Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0908507	03/27/2018
Name of Provider or Supplier	**Street Address, City, State**	
Midwest Clinic Of Dermatology	1510 24th Ave No, Saint Cloud, MN	

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 document review and interview with laboratory personnel, the laboratory failed to perform activities used to verify the accuracy of a Histopathology test procedure at least twice annually. Findings are as follows: 1. The laboratory performed Mohs Micrographic Surgery (MMS) testing under the subspecialty of Histopathology as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 03/27/18 at 1:05 p.m. 2. Verification of accuracy requirements for the MMS testing were established in the Laboratory Procedure Manual Histopathology - Mohs Surgery procedure located in the Laboratory Standards Manual. 3. Documentation of the 2016 MMS verifications were not found in laboratory records. The laboratory was unable to provide MMS verification documentation from 2016 upon request. 4. In an interview on 03/27/18 at 2:05 p.m., TP1 confirmed MMS accuracy had not been verified in 2016.
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to document the time patient specimens were received into the laboratory. Findings are as follows: 1. The laboratory performed Mohs Micrographic Surgery

	(MMS) testing under the subspecialty of Histopathology as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 03/27/18 at 1:05 p.m. 2. Requirements for documentation of patient specimen (tissue) receipt time into the laboratory were established in the Laboratory Procedure Manual Histopathology - Mohs Surgery procedure located in the Laboratory Standards Manual. 3. The time of tissue receipt into the laboratory was not documented in testing records for 4 of 4 MMS cases reviewed on date of survey. 4. In an interview on 03/27/18 at 2:55 p.m., TP1 confirmed the above finding and stated the time tissue was received into the laboratory had not been documented.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: . Based on document review and an interview with laboratory personnel, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems when identified. Findings are as follows:: 1. The laboratory performed Microscopic Examinations for parasites and fungus and Mohs Micrographic Surgery testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 03/2718 at 1:05 p.m. 2. The laboratory failed to establish a Quality Assurance program to monitor, assess, and when indicated, correct problems identified in pre-analytic, analytic, and post-analytic systems. 3. In an interview on 03/27/18 at 3:45 p.m., TP1 confirmed the above finding.