Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2159414	07/10/2023
Name of Provider or Supplier	**Street Address, City, State**	
West Michigan Dermatology	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
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 the Team Lead (TL), the laboratory failed to verify the accuracy of its Scabies testing at least twice annually for 19 (2022 and 2023) of 19 months reviewed. Findings include: 1. A record review of the "Laboratory Tests Log for KOH and Parasites" revealed a column with a "2nd Provider Sign Off." 2. A record review of the 2022 and 2023 "Laboratory Tests Log for KOH and Parasites" revealed a lack of documentation on the logs in the "2nd Provider Sign Off" column for the following accuracy reviews: a. 1st and 2nd half in 2022 b. 1st half in 2023 3. A record review of the testing logs revealed only one patient had scabies testing on 10/22/2022 with a lack of documentation of the 2nd provider sign off. 4. When queried on 7/10/2023 at 10:51 am, the TL did not know there were other means to access the accuracy. 5. A interview on 7/10/2023 at 10:51 am, the TL confirmed the twice annual verification of accuracy for the scabies testing was not performed and documented.
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:

	A. Based on observation and interview with the Team Lead (TL), the laboratory failed to calibrate and/or replace the expired timer in the dermatology laboratory for 1 (S/N 200357730) of 1 timer discovered in the Labconco hood where grossing takes place. Findings include: 1. During a tour of the laboratory on 7/10/2023 at 9:08 am, the surveyor observed a traceable timer in the grossing hood with an expiration date of 6 /15/2022. 2. An interview on 7/10/2023 at 9:12 am, the TL confirmed the timer in the dermatology laboratory had expired and was not calibrated and/or replaced. B. Based on observation and interview with the Team Lead (TL), the laboratory failed to ensure its Chlorazol reagent had not exceeded its expiration date for 1 (bottle) of 1 bottle in use. Findings include: 1. During a tour of the laboratory on 7/10/2023 at 9:08 am, the surveyor observed the Chlorazol reagent in use past the indicated expiration date of 7 /31/2022. 2. An interview on 7/10/2023 at 9:20 am the TL confirmed the Chlorazol reagent bottle in use had expired.
D5801	TEST REPORT CFR(s): 493.1291(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 record review and interview with the Team Lead (TL), the laboratory failed to establish a system to ensure the transcribed anatomical site was accurately transcribed for 2 (972870 and 279500) of 7 patient potassium hydroxide (KOH) and /or scabies testing reviewed for 19 months. Findings include: 1. A record review revealed for 2 of 7 final KOH and/or scabies reports reviewed, the anatomical site reported in the patients visit note in the laboratory information system was transcribed incorrectly from the "Laboratory Tests Log for KOH and Parasites" as follows: a. 972870 i. log - left neck ii. visit note - left inferior lateral neck and neck. b. 279500 i. log - chest ii. visit note - xiphoid and trunk 2. An interview on 7/10/2023 at 1:16 pm, the TL confirmed the transcribed anatomical site was transcribed incorrectly.