Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0650703	03/29/2021
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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the Office Manager (OM), the laboratory failed to provide safety procedures for proper protection and disposable of biohazardous materials in the Mohs' laboratory for 2 (March 2019 to March 2021) of 2 years in use. Findings include: 1. During a tour of the laboratory on 3/29/2021 at 9:34 am, the surveyor observed XS-3 Xylene Substitute made by StatLab used for Mohs' staining stored in the flammable cabinet. 2. A record review of the "Mohs Procedure Manual" states in Section 4.3 "Storage used and Handling (See MSDS forms)" subsection 4.3.6 "Reagents are disposed of according to federal, state, and local laws." The surveyor did not observe any biohazardous waste containers available in the laboratory. 3. A phone interview on 4/5/2021 at 9:45 am with the OM, confirmed there were no procedures for protection and/or disposable of biohazardous waste in the laboratory.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

	This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the Laboratory Director (LD), the laboratory failed to label the histopathology marking inks that were poured off from the original container with the lot number, storage requirements, and expiration dates for 5 (yellow, red, black, blue, and green) of 5 ink containers observed. Findings include: 1. During a tour of the laboratory on 3/29/2021 at 9:34 am the surveyor observed 5 (yellow, red, black, blue, and green) of 5 marking inks that had been poured off into small containers without the lot number, storage requirements, and expirations dates recorded on the containers. 2. A record review of the "Mohs Procedure Manual" states in "section 4.2 Preparation and Labeling" under 4.2.1 "Liquid reagents may be transferred to correctly labeled smaller containers for that particular reagent." 3. An interview on 3/29/2021 at 9:45 am with the LD confirmed the laboratory did not provide the labeling information on the histopathology marking ink poured off containers.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: A. Based on observation, lack of documentation, and interview with the Laboratory Director (LD), the laboratory failed to perform and document the traceable thermometer calibration checks as required by the manufacturer before the expiration for 8 (July 2020 to March 2021) of 24 months of operation. Findings include: 1. During a tour of the laboratory on 3/29/2021 at 9:34 am the surveyor observed a McKesson traceable thermometer in use that provides the room temperature and humidity readings being used past the expiration date of 7/12/2020. 2. A lack of documentation upon review of the laboratory records revealed the thermometer was not calibrated and/or replaced by the expiration of 7/12/2020. 3. When queried on 3/29 /2021 at 9:45 am, the LD was unable to provide the surveyor the requested calibration documents and/or proof of replacement of the thermometer. 4. A interview on 3/29 /2021 at 9:45 am, the LD confirmed the McKesson traceable thermometer was not calibrated and/or replaced by the 7/12/2020 expiration. B. Based on record review and interview with the Office Manager (OM), the laboratory failed to perform and document the weekly eyewash maintenance for 10 weeks (10/2019 week 3, 5/2020 week 4, 9/2020 weeks 3 and 4, 11/2020 weeks 1, 3 and 4, and 12/2020 weeks 2-4) of 2 years reviewed. Findings include: 1. A record review of the "WSU Dermatology Surgery Eyewash Maintenance Log" revealed for 10 weeks of 2 years reviewed lack of documentation the weekly maintenance was performed as follows: a. 10/2019 - no documentation for week 3 b. 5/2020 - no documentation for week 4 c. 9/2020 - no documentation for weeks 3 and 4 d. 11/2020 - no documentation for weeks 1, 3, and 4 e. 12/2020 - no documentation for weeks 2 - 4 2. When queried on 3/29/2020 at 1:12 pm, the OM was unable to provide the surveyor documentation for the missing preventive maintenance on the eyewash station. 3. A interview on 3/29/2021 at 1:12 pm, the OM confirmed the eyewash maintenance was not performed and documented weekly as required.

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 the Laboratory Director (LD), the laboratory failed to maintain a record system that included the time the specimen for each stage of Mohs' testing was received in the laboratory and processed for 7 (#2, #4-8, and #10) of 12 Mohs' final map reports reviewed for 2 years. Findings include: 1. A record review for 7 (#2, #4-8, and #10) of 12 Mohs' cases reviewed revealed the laboratory did not have a record system in place that included the time each stage of the Mohs' testing was received in the laboratory and processed when multiple stages were collected. 2. A interview on 3/29/2021 at 1:45 pm, the LD confirmed the time received in the laboratory and processed for each stage of the Mohs' testing was not documented. ***Repeat Deficiency from 12/17/2018 survey***
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: . Based on lack of documentation and interview with the Office Manager (OM), the Technical Supervisor (TS) failed to assess employee competency for 1(#5) of 1 testing personnel performing the high complexity Mohs grossing for 2 years. Findings include: 1. A review of the laboratory's competency records revealed a lack of documentation of competency assessments for 1 (#5) of 1 testing personnel performing the high complexity Mohs grossing in 2019 and 2020. 2. A interview on 3 /29/2021 at 10:55 am, the OM confirmed competency assessments were not available for testing personnel #5.