Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0650703	12/17/2018
Name of Provider or Supplier	**Street Address, City, State**	
Wayne Health Dearborn	5250 Auto Club Drive, Dearborn, 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
D3041	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to retain a copy of the original histopathology Mohs' map at least ten years for three (#1, #2, and #4) of 15 patient charts reviewed. Findings include: 1. On December 17, 2018 at 3:23 PM, patient chart review revealed the laboratory did not have the Mohs' map as part of the patients medical record and the laboratory did not retain the original map for as least 10 years from the date of reporting . 2. On December 17, 2018 at 3:23 PM when queried, the office staff member was unable to provide the surveyor the final copy of the Mohs' map requested. 3. During the interview on December 17, 2018 at 3:23 PM, the office manager confirmed the final Mohs' map was not retained for at least 10 years from the date of reporting.
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, the laboratory failed to at least twice annually verify the accuracy of testing for each provider using Michigan Dermatological

	Society "Physician Performed Microscopy/DTM Interpretation" and/or "Dermatopathology" examination for four (spring/fall 2017 and 2018) of four seasonal exams reviewed. Findings include: 1. On December 17, 2018 at 2:45 PM, record review of the "Physician Performed Microscopy/DTM Interpretation" exams revealed the testing personnel (TP) did not perform at least twice a year verification of accuracy as follows: a. TP #4 - no fall 2017 b. TP #1 and #2 - no spring and fall 2017 c. TP #4 - no spring 2018 d. TP #3 - no spring and fall 2018 2. On December 17, 2018 at 2:45 PM, record review of the "Dermatopathology" exams revealed the TP did not perform at least twice a year verification of accuracy as follows: a. TP#1 - no spring and fall 2017 b. TP #3 - no spring and fall 2018 3. During the interview on December 17, 2018 at approximately 4:30 PM, the office manager confirmed the spring and fall Michigan Dermatological Society examinations was not consistently completed and documented for each provider.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: The laboratory failed to meet applicable analytic system requirements and correct identified problems. Findings include: 1. The laboratory failed to document room temperature and humidity readings each day of operation. Refer to D5413. 2. The laboratory failed to was the Chlorazol Black E, Wright-Giesma stain, and CDI Tissue Marking Dyes before the manufacturer's expiration date. Refer to D5417. 3. The laboratory failed to perform and document the weekly eyewash maintenance. Refer to D5429. 4. The laboratory failed to document the corrective action taken for temperatures outside of the stated range. Refer to D5781. 5. The laboratory failed to record the specimen in/out times of receipt into the laboratory, include the identity of the testing personnel performing the Mohs' surgery, and provide the case number on the Mohs' map. Refer to D5787. The cumulative effect of the failure of the laboratory to meet the requirements of 493.1251 through 493.1289 constitutes condition-level noncompliance.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by:

	. Based on record review and interview, the laboratory failed to document the room temperature and humidity readings each day of operation for two (2017 and 2018) of two years reviewed. Findings include: 1. On December 17, 2018 at 3:00 PM, record review of the "Utility room/Mohs lab temp log" revealed the laboratory did not document and record temperatures every day of operation as follows: room temperature a. 2017 - no temperatures documented for the following days of operation 1. January 30 2. April 3 3. July 17 4. October 2 and 30 b. 2018 - no temperatures documented for the following days of operation 1. February 5 2. March 20 3. April 24 4. May 22 5. June 4 and 19 6. August 21 and 27 7. October 30 8. November 27 2. On December 17, 2018 at 3:00 PM, lack of records revealed the laboratory failed to document each day of operation the humidity of the laboratory to ensure proper operation of the instrumentation for 2017 and 2018. 3. During the interview on December 17, 2018 at 3:00 PM, the office manager confirmed temperature and humidity readings were not performed and documented each day of operation.
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: . Based on observation and interview, the laboratory was using seven (Chlorazol Black E, Wright-Giesma stain, and CDI Tissue Marking Dyes) of nine reagents that exceeded the manufacturer's expiration date. Findings include: 1. On December 17, 2018 at 1:08 PM during a tour of the laboratory, the surveyor observed reagents being used past the manufacturer's stated expiration dates as follows: a. Chlorazol Black E - expired November 2014 b. Wright-Giesma stain - expired May 4, 2016 c. CDI Tissue Marking Dyes 1. red - lot #7096 expired July 2018 2. black - lot #7134 expired August 2016 3. yellow - lot #7123 expired August 2016 4. green - lot #7126 expired August 2016 5. blue - lot #7127 expired August 1, 2016 2. During the interview on December 17, 2018 at approximately 4:30 PM, the office manager confirmed the reagents in use exceeded the manufacturer's expiration dates.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to perform and document the weekly eyewash maintenance for 46 (January to second week December) of 50 weeks reviewed in 2018. Findings include: 1. On December 17, 2018 at 3:00 PM, record review of the "Eyewash Maintenance Log" revealed the laboratory did not document and record the weekly maintenance to ensure proper operation as follows: a. January - three of five weeks missed b. February - two of four weeks missed c. March - four of four weeks missed d. April - five of five weeks missed e. May - four of four weeks missed f. June - four of four weeks missed g. July

	- five of five weeks missed h. August - four of four weeks missed i. September - five of five weeks missed j. October - four of four weeks missed k. November - four of four weeks missed l. December - one of two weeks missed 2. During the interview on December 17, 2018 at 3:00 PM, the office manager confirmed the weekly eyewash station maintenance was not performed and documented as required.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to document the corrective action taken for temperatures outside the stated range for four (January to April 2017) of 19 days recorded on the "Utility room/Mohs lab temp log". Findings include: 1. On December 17, 2018 at 3:00 PM, record review of the "Utility room /Mohs lab temp log" revealed for four temperatures recorded in 2017 the temperatures were below the operational range of 18-35 degree C / 64.4-95 degree F for the histopathology Mohs' cryostat instrument as follows: a. January 29, 2017 - 57 degree F b. February 20, 2017 - 62 degree F c. March 6, 2017 - 63 degree F d. April 17, 2017 - 63 degree F 2. On December 17, 2018 at 3:00 PM when queried, the office manager was not able to provide the surveyor documentation to show corrective action was taken for the temperatures below the stated range. 3. During the interview on December 17, 2018 at 3:00 PM, the office manager confirmed the laboratory did not document corrective action for the temperatures outside the stated range.
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, the laboratory failed to 1) record the specimen in/out time of receipt into the laboratory for the Mohs' tissue and frozen section specimens for eight (#1- #8) of 15 patient charts audited, and 2) include the identity of the testing personnel performing the Mohs' surgery for seven (#1 - #7) of 15 patient charts audited on the Mohs' map, and 3) provide the case number on the Mohs' map for one (#5) of 15 patient charts audited. Findings include: 1. On

	December 17, 2018 at 3:23 PM, record review of patients charts revealed the laboratory did not 1) record the specimen in/out time of receipt for the Mohs' tissue and frozen section on the Mohs' map, and 2) identity of the Mohs' surgeon, and 3) include the case number on the Mohs' map as follows: a. specimen #1-#8 - no in/out time recorded for each stage of testing b. specimen #1-#7 - no surgeon identity recorded on the Mohs' map c. specimen #5 -no case number recorded on the Mohs' map 2. During the interview on December 17, 2018 at 3:23 PM, the office manager and staff member confirmed the specimen receipt times, surgeons identity, and the case number was not consistently recorded on the Mohs' map.
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, the laboratory failed to establish a system to ensure the manually entered patient final test results were entered into the patient's electronic medical record (EMR) for one (#11) of 15 patient charts audited. Findings include: 1. On December 17, 2018 at 3:23 PM, record review for patient charts audited revealed the final patient test result for the mycology potassium hydroxide (KOH) testing was not included in the patient's EMR chart. 2. During the interview on December 17, 2018 at 3:23 PM, an office staff member confirmed the final KOH testing results was not included in the patient's EMR chart.