Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0604249	02/19/2025
Name of Provider or Supplier	**Street Address, City, State**	
Marinhealth Dermatology	5000 Civic Center Dr, San Rafael, CA	

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
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policies & procedures, randomly chosen patient test records, and interview with the office manger (OM), it was determined that the laboratory failed to establish a written policy and procedure to assess the quality of its preanalytical, analytical, and postanalytical systems. The findings include: 1. Based on the surveyor's review of the laboratory's policies and procedures, it was determined that the laboratory did not have any written, signed, and approved protocol for the quality assessment system established to identify problems in the preanalytical, analytical, and postanalytical systems. 2. During an interview on February 19, 2025, at approximately 9:30 a.m., the OM acknowledged that there is no established policy and procedure for quality assessment. The laboratory conducts random patient record checks monthly; however, there is no documentation to track these checks. 3. Based on the laboratory's testing declaration submitted at the time of the survey, the laboratory performed approximately 800 tests annually for Histopathology during the time that no policy, procedure and documentation for quality assessment were established and documented. Therefore, the quality of patient test records cannot be assured.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1)

	Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on the surveyor's observation during the laboratory's tour and interview with the office manager (OM); it was determined that the laboratory failed to label various reagents and solutions used in the laboratory to indicate, as appropriate, the identity, opening, preparation, and expiration dates when such reagents and solutions are used in the laboratory. The findings include: 1. Based on the surveyor's observation during the laboratory tour on February 19, 2025, at approximately 10:50 a. m.; it was noted that the laboratory lacked labeling for various reagents and solutions for identity (name, titer, strength, or concentration), received, opening, preparation, and/or expiration dates, as appropriate, that were used throughout the laboratory. Some specific examples include: a. Tissue marking green dye, lot number:120246, which had expired on 2-28-2023; b. Tissue marking red dye, lot number 090497, which had expired on 11-30-2021; c. Tissue marking blue dye, lot number 1182, which had no received or opening date listed, but an expiration date of 7-01-2025; d. Tissue marking yellow dye, lot number 0727-5, which lacked received, opening, and expiration dates; e. Coplin jars for alcohol used in staining were not labeled with opening, preparation, or expiration dates; f. Tissue Plus OCT compound, lot number 4586, did not have an opening date indicated. 2. The laboratory's OM affirmed in an interview on February 19, 2025 at approximately 10:50 a.m., that the reagent and solution materials mentioned in statement #1 above were not labeled with the received, opening, preparation, and/or expiration dates, as applicable. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 800 Histopathology tests for which various reagents and solutions were not labelled.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on the surveyor's review of policies and procedures, observations during the tour of the facility, and interview with the office manager (OM); it was determined that the laboratory lacked a policy and procedure in place for preventive maintenance (PM) and calibration. The laboratory is herein cited for the deficient practice in failure to perform and document PM and calibration as defined by the manufacturer, with at least the frequency recommended for the laboratory's equipment prior to patient testing. The findings include: 1. Based on the surveyor's review of the laboratory's protocols, it was determined that the laboratory lacked a policy and procedure for the PM and calibration for the microscope according to manufacturer's requirements, to be performed prior to patient testing for the years 2022, 2023 and 2024. 2. Based on the surveyor's observations during the tour of the facility: a. The laboratory's only record of preventive maintenance was a sticker on the Nikon Alphaphot-2 YS2 microscope indicating it was calibrated in August 2023. b. One of the three fire extinguishers was overlooked for inspection and maintenance in 2024, with the tag showing the last maintenance date as 2/20/2009. 3. The OM affirmed by interview on

	February 19, 2025, at approximately 9:20 a.m. that the laboratory did not have a policy, procedure and documentation records for the equipment PM and calibration applicable to the years 2022, 2023, and 2024. 4. According to the testing volume declaration submitted at the time of survey, the laboratory performed approximately 800 tests annually for Histopathology during the time that no policy and procedure for equipment PM were established and documented.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) (e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policies and procedures, randomly selected patient test records, observations during the tour of the facility, and interview with the office manager on February 19, 2025, it was determined that the laboratory director is cited herein due to failure to ensure that several aspects of the preanalytic, analytical, and postanalytic phases of the laboratory testing were monitored. The findings include: 1. No policy, procedure, and documentation for quality assessment. See D5391. 2. Test systems, equipment, instruments, reagent. See D5415. 3. Missing records for preventive maintenance. See D5429.