Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2141563	10/26/2023
Name of Provider or Supplier	**Street Address, City, State**	
Hw Dermatology, Pllc	10238 E Hampton Ave Ste 404, Mesa, AZ	

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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of one out of three patient test records for Mohs testing and interview with the facility personnel, the laboratory failed to ensure positive identification of dermatopathology specimens from the time of collection of the specimen through completion of testing and reporting of test results. Findings include: 1. The laboratory performs Mohs testing under the subspecialty of Histopathology with an annual test volume of 800. The Mohs test records maintained by the laboratory include a Mohs log, operative report (pathology report) maintained in the electronic medical record (EMR), Mohs map and patient slides. It is the practice of the laboratory to assign a unique accession (case) number to each patient's specimen. The unique case number is listed on the Mohs log, Mohs map, operative report and patient's slides. 2. One out of three Mohs test results reviewed during the survey (case# 241-22 from 9/23/2022) failed to ensure positive identification throughout the entire testing process. The slides were labeled with the patient's first name listed as "Ashley," while the Mohs log, Mohs map and the operative report maintained in the EMR listed the first name as "Ashleigh". 3. The yearly Mohs logs reviewed during the survey from 2021, 2022 and 2023 (through the date of the survey) failed to ensure positive identification of a patient's specimen as evidenced by failing to assign a unique case number for each patient listed in the Mohs log. The Mohs logs reviewed for each year listed each case number as a three digit number, but failed to include the year prefix (21-001 or 22-001, for example) which would identify the case number as unique from the previous years. 4. The facility personnel interviewed on 10/26/2023

	at 1:20 PM acknowledged that the laboratory failed to ensure positive identification of the patient's specimens from the time of collection through completion of testing and reporting of results, as evidenced by the name error that occurred on 9/23/2022 and failure to include the full case number, including the year prefix, in the yearly Mohs logs.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on lack of Quality Assessment (QA) documentation and interview with the facility personnel, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. Findings include: 1. No evidence was provided for review to indicate the laboratory established written QA policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. 2. The facility personnel interviewed on 10/26/23 at 2:05 PM confirmed that the laboratory failed to establish preanalytic QA policies and procedures.
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 direct observation of histopathology stain reagents and interview with the facility personnel, the laboratory used the stain reagent, Acetone, past the expiration date. Findings include: 1. The laboratory performs the Hematoxylin and Eosin (H&E) stain on patient slides in conjunction with Mohs testing, with an annual test volume of 800. The laboratory uses Acetone as part of the H&E stain protocol. 2. Direct inspection of the Acetone reagent (lot #2104111) in use at the time of the survey conducted on October 26, 2023 indicated an expiration date of August 18, 2023. 3. The total number of patients tested using the expired reagent could not be determined at the time of the survey. 4. The facility personnel interviewed on 10/26/23 at 1:50 PM confirmed the expired reagent indicated above was in use at the time of the survey.
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 lack of quality assessment (QA) policies and procedures and interview with the facility personnel, the laboratory failed to establish QA policies and procedures to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. Findings include: 1. No QA documentation was provided for review during the survey conducted on 10/26/23 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the analytic systems specified at 493. 1231 through 493.1236. 2. The facility personnel interviewed on 10/26/23 at 2:05 PM confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified in the analytic systems requirements.
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 review of patient test results maintained in the Electronic Health Record (EHR) and interview with the facility personnel, the laboratory failed to have a system in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (entered manually) to final report destination, in a timely manner. Findings include: 1. Patient-specific data and the final test result information for Mohs testing is manually transcribed by laboratory personnel into the patient's EHR. 2. No documentation was presented for review during the survey conducted on 10/26/23 to indicate the laboratory has a system in place to ensure the accuracy of patient test results that are manually entered into the EMR. 3. The facility personnel interviewed on 10/26/23 at 2:00 PM confirmed that the laboratory failed to have a system in place to verify the accuracy of patient test results that are manually entered into the 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: Based on review of Mohs test reports maintained in the Electronic Health Record (EHR) and interview with the facility personnel, one out of three Mohs test reports reviewed in the EHR failed to include the final test result and the correct number of Mohs stages performed. Findings include: 1. The laboratory reads and interprets slides in conjunction with the Mohs procedure in the sub-specialty of histopathology with an approximate annual test volume of 800. 2. It is the practice of the laboratory to maintain the Mohs test report (Mohs operative report and Mohs map) in an electronic record system. The total number of stages is documented on the test report (operative note) maintained in the EHR and on the Mohs map. 3. One out of three Mohs test reports (case# 226-23) reviewed in the EHR during the survey failed to include the final test result. The Mohs log, Mohs map (noted as "clear" at Stage 2), and slides indicated the case had two stages. The Mohs operative report maintained in the EHR stated, "Number of Stages: 2", however the operative report failed to include information for Stage 2. The test report only listed "STAGE 1:...Frozen section analysis showed: residual tumor seen." 4. The facility personnel interviewed on 10/26 /23 at 1:40 PM confirmed the Mohs operative report for the patient indicated above failed to include the final test result and the correct number of stages performed.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on lack of postanalytic Quality Assessment (QA) policies and procedures, review of patient test reports and interview with the facility personnel, the laboratory failed to establish policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291, including, but not limited to, policies for signing off on pathology test reports in a timely manner. Findings include: 1. The laboratory performs Mohs testing on patient specimens under the subspecialty of histopathology, with an annual test volume of 800. The laboratory utilizes an electronic medical record (EMR) system to maintain patient records, including Mohs operative (test) reports which are electronically signed by the individual who performed the examination and made the diagnosis. 2. No documentation was presented for review during the survey to indicate the laboratory established QA policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291, including but not limited to, signing off on test reports maintained in the electronic record in a timely manner. 3. Review of the Mohs test reports maintained in the EMR indicated the individual who performed the examination and made the diagnosis electronically signed one out of three pathology test report as follows: Case# 220-21 - Date of Service 12/03/21- electronically signed on 12/29/21. 4. The facility personnel interviewed on 10/26/23 at 2:05 PM confirmed the laboratory failed to provide evidence of QA policies and

	procedures for the postanalytic systems, and confirmed the Mohs test report indicated above was not signed in a timely manner by the individual who performed the examination and made the diagnosis.