Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2138121	08/06/2019
Name of Provider or Supplier	**Street Address, City, State**	
Levy Dermatology, Pc	1125 Schilling Blvd East Suite 105, Collierville, 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
D5028	HISTOPATHOLOGY CFR(s): 493.1219 If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1273, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: The laboratory failed to ensure positive patient identification for labeling Mohs histological slides (Refer to D5203); failed to verify the accuracy of the biopsy analyte twice per year (Refer to D5219); failed to establish a written policy/procedure for the patient test management assessment (Refer to D5291); failed to ensure the hematoxylin and eosin stain solution were not in use after expiration date (Refer to D5417) and, failed to include the lot numbers, date prepared/opened, expiration dates, the actual reactions and/or observations and demonstrated that controls were tested when shipments of stains were opened (Refer to D5609).
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure manual and interview with testing personnel number two, the laboratory failed to follow the procedure to ensure positive patient identification for labeling Mohs histological

	slides. The findings include: 1) Observation on August 6, 2019, at 11:55 a.m. of the laboratory revealed on July 29, 2019, patient number three had three slides prepared for Mohs testing, with one slide labeled, "QA 7-29-19" 2) Review of the procedure manual revealed, "3.4.9 Laboratory technician will cut frozen sections and stain. Slides are labeled with Mohs number, patient last name and 1st initial, stage (S1L1), piece # (numbers) and slide# (letters)." 3) Interview on August 6, 2019 at 11:56 a.m. with testing personnel number two confirmed that during 2018 and 2019 each morning the first patient slide prepared is used for daily quality control and is labeled as QA. The slide labeled as QA is also in use for patient reporting but does not have the positive patient identification labeled on the slide.
D5219	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2) At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the procedure manual, the quality control records and interview with testing personnel number two, the laboratory failed to verify the accuracy of the biopsy twice per year in 2018 and 2019. The findings include: 1) Based on review of the procedure manual revealed the following: "Quality Control X 6.1.4 The laboratory participates in the Quality Assurance reading of slides sent to _(redacted pathologist name), MD at (redacted name of facility). A minimum of 2 random slides between cases are sent every 6 months." 2) Review of the quality control records revealed no biopsy slides were included in the quality assurance reviews in 2018 and 2019. 3) Interview on August 6, 2019 at 10:45 a.m. with testing personnel number two confirmed that no biopsy slides were sent for verification of accuracy in 2018 and 2019.
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 observation of the laboratory, review of the laboratory procedures, the "Quarterly Patient QA" records, and interview with testing personnel number two, the laboratory failed to establish a written policy/procedure for the patient test management assessment, in 2018 and 2019. The findings include: 1) Observation on August 6, 2019, at 11:53 a.m. of the laboratory revealed two slides on patient number two for Mohs testing. 2) Review of the laboratory procedures revealed no written procedure for the quarterly patient quality assessment process. 3) Review of the Quarterly Patient QA records revealed on 7-29-19, patient number two records and slides were reviewed for quality assessment. 4) Interview on August 6, 2019, at 12:05 p.m. with testing personnel number two confirmed there is no written procedure for the quarterly patient quality assessment process. Patient number two records indicated

	that there are three slides but only two slides were located. There is no written procedure for how to monitor, assess, and correct problems for the patient test management pre-analytic, analytic and post-analytic processes.
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 the laboratory and interview with testing personnel number two, the laboratory failed to ensure the hematoxylin and eosin stains were not in use after the expiration dates. The findings include: 1) Observation on August 6, 2019 at 11:06 a.m. of the laboratory revealed the Gill 3 Hematoxylin lot number 062851 expiration date 06/19 and Avantik Eosin Working Solution lot number G128-02 expiration date 5/8/19 in use for patient testing. 2) Interview on August 6, 2019 at 11: 06 a.m. with testing personnel number two confirmed the hematoxylin and eosin stains were expired and in use for patient testing.
D5609	HISTOPATHOLOGY CFR(s): 493.1273(e)(f) (e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the Mohs Lab Controls-Maintenance for Linistat Stainer records, the Quality Assurance (QA) Slides records and interview with testing personnel number two, the laboratory failed to include the lot numbers, date prepared/opened, expiration dates, the actual reactions and/or observations, and demonstrated that controls were tested when shipments of stains were opened, in 2018 and 2019. The findings include: 1) Review of the Mohs Lab Controls-Maintenance for Linistat Stainer records and the Quality Assurance (QA) Slides records revealed following were not documented for the hematoxylin and eosin stains: lot number, expiration dates, opened dates, actual reactions of the stain, and when the new lot of stains were opened and tested. 2) Interview on August 6, 2019 at 11:30 a.m. with testing personnel number two confirmed the lot number, expiration dates, opened dates, actual reactions of the stains and the new lot of stain when opened and tested were not documented in 2018 and 2019. Patient testing was performed and reported in 2018 and 2019.