Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D2052874	07/09/2024
Name of Provider or Supplier	**Street Address, City, State**	
Bend Dermatology Clinic-Redmond	1475 Nw 4th St, Redmond, OR	

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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with HT1, the laboratory failed to establish a procedure for Quality Assessment (QA) and QA monitoring events relative to this laboratory. Findings include: 1. Upon review of the procedure manual for this laboratory, no QA procedure or evidence of QA monitoring events could be found. 2. Interview with HT1 at 1:30 pm confirmed that no QA monitors had been put into place to his knowledge. 3. The laboratory reports performing 127 Mohs cases since 2/20/2024 at date of survey.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the procedure manual for this laboratory and interview with HT1, the laboratory failed to have a complete and current standard operating procedure (SOP) detailing the Mohs surgical procedure. Findings include: 1. Upon review of the

	procedure manual for this site, no SOP for the Mohs procedure could be found. 2. Interview with HT1 at 1:30 pm confirmed that there was no other procedure outside of the staining procedure for tissue retrieved during Mohs surgery. 3. The laboratory reports performing 127 Mohs cases since 2/20/2024 at date of survey.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of laboratory temperature records and interview with HT1 during survey, the laboratory failed to ensure the ambient temperature the Cryo-stat, the refrigerator, and ambient temperature and humidity in the lab were recorded each day of patient testing. Findings incude: 1. Upon request for the temperature logs for the Cryo-stat in use for Mohs surgery patients, none could be provided. 2. Upon request for the temperature logs for the refrigerator in use for Mohs surgery patients requiring special immunohistochemical (IHC) stains that require refrigeration, none could be provided. 3. Upon request for the temperature log for ambient room temperature and relative humidity, none could be provided. 4. Interview with HT1 at 1:00 pm confirmed that he did not record/ have written evidence of any of the temperatures for the Cryo-stat, the refrigerator used to store special IHC reagents, ambient room temperature or relative humidity. 5. The laboratory reports performing 127 Mohs cases since 2/20/2024 at date of survey.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation of fluids in the flammables cabinet on site and interview with HT1, the laboratory failed to discard expired reagents used in the staining process for Mohs surgical patients. Findings include: 1. Upon inspection of reagents contained in the flammables cabinet on site, it was revealed that expired reagents were housed in the cabinet. 1. 3 gallons of FLEX 100, used in the Hematoxylin and Eosin (H&E) staining procedure outdated as of 06/2024. 2. Approximately one half of a 500 ml bottle of Gil Hematoxylin, used in the H&E staining procedure outdated as of 06 /2024. 2. Interview with HT1 at 1:00 pm confirmed that these fluids were all outdated during survey. 3. The laboratory reports performing 127 Mohs cases since 2/20/2024 at date of survey.
D5445	CONTROL PROCEDURES

	CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory records for quality control (QC) performed for Hematoxylin and Eosin (H&E) and Immunohistochemical (IHC) stains and interview with HT1, the laboratory failed to follow their standard operating procedure (SOP) for performing and documenting slide QC. Findings include: 1. Upon request for QC records for H&E and IHC stains, none could be produced. 2. Review of the SOP for the IHC stain MART-1, the QC section stated that the QC for this stain would be recorded in the QC log, which was to be kept in the procedure book. 3. Review of the SOP for the H&E stain, the QC section stated that the QC for this stain would be processed and evaluated for stain quality each morning Mohs patients are seen. 4. Interview with HT1 at 12:30 pm confirmed that he had no written record of QC for either stain since the clinic opened 2/20/2024. 5. Interview with the Laboratory Director (LD) at 2:05 pm confirme that she does evaluate QC but that no written record was created for either stain. 6. The laboratory reports performing 127 Mohs cases since 2/20/2024 at date of survey.
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 a patient test report requested during initial survey, the laboratory failed to ensure the address of the site where Mohs surgery was performed, was evident on the patient test report. Findings include: 1. Upon review of the patient report submitted for my review during survey, the correct address/location of the Redmond site, where the Mohs surgery was performed was not present on the patient report. 2. Interview with the HT1 at 1:00 pm confirmed that the address of this site was not on the patient report. 3. The laboratory reports performing 127 Mohs cases since 2/20/2024 at date of survey.