25, 2024: documented temperature of 28 degrees F June 26, 2024: documented temperature of 28 degrees F June 27, 2024: documented temperature of 28 degrees F July 1, 2024: documented temperature of 30 degrees F July 2, 2024: documented temperature of 30 degrees F July 3, 2024: documented temperature of 30 degrees F July 8, 2024: documented temperature of 30 degrees F July 9, 2024: documented temperature of 30 degrees F July 10, 2024: documented temperature of 30 degrees F July 11, 2024: documented temperature of 30 degrees F July 15, 2024: documented temperature of 30 degrees F July 16, 2024: documented temperature of 30 degrees F July 17, 2024: documented temperature of 30 degrees F July 18, 2024: documented temperature of 30 degrees F July 22, 2024: documented temperature of 30 degrees F July 23, 2024: documented temperature of 30 degrees F July 24, 2024: documented temperature of 30 degrees F July 25, 2024: documented temperature of 30 degrees F July 30, 2024: documented temperature of

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D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) (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. Refer to D5309.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure the quality assessment program was maintained to assure the quality of laboratory testing and identify failures. Refer to D5393.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratorys established performance specifications are identified, and that patient test results are reported only when the system is functioning properly; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure corrective actions were performed when deviations from the laboratory's specifications occurred. Refer to D5785.