Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0956762	07/24/2019
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
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: . Based on patient chart review and interview with Testing Personnel #4 (TP4), the laboratory failed to have a electronic request for patient testing from an authorized person for the potassium hydroxide (KOH) testing for 1 (patients #2) of 29 patient charts audited. Findings include: 1. A patient chart review conducted on 29 patient charts revealed for 1 (#2) the laboratory did not have an electronic request for the KOH testing performed on 12/21/2017. 2. An interview on July 24, 2019 at approximately 11:45 am with TP4 confirmed no electronic request for patient testing from a authorized person was present in the patient's electronic medical record.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #4 (TP4), the laboratory failed to maintain a record system that included the identity of the testing

	personnel performing the Mohs Micrographic surgery for 1 (#17) of 29 patient charts audited. Findings include: 1. Record review for 29 patient charts audited revealed the laboratory did not have a record system in place that included the identity of the testing personnel who performed the Mohs surgery on the final patient Mohs Map. 2. During the interview on July 24, 2019 at approximately 11:45 am, TP4 confirmed the identity of the testing personnel was not available on the patient's final Mohs Map report. ***Repeat Deficiency from 2/6/2017 survey***
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 Testing Personnel #4 (TP4), the laboratory failed to ensure test results are accurately and reliably sent from the point of data entry to the final report destination for 1 (#2) of 29 patient charts audited. Findings include: 1. A record review exposed a lack of documentation for 1 (#2) of 29 patient charts audited to verify manual entry of results were being accurately and reliably conveyed to the final report destination. 2. An interview on July 24, 2019 at approximately 11:45 am with TP4 confirmed the laboratories routine checks to verify manual entry of results to the final report destination were not dependable.