Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 23D2159414	**(X3) Date Survey Completed** 12/01/2021
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**
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: . Based on observation, lack of documentation, and interview with the Clinical Manager, the laboratory failed to report all SARS-CoV-2 test results every day of patient testing for 9 (March 2021 to December 2021) of 9 months the laboratory has been testing for SARS-CoV-2. Findings include: 1. The surveyor observed the laboratory's BD Veritor SARS-CoV-2 Antigen test system on 12/1/21 at 9:44 am. 2. The surveyor requested the laboratory's policy on reporting SARS-CoV-2 results to the health department on 12/1/21 at 1:43 pm and it was not made available. 3. An interview on 12/1/21 at 9:44 am with the Clinical Manager revealed the laboratory started testing in March 2021 and had not been reporting negative results to the health department.
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 interviews, the laboratory failed to establish procedures to assess testing personnel competency for Potassium Hydroxide preparations (KOH preps), Scabies preparations, and Dermatophyte Test Medium (DTM) cultures for 2 (December 2019 to December 2021) of 2 years reviewed. Findings include: 1. A review of the laboratory's competency assessments for KOH preps, Scabies preparations, and DTM cultures revealed they had been photocopied, the initials of the reviewer did not match personnel listed on the CMS-209 form, and the documentation did not specify where the competency assessments were performed. 2. An interview on 12/1/21 at 11:14 am with Clinic Personnel revealed the individual initialling the laboratory's competency assessments was not qualified as a Technical Consultant. 3. An interview on 12/1/21 at 1:43 pm with Clinic Personnel revealed the competency assessments are performed at one of the facility's locations, are then photocopied, and the copies are kept at this location.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: . Based on observation and interview with the Clinical Manager, the laboratory failed to ensure tissue marking dyes used in tissue specimen grossing were not expired for 4 (lot numbers 87100, 87104, 86845, and 86921) of 5 tissue marking dyes observed. Findings include: 1. The surveyor observed 4 expired Platinum Line tissue marking dyes on 12/1/21 during a tour of the laboratory at 9:17 am with the following dates of expiration: a. Blue lot number 87100, expiration date August 2021 b. Red lot number 87104 expiration date June 2021 c. Black lot number 86845 expiration date August 2021 d. Yellow lot number 86921 expiration date August 2021 2. An interview on 12 /1/21 at 9:17 am with the Clinical Manager confirmed the tissue marking dyes used were expired.
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 the Clinical Manager, 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. ***This is a repeated deficiency from the 3/9/20 initial survey***

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 Clinical Manager, the laboratory failed to ensure testing personnel performing high complexity testing were qualified for 2 (Testing Personnel #10 and 11) of 12 testing personnel listed on Form CMS-209. Findings include: 1. A review of testing personnel credentials revealed a lack of documentation showing Testing Personnel #10 and #11 were qualified to perform high complexity testing. 2. An interview on 12/1/21 at 12:48 pm with the Clinical Manager confirmed the documentation showing Testing Personnel #10 and #11 were qualified to perform high complexity testing were not available. 3. The laboratory was granted an additional 7 days to submit missing credentials to the surveyor and they were not made available. ***This is a repeated deficiency from the 3/9/20 initial survey***