Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2175460	08/30/2021
Name of Provider or Supplier	**Street Address, City, State**	
Levy Dermatology-Jackson	15a Old Humboldt Rd, Jackson, 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
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 patient test reports for histopathology and interview with the laboratory lead, the final patient test report failed to include the name and address of the laboratory. The findings include: 1. Review of final patient histopathology reports from 2020 and 2021 revealed the name and address of the laboratory was not included for seven of nine reports reviewed in 2020 and 2021 (Case numbers B009, B21-004, B21-010, M20-062, M21-386, E20-011, and E21-015). 2. Interview with the laboratory lead on August 30, 2021 at approximately 12 pm confirmed that the final patient reports for histopathology did not include the name and address of the laboratory in 2020 and 2021.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain

	their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services Personnel Report (Form CMS-209), laboratory competency assessment records, verification of accuracy documents, and interview with the lead testing person, the technical supervisor failed to perform competency assessment for dermatologist number two in 2020 and 2021 for performance of histopathology procedures. The findings include: 1. Review of the Form CMS-209 revealed two dermatologists who perform tests for histopathology. 2. Review of laboratory competency assessment records revealed no competency assessments were performed for dermatologist number two. 3. Review of verification of accuracy documents for quarter one of 2021 for histopathology procedures performed by dermatologist number two revealed no review or signature of the technical supervisor. 3. Email communication with the laboratory lead on September 1, 2021 at 10:47 am confirmed the technical supervisor failed to perform competency assessments for dermatologist number two in 2020 and 2021.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Laboratory testing personnel performing high complexity inking of tissue removed during MOHS procedure failed to meet the regulatory education requirements (Refer to D6171).
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At

least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, interview with testing person number two, review of testing personnel education documents and the Centers for Medicare and Medicaid Services Personnel Report (CMS-209), review of the laboratory procedure manual, and interview with the laboratory lead, testing personnel performing inking of tissue removed during MOHS procedures failed to meet the high-complexity testing personnel requirements. The findings include: 1. Observation of the laboratory on August 30, 2021 at approximately 8:45 am revealed a microscope, reagents, stains and dyes in use for histopathology procedures. 2. Interview on August 30, 2021 at approximately 9:00 am with testing person number two revealed that testing person number two performs inking of tissue removed during MOHS procedure. 3. Review of education documents for testing personnel listed on the CMS-209 who perform inking of tissue removed during MOHS procedures revealed no documentation that the three persons listed met high-complexity education requirements. 4. Review of the laboratory procedure manual revealed the following under section 3.2 SPECIMEN COLLECTION PROCEDURE: "edges of the specimens are marked with colored dyes by the Mohs tech." The following was noted under Section 7.1 PROCEDURE FOR SECTIONING THE SPECIMEN: "The specimen is inked and mapped by the

	technician and or surgeon." 4. Interview with the lead testing person on August 30, 2021 at approximately 12 pm confirmed that three personnel listed on the CMS-209 perform inking of tissue removed during MOHS procedure. No education documents were present that qualified the personnel to perform high-complexity, inking of tissue removed during MOHS procedures.