Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D2302904	01/22/2025
Name of Provider or Supplier	**Street Address, City, State**	
Core Dermatology Davenport	1950 E 54th St, Davenport, IA	

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
D5801	TEST REPORT CFR(s): 493.1291(a) (a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of the Mohs surgery log, patient specimen slides, Mohs map, patient test report, and confirmed by interview with testing personnel identifier #4 (TP #4) at 9:40 am on 01/22/2025, the laboratory failed to have a system in place to ensure the accuracy and reliability of Mohs surgery stages manually transcribed into patient electronic health records (EHR) for one out of four patients reviewed from November 2024. The findings include: 1. Patient A had Mohs surgery performed on 11/06/2024. 2. Review of the Mohs surgery log, patient specimen slides, and Mohs map for patient A all showed the surgeon performed Mohs surgery in two stages. The Mohs map indicated persistence of the tumor after stage one and that the margins were clear after stage two. 3. The test report for patient A included the following verbiage for stage one of the Mohs surgery: "The tissue was taken to laboratory in 1 specimen(s) for processing in fresh tissue technique. All specimens were then evaluated by myself and microscopic tumor was not found persisting, margins clear." 4. The test report for patient A included the following verbiage for stage two of the Mohs surgery: "The tissue was taken to laboratory in 1 specimen(s) for processing in fresh tissue technique. All specimens were then evaluated by myself and microscopic tumor was found in 1 section (areas of remaining tumor were marked in the reference map using

	a red pencil)." 5. At the time of the survey, TP #4 confirmed the information in patient A's test report for stages one and two are transposed and incorrect.
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 review of the Clinical Laboratory Improvement Amendment (CLIA) application (Form CMS-116), patient test reports, and confirmed by interview with testing personnel identifier #4 (TP #4) at 9:40 am on 01/22/2025, the laboratory failed to indicate the name and address of the testing facility for four out of four patient test reports reviewed from November 2024. The findings include: 1. Patient A had Mohs surgery performed on 11/06/2024. 2. Patients B and C had Mohs surgery performed on 11/07/2024. 3. Patient D had Mohs surgery performed on 11/15/2024. 4. The CLIA application listed the name and address of the facility as Core Dermatology Davenport; 1950 E 54th Street; Davenport, IA 52807. 5. The test reports for patients A, B, C, and D listed the performing laboratory as Moline Laboratory Soderstrom Dermatology Center, S.C. 6. At the time of the survey, TP #4 confirmed the test reports for patients A, B, C, and D did not include the correct name and address of the performing laboratory.
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 review of laboratory personnel records and confirmed by interview with Testing Personnel identifier #4 (TP #4) at 11:15 am on 01/22/2025, the laboratory failed to meet the testing personnel requirements by providing documentation to qualify the testing personnel who perform high complexity testing as specified in standard 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 review of laboratory personnel records and confirmed by interview with Testing Personnel identifier #4 (TP #4) at 11:15 am on 01/22/2025, the laboratory failed to ensure two out of six testing personnel met the educational requirements for performing high complexity testing. The findings include: 1. Testing personnel identifiers #5 (TP #5) and #6 (TP #6) performed grossing of tissues, which is consider high complexity testing. 2. Review of educational documentation and transcripts for TP #5 revealed they did not meet the minimum semester hours required to perform high complexity testing. 3. At the time of the survey, TP #4 indicated TP #6 would not be performing grossing any longer and did not provide educational documentation for TP #6.