Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2105735	08/21/2025
Name of Provider or Supplier	**Street Address, City, State**	
Sheth Dermatology & Mohs Surgery Ctr	9131 West 151 St Street, Orland Park, IL	

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
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: Based on review of laboratory policies and procedures, review of laboratory records, and interview with the laboratory representative; the laboratory failed to perform bi-annual method accuracy (proficiency testing/peer reviewed histopathology interpretations) at least twice annually for histopathology testing from 2023 to the date of survey, 08/21/25. Findings include: 1. Review of laboratory policies and procedures revealed the procedure, "Quality Control Program ", which stated under section "3.2.26 Proficiency Testing ", "Slides will be sent out for review Bi-Annually, approximately 6 months apart. This will be 5 cases every 6 months, totaling 10 cases per year that will be submitted to a third party pathologist to verify histology proficiency." 2. Review of laboratory records, including that of bi-annual peer reviewed histopathology interpretations, revealed the laboratory sent out cases one time per year in 2023 and 2024. Laboratory records also indicated that the laboratory failed to ensure that a total of 10 cases were being reviewed for each year. Year Number of Case #: 2024 nine 2023 eight 3. Interview with the laboratory representative on 08/21/2025, at 09:45 am, confirmed the laboratory failed to perform bi-annual method accuracy testing at least twice annually for histopathology testing in the years of 2023 and 2024.
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 laboratory policy and procedure manuals, review of laboratory records, and interview with the laboratory representative; the laboratory failed to establish and follow written policies and procedures for monitoring, assessing, and correcting problems identified in the general laboratory systems. Findings Include: 1. Review of laboratory policy and procedure manuals revealed a document titled "3.2.27 Laboratory Quality Assessment Protocol" which stated, "To define the quality assessment protocol at this lab. It has been determined that a continuing review of previous cases, should be examined for the purposes of ensuring that the process of this lab are appropriately performed .... These metrics will be check and recorded on the quality assessment log, to help facilitate an awareness of a possible problems, and create opportunities for continual improvement in our service." 2. Review of laboratory records revealed that the laboratory failed to maintain records related to quality assurance activities. 3. Interview with the laboratory representative on 08/21 /2025, at 9:50 am, confirmed the laboratory failed to maintain records of quality assurance activities completed from 2023 to the date of the survey, 08/21/25.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(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: A. Based on review of laboratory policies and procedures, review of laboratory records, and interview with the laboratory representative; the laboratory director failed to ensure that bi-annual method accuracy/ proficiency testing was completed as required from 2023 to the date of the survey, 08/21/25. See D5217. B. Based on review of laboratory policies and procedures, laboratory records, and interview with the laboratory representative, the laboratory director failed to ensure that the quality assessment protocol was maintained. See D5291.