Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1103500	06/11/2026
Name of Provider or Supplier	**Street Address, City, State**	
Levy Dermatology, Pc	6254 Poplar Avenue, Memphis, TN	

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 laboratory observation, a review of the laboratory procedure manual, a review of the laboratory's alternative proficiency testing records, lack of documentation, a review of the Centers for Medicaid and Medicare Services Laboratory Personnel Report (CLIA) (FORM CMS-209), and a staff interview, the laboratory policy failed to specify corrective action to take when discrepant diagnostic interpretations occurred in case reviews, resulting in the failure to perform corrective action for three of three alternative proficiency testing case reviews with discrepant diagnostic interpretations in 2024 and 2025. The findings include: 1. Laboratory observation on 06/11/26 at approximately 11:40 a.m. revealed equipment and stains used to process tissue removed during Mohs surgery procedures and skin biopsies. A microscope was also observed and used to perform diagnostic interpretation of dermatological tissues. 2. A review of the laboratory procedure manual revealed the following in section 6.1.3: The laboratory participates in Quality Assurance reading /Proficiency Testing for Mohs biopsies and excisions by sending slides to an outside dermatopathologist. The policy did not specify corrective actions to take when discrepancies in diagnostic interpretation were received.. 3. A review of the alternative proficiency testing records for 2023, 2024, 2025, and 2026 revealed that three of seventeen case reviews showed disagreement in diagnostic interpretation as follows: B24-90 - initial interpretation = SCCIS, 2nd read = No tumor; agreement was marked as "N" B24-93 - initial interpretation = SCC, 2nd read = No tumor seen; agreement was marked as "N" M25-620 - initial interpretation = SCC, 2nd read = No

	tumor seen; agreement was marked as "N" Testing Person Two (as listed on FORM CMS-209) read all three cases with discrepant diagnostic interpretations. No corrective action was documented for the diagnostic discrepancies. 4. The laboratory director confirmed the survey findings during an interview on 06/11/26 at approximately 1:30 p.m. Word Key: N=No SCC=Squamous Cell Carcinoma SCCIS=Squamous Cell Carcinoma In-Situ
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on laboratory observation, a review of the Aspen Web 116 database, a review of patient test records, a review of the CLIA regulations and staff interview, the laboratory director failed to ensure compliance with the CLIA regulations when the laboratory performed patient testing from May 27, 2026 to the date of the onsite survey on June, 11, 2026 on an expired CLIA certificate with approximately 59 patients reported during the gap in certification. The findings include: 1) Laboratory observations on 06/11/26 revealed the following: At approximately 11:40 a.m., equipment and stains used to process tissue removed during Mohs surgery procedures and skin biopsies, and a microscope used to perform diagnostic interpretation of dermatological tissues were observed. At approximately 1:00 p.m., tissue specimens were observed waiting on tissue processing and slide preparation. 2) A review of the Aspen Web 116 database revealed the laboratory's previous CLIA certificate expired on May 26, 2026, due to nonpayment of fees. 3) A review of patient test reports and accessioning logs revealed the laboratory continued patient testing from May 27, 2026, (patient case number M26-422), to the date of the onsite survey on June 11, 2026, with approximately 59 patients reported through June 10, 2026 (case number M26-480) during the gap in certification. 4) A review of the CLIA regulation at 493.1 revealed the following: "This part sets forth the conditions that all laboratories must meet to be certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA)." 5) A review of the CLIA regulations at 493.3 revealed the following: "Applicability: (a) Basic rule. Except as specified in paragraph (b) of this section, a laboratory will be cited as out of compliance with section 353 of the Public Health Service Act unless it- (1) Has a current, unrevoked or unsuspended certificate of waiver, a registration certificate, certificate of compliance, certificate for PPM procedures, or certificate of accreditation issued by HHS applicable to the category of examinations or procedures performed by the laboratory." 6) The laboratory director confirmed the survey findings during an interview on 06/11/26 at approximately 1:30 p.m. Word Key: CLIA=Clinical Laboratory Improvement Amendments HHS=Health and Human Services