Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0650703	10/18/2022
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 with the Laboratory Director (LD) and laboratory liaison (LL), the laboratory failed to retain a copy of the original histopathology Mohs' map at least ten years for 1 (D16-1) of 11 patient charts reviewed. Findings include: 1. Record review revealed a lack of documentation for the Mohs' map in the patient's electronic medical record (EMR) for 1 of 11 patient charts reviewed. 2. When queried on 10/18/2022 at 10:50 am, the LD and LL were unable to provide the surveyor a scanned or a paper copy of the Mohs' map. 3. An interview on 10/18/2022 at 12:45 pm, the LD and LL confirmed the Mohs' map was not retained for at least 10 years from the date of reporting in the patient's EMR. ***Repeat Deficiency from 12/17/2018 survey ***
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 record review and interview with the Laboratory Director (LD) and laboratory liaison (LL), the laboratory failed to have a documented electronic request

	for patient testing from an authorized person for 1 (patient 699075) of 4 patient charts reviewed. Findings include: 1. A record review of patient charts revealed for 1 (patient 699075) of 4 patient charts reviewed there was no electronic order for the potassium hydroxide (KOH) testing performed and resulted on 8/05/2021 in the patients electronic medical record (EMR). 2. An interview on 10/18/2022 at 12:45 pm, the LD and LL confirmed there were no orders documented in the patients EMR for the KOH test performed and resulted on 8/05/2021.
D5803	TEST REPORT CFR(s): 493.1291(b) Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director (LD) and laboratory liaison (LL), the laboratory failed to provide test reports maintained as part of the patients' chart for 1 (D22-024) of 11 patient test reports reviewed. Findings include: 1. A record review revealed for 1 (D22-024) of 11 patient charts reviewed, the laboratory did not provide a copy of the Pathology Report which brought the patient to this laboratory for further testing (Mohs'). 2. When queried on 10/18/2022 at 11:45 am, the LL was not able to provide the surveyor the document requested. 3. An interview on 10/18/2022 at 12:45 pm, the LD and LL confirmed the laboratory did not maintain a copy of the Pathology Report in the patient's EMR.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: A. Based on record review and interview with the Laboratory Director (LD) and the laboratory liaison (LL), the laboratory failed to indicate the surgical site on the Mohs' map as part of the test report for 2 (D21-042 and D21-070) of 11 patient test records reviewed. Findings include: 1. Record review revealed for 2 of 11 patient test reports the surgical site was not recorded on the Mohs' map as part of the test report. 2. An interview on 10/18/2022 at 12:45 pm, the LD and LL confirmed the laboratory did not indicate the surgical site on the Mohs' maps for the patients listed above. B. Based on record review and interview with the Laboratory Director (LD) and the laboratory liaison (LL), the laboratory failed to correctly label the surgical site on the Mohs' log for 1 (D21-055) of 11 patient test records reviewed. Findings include: 1. A record review performed on 10/18/2022 at 10:57 am revealed the "Dermatopathology Report", the Mohs' map, and the "Mohs' micrographic surgery" notation in the patients electronic medical record (EMR) labeled the surgical site as "right medial

	cheek" while the Mohs' log labeled the surgical site as "right cheek." 2. An interview on 10/18/2022 at 12:45 pm, the LD and LL confirmed the surgical site on the Mohs' log was not consistent with the "Dermatopathology Report", the Mohs' map, and the Mohs' notation in the patients EMR. C. Based on record review and interview with the Laboratory Director (LD) and the laboratory liaison (LL), the laboratory failed to establish a system to ensure the transcribed Mohs' surgical site was accurately transcribed onto the Mohs' map, Mohs' log and, in the patient's electronic medical record (EMR) visit note for 1 of (D22-048) of 11 patient test records reviewed. Findings include: 1. A record review revealed for 1 of 11 Mohs' cases reviewed, the surgical site on the patient's Mohs' map and the visit note in the EMR system was not transcribed accurately as follows: D22-048 i. Pathology report and Mohs' log - right upper cheek ii. Mohs' map and the visit note in EMR - right lower eyelid 2. An interview on 10/18/2022 at 12:45 pm, the LD and LL confirmed the surgical site locations was not transcribed accurately.