Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0687229	03/01/2021
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Associates Of West Michigan	1740 E Paris Avenue Se, Grand Rapids, MI	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #16, the laboratory failed to verify the accuracy of its dermatopathology testing for 1 (2020) of 2 years reviewed. Findings include: 1. A review of the laboratory's "DAWM Quality Assurance for Pathology DAWM//Outside Lab (Slide Consults)" log revealed a lack of documentation of the performance of verification of accuracy for its dermatopathology testing at least twice annually for 2020. 2. A review of the laboratory's "Pathology Comparison Testing/Quality Assurance" policy revealed a section stating, "Twice a year, documentation from the past 6 month's reports will be collected. 5 difference reports will be chosen; showing the office visit date, slide number, patient initials, biopsy diagnosis, and the yes/no agreement of that diagnosis between the DAWM physician and the outside lab." 3. An interview on 3/1/21 at 9:30 am with Testing Personnel #16 confirmed the laboratory had not verified the accuracy of its dermatopathology testing at least twice annually in 2020.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities

	specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #16, the laboratory failed to follow its established microscope maintenance procedures for 1 (Olympus CH-2) of 12 microscopes observed. Findings include: 1. The surveyor observed an Olympus CH-2 microscope with a calibration and maintenance sticker with the date of 9/30/19 during a tour of the facility on 3/1/21 at 9:00 am. 2. A review of the laboratory's "Quality Control/Quality Assurance Policy" revealed a section stating, "Microscope maintenance will be done annually by Toby's Instrument Shop and recorded." 3. An interview on 3/1/21 at 9:39 am with Testing Personnel #16 confirmed the microscope had not been serviced annually for 2020.
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 record review and interview with Testing Personnel #16, the Technical Supervisor failed to assess employee competency for 8 (Testing Personnel 3, 4, 6, 9, 10, 11, 12, and 13) of 16 testing personnel listed on the CMS-209 form. Findings include: 1. A review of the laboratory's competency records revealed a lack of documentation of competency assessments for the following testing personnel: a. Testing Personnel #3 had a lack of documentation for 2020 b. Testing Personnel #4 had a lack of documentation for 2020 c. Testing Personnel #6 had a lack of documentation for 2020 d. Testing Personnel #9 had a lack of documentation for 2019 and 2020 e. Testing Personnel #10 had a lack of documentation for 2019 and 2020 f. Testing Personnel #11 had a lack of documentation for 2019 and 2020 g. Testing Personnel #12 had a lack of documentation for 2019 and 2020 i. Testing Personnel #13 had a lack of documentation for 2019 and 2020 2. A review of the laboratory's "Quality Control/Quality Assurance Policy" revealed a section stating, "All testing personnel in the office will complete and document competency through CME or training twice a year. All certificates will be kept on file in the Q. A. manual." 3. An interview on 3/1/21 at 11:36 am with Testing Personnel #16 and the Clinical Manager confirmed competency assessments were not available for the staff listed above.
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 interview with Testing Personnel #16, the laboratory failed to ensure testing personnel performing highly complex testing met the qualification requirements of 493.1489. Findings include: 1. The laboratory failed to ensure testing personnel were qualified to perform high complexity testing. 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 record review and interview with Testing Personnel #16, the laboratory failed to ensure testing personnel performing highly complex testing met the qualification requirements of 493.1489 for 1 (Testing Personnel #16) of 16 testing personnel listed on the CMS 209 form. Findings include: 1. The surveyor reviewed the qualification documentation for personnel listed on the laboratory's CMS-209 form and the laboratory did not have qualification documentation for Testing Personnel #16 to qualify as high complexity testing personnel. 2. An interview on 3/1/21 at 10:11 am with Testing Personnel #16 revealed they are performing tissue specimen gross examinations. 3. The laboratory was provided an additional 7 days to provide qualification documentation for Testing Personnel #16 and it was not available.