Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D1068281	04/22/2025
Name of Provider or Supplier	**Street Address, City, State**	
Cincinnati Dermatology Center	7730 Montgomery Road Suite 200, Cincinnati, OH	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and an interview with the Practice Manager (PM), the laboratory failed to establish and follow written policies and procedures to assess the competency of the Clinical Consultant (CC), Technical Supervisor (TS), and the General Supervisor (GS) based on the responsibilities of the position, at a frequency determined by the laboratory as specified in the personnel requirements in Subpart M for high complexity testing. This deficient practice had the potential to affect 300 out of 300 patients tested in the subspecialty of Histopathology from 01/13/2025 through 04/22/2025. Findings Include: 1. Review of the laboratory's Form CMS-209, provided on the date of the inspection and approved by the Laboratory Director on 03/17/2025, found one individual listed and qualified to function as a CC and another individual to function as the TS and GS. 2. Review of the laboratory's policy and procedure manual titled, "Mona Dermatology Mohs Manual" approved via signature and date by the Laboratory Director on 01/02/2025, did not find any policies and procedures to assess the competency of the CC, TS and GS based on the responsibilities of the position. 3. The PM confirmed the laboratory did not have a policy and procedure to assess the competency of the CC, TS and GS and was unable to provide the requested documents on the date of inspection. The interview occurred on 04/22/2025 at 10:20 AM.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)

	(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on record review and interviews with the Practice Manager (PM) and Testing Personnel (TP)#2, the laboratory failed to establish and follow written policies and procedures for specimen acceptability and rejection of tissue specimens collected for testing. This deficient practice had the potential to affect 300 out of 300 patients tested under the subspecialty of Histopathology from 01/13/2025 through 04/22/2025. Findings Include: 1. Review of the laboratory's policy and procedure manual titled "Mona Dermatology Mohs Manual", approved via signature and date by the Laboratory Director on 01/02/2025, did not find any mention of policies and procedures for specimen acceptability and rejection of tissue specimens. 2. The inspector requested policies and procedures for specimen acceptability and rejection of tissue specimens collected for testing from the PM and TP#2. The PM and TP#2 confirmed the laboratory did not have written policies and procedures for specimen acceptability and rejection of tissue specimens and were unable to provide the requested information. The interview occurred on 04/22/2025 at 11:30 AM. ITEM 2 Based on record review and interviews with the Practice manager (PM) and Testing Personnel (TP)#2, the laboratory failed to establish and follow written policies and procedures for the conditions of tissue specimen transportation. This deficient practice had the potential to affect 300 out of 300 patients tested under the subspecialty of Histopathology from 01/13/2025 through 04/22/2025. Findings Include: 1. Review of the laboratory's policy and procedure manual titled "Mona Dermatology Mohs Manual", approved via signature and date by the Laboratory Director on 01/02/2025, did not find any mention of policies and procedures for tissue specimen transportation. 2. The inspector requested policies and procedures for specimen transportation from the PM and TP#2. The PM and TP#2 confirmed the laboratory did not have written policies and procedures for tissue specimen transportation and were unable to provide the requested information. The interview occurred on 04/22/2025 at 11:30 AM.
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 record review and an interview with the Practice Manager (PM), the laboratory failed to ensure test reports indicated the laboratory location for Mohs

	testing. This deficient practice had the potential to affect 300 out of 300 patients tested under the subspecialty of Histopathology from 01/13/2025 through 04/22/2025. Findings Include: 1. Review of the laboratory's Form CMS-116, approved by the Laboratory Director via signature and date on 03/17/2025 revealed the laboratory performed Histopathology testing procedures. 2. Review of the following Mohs patient final test reports found no address where the testing was performed. Accession Number: 38079 4386 7390 3. The PM confirmed the Mohs patient final test reports did not contain the address for the Histopathology test procedures. The interview occurred on 04/22/2025 at 12:30 PM.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) (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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on record review and interviews with the Practice Manager (PM) and the Testing Personnel (TP) #2, the laboratory failed to establish and follow written policies and procedures, and document all assessment activities of an ongoing mechanism to monitor, assess, and correct problems identified in the post analytic systems. This deficient practice had the potential to affect 300 out of 300 patients tested in the subspecialty of Histopathology from 01/13/2025 through 04/22/2025. Findings Include: 1. Review of the laboratory's policy and procedure manual titled "Mona Dermatology Mohs Manual", approved via signature and date by the Laboratory Director on 01/02/2025, did not find any mention of policies and procedures for an ongoing mechanism to monitor, assess, and correct problems identified in the post analytic systems. 2. Review of the 2025 "Mohs Review and Verification Log" found only check marks on a sheet for the following dates: April 7, 2025 April 14, 2025 April 21, 2025 3. The inspector requested detailed documentation of post analytic assessment activities which included all facets of the laboratory's technical and nontechnical functions from the PM and TP#2. The PM and TP#2 were unable to provide details for the "Mohs Review and Verification Log". The interviews occurred on 04/22/2025 at 12:45 PM.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) (e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on record review and an interview with the Practice Manager (PM), the Laboratory Director failed to ensure testing personnel (TP) #2 had demonstrated they could perform all tissue grossing procedures reliably to provide and report accurate results prior to performing patient testing in the subspecialty of Histopathology. This deficient practice had the potential to affect all patient tissue grossing procedures performed by TP#2 from 01/13/2025 through 04/22/2025. Findings Include: 1.

	Review of the laboratory's Form CMS-209, signed and dated by the Laboratory Director on 03/17/2025, revealed two individuals listed and credentialed as TP to conduct high complexity patient tissue grossing testing procedures. 2. Review of the laboratory's training and demonstration of competency documentation, prior to beginning patient testing on 01/13/2025, failed to find the required documentation for TP#2. 3. The Inspector requested the laboratory's training and initial demonstration of competence for TP#2, prior to beginning patient testing from the PM. The PM confirmed the laboratory did not document training initial demonstration of competence for TP#2 prior to independent patient tissue grossing procedures performed and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 4/22/2025 at 10:20 AM.
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: Based on record review and an interview with the Practice Manager (PM), the laboratory failed to ensure Testing Personnel (TP) #2 met the qualification requirements of 493.1489 for high complexity testing. This deficient practice had the potential to affect 300 out of 300 patients tested in the subspecialty of Histopathology from 01/13/2025 through 04/22/2025. Findings Include: 1. The laboratory failed to ensure TP #2 met the high complexity testing personnel qualification 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 (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures

	training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (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. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on record review and an interview with the Practice Manager (PM), and Testing Personnel (TP) #2, the laboratory failed to ensure TP #2 met the qualification requirements of 493.1489 for high complexity tissue biopsy grossing test procedures performed in the subspecialty of Histopathology. This deficient practice had the potential to affect all patient tissue specimens grossed by TP #2 from 01/13/2025 through 04/22/2025. Findings Include: 1. Review of the laboratory's Form CMS-209, approved and signed by the Laboratory Director on 03/17/2025, found two individuals listed and certified by the Laboratory Director to perform high complexity tissue grossing test procedures. 2. Review of education documents provided on the date of the inspection revealed TP #2 possessed an Associate of Applied Science for a Licensed Practical Nurse (LPN), which did not achieve the required number of credit hours in chemistry, biology and/or medical laboratory technology and does not meet the minimum TP qualifications for high complexity laboratory testing. 3. The PM confirmed the laboratory did not have adequate documentation to show TP #2 met the high complexity testing personnel requirements. The interview occurred on 04/22 /2025 at 10:00 AM.