

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2119620	(X3) Date Survey Completed 01/16/2019
Name of Provider or Supplier Tru North Dermatology	Street Address, City, State 315 Oak Grove St, Manistee, 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	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on record review, and interview, the laboratory failed to 1) at least twice annually verify the accuracy of the histopathology Mohs' tissue slide examination for one (2nd six months 2018) of four events reviewed and 2) failed to twice annually verify the accuracy of the microbiology testing for two (2017 and 2018) of two years testing. Findings include: 1. Review of the "Mohs' Micrographic Surgery Skin Specimens" procedure states "two cases" will be sent out two times a year for review by "another physician and/or hospital" for evaluation. 2. On January 16, 2019 at 10:00 AM, record review of the twice a year verification of accuracy for the Mohs' tissue slide examination revealed the laboratory did not have any documentation to show the evaluation was performed during the second six months of 2018. 3. On January 16, 2019 at approximately 12:00 PM, lack of records to show documentation for the twice a year verification of accuracy for the microbiology mycology and parasitology testing was not available. 4. On January 16, 2019 at 10:00 AM and approximately 12:00 PM when requested, the laboratory was unable to provide the surveyor the documents requested. 5. During the interview on January 16, 2019 at 10:00 AM and 12:00 PM, the office manager confirmed the twice a year verification of accuracy was not performed and documented for the Mohs' tissue slide examination for the second six month evaluation in 2018 and the mycology and parasitology testing for 2017 and 2018.</p>
D5301	<p>TEST REQUEST CFR(s): 493.1241(a)</p>

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 record review and interview, the laboratory failed to have a electronic request for patient testing from an authorized person for the microbiology testing for three (#10 - #12) of 12 patient charts reviewed. Findings include: 1. On January 16, 2019 at 2:15 PM, record review revealed the laboratory did not have a electronic request for the scabies testing that was performed and resulted in the patient's electronic medical record (EMR). 2. On January 16, 2019 at 2:15 PM when requested, the office manager was unable to provide the surveyor the documentation requested. 3. During the interview on January 16, 2019 at 2:15 PM, the office manager confirmed no electronic orders were available in the patient's EMR file.