Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2015090	11/02/2022
Name of Provider or Supplier	**Street Address, City, State**	
Abbasi Dermatology	21401 Allen Rd, Woodhaven, 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
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: . Based on document review and interview with the Laboratory Director (LD) and the Office Manager (OM), the laboratory failed to perform and document function checks for the Olympus CX31 microscope for 17 (June 2021 to October 2022) of 17 months in use. Findings include: 1. A record review of the "Microscope Maintenance" log revealed a lack of documentation of the "Monthly dusting, testing of objectives, etc." for 17 (June 2021 to October 2022) of 17 months in use. 2. When queried on 11/02 /2022 at 12:05 pm, the OM stated they had been looking for this log and were unable to locate. 3. A review of the Policy and Procedure Manual "Section VIII. Quality Control Program" states under "Test Methods, Equipment, Reagents, Materials and Supplies" in paragraph two "All equipment within the laboratory will be properly maintained according to the manufacturer's specification. The laboratory personnel will be responsilbe for ensuring that all maintenance and repair of equipment are completed in a timely fashion. All maintenance and repairs will be recorded and maintained by the laboratory personnel and will be reviewed by the Laboratory Director on a periodic basis." 4. A interview on 11/02/2022 at 12:05 pm, the LD and OM confirmed there was no documentation to show the microscope monthly cleaning had been performed or documented for 17 months.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f)

	(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: . Based on observation, lack of documentation, and interview with the Laboratory Director (LD), the laboratory failed to document the quality of the slide staining for the Hematoxylin & Eosinophil (H&E) stain for the dermatopathology testing for 4 (SP21-15, SP22-39, SP22-50, and SP22-59) of 7 dermatopathology final case reports reviewed. Findings include: 1. On November 2, 2022 at 11:43 am during patient chart review, the surveyor observed the dermatological tissue specimen processing was being performed at an outside laboratory. 2. No documentation was found to show the quality of the stain from the outside laboratory processing was acceptable by the Laboratory Director (LD) reading the final tissue specimen slides for 4 of 7 cases reviewed as follows: a. Case SP21-15 performed on 2/01/2021 b. Case SP22-39 performed on 6/21/2022 c. Case SP22-50 performed on 7/16/2022 d. Case SP22-59 performed on 9/0/72022 3. During the interview on November 2, 2022 at 12:05 pm, the LD confirmed the stain quality of the slides processed from an outside laboratory was not documented. ***Repeat Deficiency from 3/18/2019 survey***
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: . Based on record review and interview with the Laboratory Director (LD) and the Office Manager (OM), the laboratory failed to establish a system to ensure the transcribed Mohs' surgical site was accurately transcribed from the Pathology Report onto the Mohs' map, Mohs' log, and in the patient's electronic medical record (EMR) visit note for 2 of (A22-008 and A22-082) of 11 patient test records reviewed. Findings include: 1. A record review revealed for 2 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: A22-008 i. Pathology report, Mohs' log, and Mohs' log - right lateral proximal pretibial region ii. Visit note in EMR - right proximal pretibial region A22-082 i. Pathology report, Mohs' log, and Mohs' log - right ventral lateral distal forearm ii. Visit note in EMR - right ventral distal forearm 2. An interview on 11/02/2022 at 12:05 pm, the LD and OM confirmed the surgical site locations were not transcribed accurately from the Pathology Report to the patient's visit note in the EMR.