Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0956762	03/15/2023
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology & Skin Surgery Center	300 E Maiden Ln, St Joseph, 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 Office Manager, the laboratory failed to verify the accuracy of its histopathology testing at least twice annually for 2 (2021 and 2022) of 2 years reviewed. Findings include: 1. A review of the laboratory's verification of accuracy records revealed histopathology cases had been sent to an outside laboratory for verification on 6/18/21 and 12/20/22. There was a lack of documentation of second verification of accuracy events for 2021 and 2022. 2. A review of the laboratory's "Protocol for Peer Review" policy revealed a section stating, "There are to be four cases sent for the year. Two cases are to be sent from the first 6 months of the year, and two cases from the second six months of the year." 3. An interview on 3/15/23 at 11:25 am with the Office Manager confirmed the laboratory had not performed verification of accuracy for histopathology testing at least twice annually in 2021 and 2022.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager, the laboratory failed to have the procedures for Mohs Micrographic Surgery testing, Potassium Hydroxide

	(KOH), and Scabies testing approved, signed, and dated by the Laboratory Director before use for 19 (August 2021 to March 2023) of 19 months reviewed. Findings include: 1. A review of the laboratory's policies and procedures revealed the Mohs Micrographic Surgery Testing procedures had been signed and approved by Testing Personnel #2, not the Laboratory Director. 2. A review of the laboratory's policies and procedures revealed a lack of established procedure for the performance of KOH and Scabies testing. 3. The surveyor requested the KOH and Scabies preparation procedures on 3/15/23 at 11:00 am. The Office Manager provided a copy of a procedure that had been in use by Testing Personnel #3 and #4 but was not part of the procedure manual. The procedures provided had not indicated the Laboratory Director had approved the test procedures. 4. An interview on 3/15/23 at 11:05 am with the Office Manager confirmed the Laboratory Director had not approved, signed, and dated the Mohs Micrographic Surgery testing, KOH preparation testing, or Scabies preparation testing procedures.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager, the Laboratory Director failed to ensure the laboratory's quality assessment program was maintained according to its established policy for 21 (last performed on 6/28/21) of 21 months reviewed. Findings include: 1. A review of the laboratory's "Quality Assurance" policy revealed a section stating, "Every six months log books are to be checked for accuracy. Ten or so charts will be chosen at random from the KOH, DTM, Tzank, scabies, and Mohs charts. These charts are to be checked by making sure all information in the log is the in the chart. All results are to be logged on Quality Assessment chart review sheets located in the QA binder located in the lab." 2. A review of the laboratory's "Quality Assessment Chart Reviews" revealed the most recent review was performed on 6/28/21 and only covered patients receiving Potassium Hydroxide (KOH) and Scabies preparation testing. 3. An interview on 3/15 /23 at 11:25 am with the Office Manager confirmed the laboratory did not have documentation of quality assessments performed since 6/28/21.