Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2148519	05/09/2025
Name of Provider or Supplier	**Street Address, City, State**	
Sanova Dermatology-Bee Cave	3944 S Fm 620 S, Bldg 6, Suite 201, Bee Cave, TX	

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	The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended. Standard level deficiencies were cited.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: I. Based on review of laboratory policy and procedure, accuracy assessments, pre-survey paperwork, and interview, the laboratory failed to perform twice per year accuracy assessments for Mohs in 2023 for one of three events reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled Proficiency Testing for Mohs Micrographic Surgery, approved 10/10/2024, under Procedure For Mohs stated, "Three random cases will be chosen, at least biannually..." B. Review of accuracy assessments from 2023 and 2024 showed one accuracy assessment in 2023. Additional accuracy assessments were requested on May 9, 2025 at 1050 hours but not provided. C. Review of the pre-survey paperwork showed approximately 400 Mohs blocks were performed per year. D. Interview with the histotechnologist on May 9, 2025 at 1050 hours in the breakroom confirmed they were missing an accuracy assessment in 2023. II. Based on review of laboratory policy and procedure, accuracy assessments, pre-survey paperwork, and interview, the laboratory failed to verify the accuracy of its KOH (potassium hydroxide) for fungal elements at least twice annually for KOH in 2023 for one of four events reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled Proficiency Testing Standards for PPM, approved 10/10/2024, under Procedure atated, "1. Proficiency Testing by Physician Review a. Slides are chosen at random for biannual review. b. The physician reviews the slides and indicates the result on the PPM Test Log. c. A

	separate physician will also review the slides and indicate if they agree or disagree with the initial result. This is indicated on the PPM Test Log. d. Any corrective action is noted. The test is repeated, if necessary. 2. Proficiency Testing by Physician Review may not always be possible. a. In this case, the provider performing PPM testing will complete the PPM Proficiency Review Form, biannually. b. The provider should complete a different PPM Proficiency Review version each time. c. The PPM Proficiency Review Form will consist of 4 different images, the provider will indicate whether each image is positive or negative. d. There are 3 multiple-choice questions to assess problem-solving skills. e. The Laboratory Director will indicate agree or disagree with the initial provider's reading...." B. Review of accuracy assessments from 2023 and 2024 showed one accuracy assessment in 2023. Additional accuracy assessments were requested on May 9, 2025 at 1040 hours but not provided. C. Review of the pre-survey paperwork titled Annual Test Volume & Proficiency Testing Programs Worksheet showed approximately 10 KOH were performed per year. D. Interview with the histotechnologist on May 9, 2025 at 1040 hours in the breakroom confirmed they were missing an accuracy assessment in 2023.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, quality control records, pre-survey paperwork, and interview, the testing personnel failed to document the negative and positive intended reactivity of quality control slides for Hematoxylin & Eosin (H&E) used in Mohs interpretations for 51 of 53 testing days reviewed in 2023-2025. Findings follow. A. Review of the laboratory's policy and procedure titled Production Quality Control, approved 10/10/2024, under Principle stated, " This procedure is to establish specific policies for monitoring and maintaining the quality of the slides produced by the Mohs technician, including embedding, microtomy, and stain quality. By ensuring that the laboratory is producing quality slides, the patient is ensured quality results from the lab." And under Procedure stated, "1. At the beginning of the day, a section from the first case of that day is cut, stained, and cover slipped. 2. The Mohs technician assesses the quality of the stain grossly. a. Any notable staining inconsistencies are investigated and rectified before staining patient tissue. 3. The technician and/or physician indicate stain quality on the form." An initial review can be performed by the histotechnologist prior to submitting to the Mohs surgeon, but the slide quality must be performed and documented by the Mohs surgeon as he is the testing personnel/technical supervisor for the diagnostic interpretation of the slides. B. Review of the H&E Stain Quality Control Log from 04 /13/2023 - 05/08/2025 showed 51 of 53 testing days with the initials of the histotechnologist versus the testing personnel/technical supervisor responsible for performing the diagnostic interpretations of the slides. C. Review of the pre-survey paperwork showed approximately 400 Mohs blocks were performed per year. D. Interview with the histotechnologist on May 9, 2025 at 1200 hours in the breakroom confirmed the findings.
D5805	TEST REPORT CFR(s): 493.1291(c)

	(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 Mohs test report and interview, the laboratory failed to include the address of the facility on the Mohs map for four of 10 cases reviewed from Dec 2024 - April 2025. Findings follow. A. Review of the Mohs maps showed no address of the facility where the testing was performed. The following reports were reviewed as listed by case number and date of service: 1. 12/05/2024 C24-1030 2. 01/16/2025 C25-012 3. 03/27/2025 C25-067 4. 04/03/2025 C25-075 B. Interview with the histotechnologist on May 9, 2025 at 1215 hours in the breakroom confirmed the findings.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, competency evaluations, pre-survey paperwork, and interview, the technical consultant failed to perform annual competency evaluations of individuals performing KOH (potassium hydroxide) for fungal elements at least annually for one of one testing personnel in 2023. Findings follow. A. Review of the laboratory's policy and procedure titled CLIA Competency and Assessment, approved 10/17/2024, under Procedure stated, "Evaluation and documenting competency of personnel responsible for testing is required semi-annually during the employee's first year and annually thereafter." B. Review of competency evaluations from 2023 and 2024 for KOH for fungal elements showed none for 2023. Competency evaluations were requested but not provided on May 9, 2025 at 1030 hours. C. Review of the pre-survey paperwork titled Annual Test Volume & Proficiency Testing Programs Worksheet showed approximately 10 KOH were performed per year. D. Interview with the histotechnologist on May 9, 2025 at 1030 hours in the breakroom confirmed they were missing competency evaluations in 2023.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals performance must be reevaluated to include the use of the new test methodology or instrumentation.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, competency evaluations, pre-survey paperwork, and interview, the technical consultant failed to perform annual competency evaluations of individuals performing inking and dissecting in Mohs at least annually for one of one testing personnel in 2023. Findings follow. A. Review of the laboratory's policy and procedure titled CLIA Competency and Assessment, approved 10/17/2024, under Procedure stated, "Evaluation and documenting competency of personnel responsible for testing is required semi-annually during the employee's first year and annually thereafter." B. Review of competency evaluations from 2023 and 2024 for the inking and dissecting in Mohs showed none for 2023. Competency evaluations were requested but not provided on May 9, 2025 at 1030 hours. C. Review of the pre-survey paperwork showed approximately 400 Mohs blocks were performed per year. D. Interview with the histotechnologist on May 9, 2025 at 1030 hours in the breakroom confirmed they were missing competency evaluations in 2023.