Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2141563	05/14/2021
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
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 lack of accuracy verification documentation for review and interview with the facility personnel, the laboratory failed to verify the accuracy of testing performed under the sub-specialty of Histopathology at least twice annually during 2020. Findings include: 1. No documentation was presented for review during the survey to indicate the laboratory verified the accuracy of Mohs testing at least twice annually during 2020. 2. The facility personnel confirmed that the laboratory failed to verify the accuracy of Mohs testing at least twice annually during 2020. 3. The laboratory's approximate annual test volume under the sub-specialty of Histopathology is 222.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on lack of written Quality Assessment policies and procedures and interview with the facility personnel, the laboratory failed to establish policies related to accuracy verification for histopathology testing performed by the laboratory. Findings include: 1. The laboratory performs slide interpretation for Mohs testing under the sub-

	specialty of Histopathology, with an approximate annual test volume of 222. 2. No documentation was presented during the survey to indicate the laboratory had an established policy related to the verification of accuracy process for the testing indicated above, including but not limited to, information specific to the frequency of the review, number of cases reviewed, individual or laboratory performing the review and a remedial action plan in the event of a noted discrepancy. 3. The facility personnel confirmed that the laboratory failed to have an established written policy in place at the time of the survey conducted on May 14, 2021 specific to the verification of accuracy process for histopathology testing performed by the laboratory.
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 review of laboratory policies and procedures, review of Mohs test records and interview with the facility personnel, the laboratory failed to establish a written policy with regard to signing off on pathology test reports in a timely manner. Findings include: 1. The laboratory performs the Mohs procedure and issues a diagnosis under the sub-specialty of Histopathology, with an approximate annual test volume of 222. 2. It is the practice of the laboratory to document the Mohs test procedure on the Mohs map and on the Mohs Operative Note contained in the Electronic Medical Record (EMR), in which the individual that performed the procedure and made the diagnosis electronically approves and signs the Mohs Operative Note contained in the EMR. 3. The laboratory failed to establish a policy indicating the acceptable timeframe for the individual making the diagnosis to electronically sign off on the Mohs Operative Note. 4. Four out of four Mohs Operative Notes reviewed during the survey were electronically signed at a later date than the procedure date. Patient #049-19 procedure date was 10/10/19 and electronically signed on 10/16/19; patient #050-20 procedure date was 3/11/20 and electronically signed on 3/19/20; patient #111-20 procedure date was 9/17/20 and electronically signed on 10/04/20 and patient #059-21 procedure date was 3/26/21 and electronically signed on 4/08/21 . 5. The facility personnel confirmed that the laboratory failed to have an established policy related to the process of signing off on Mohs test reports in a timely manner.