Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 23D2159414	**(X3) Date Survey Completed** 03/09/2020
Name of Provider or Supplier West Michigan Dermatology	**Street Address, City, State** 3434 Rivertown Point Court Sw, Grandville, 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**
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: . Based on record review and interview with the office manager, the Technical Consultant failed to evaluate the performance of testing personnel at least semiannually during the first year for 6 (Testing Personnel #1, 2, 5, 6, 7, and 9) of 14 testing personnel. Findings include: 1. An interview on 3/9/2020 at 11:00 am with the office manager revealed the laboratory initially started testing in May 2019. 2. A review of the laboratory's "Competency/Proficiency Testing Policy" revealed it did not contain a policy for the semiannual evaluation of testing personnel in the first year. 3. A review of testing personnel competency assessments revealed the following personnel did not have a semiannual performance evaluation: a. Testing Personnel #1 most recent evaluation was performed 5/3/19 b. Testing Personnel #2 most recent evaluation was performed 5/13/19 c. Testing Personnel #5 most recent evaluation was performed 5/13/19 d. Testing Personnel #6 most recent evaluation was performed 5/13 /19 e. Testing Personnel #7 most recent evaluation was performed 5/13/19 f. Testing Personnel #9 most recent evaluation was performed 5/13/19 3. An interview on 3/9 /2020 at 11:37 am with the office manager confirmed the testing personnel above did not have semiannual performance evaluations.
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 document review, and interview with the General Supervisor (GS), the laboratory failed to ensure personnel performing high complexity histopathology testing met educational requirements at 42 CFR 493.1489 for 1 (Testing Personnel #14) of 14 testing personnel. Findings include: 1. The laboratory failed to ensure testing personnel performing high complexity testing were qualified before performing 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 the office manager, the laboratory failed to ensure testing personnel performing high complexity testing were qualified for 1 (Testing Personnel #14) of 14 testing personnel. Findings include: 1. A review of testing personnel credentials revealed a lack of credentials for Testing Personnel #14. 2. A review of the initial competency assessment for Testing Personnel #14 showed a completion date of 11/25/19. 3. An interview on 3/9/2020 at 11:52 am with the office manager confirmed the credentials for Testing Personnel #14 were not available. 4. The laboratory was granted an additional 7 days to submit missing credentials to the surveyor and they were not made available.