Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2020401	08/01/2019
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Skin Institute, Inc	3800 Geer Rd Ste 200, Turlock, CA	

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
D3043	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7) The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen. This STANDARD is not met as evidenced by: Based on random dermatopatholgy record review and interview with the laboratory staff on August 1, 2019, the laboratory failed to retain histopathology pathology specimen blocks for at least 2 years from the date of examination. The findings included: a. On the day of survey a random sampling of the laboratory's dermatopathlogy patient logs (January 3, 2018 to June 13, 2019) were reviewed for a patient sample selection of slides and blocks to assess the laboratory's retention processes. b. For six (6) dermatopatholgy cases selected, the laboratory could not retrieve one (1) block (4-1-19, acc# 19A0730). c. The laboratory staff confirmed by interview on August 1, 2019, at 10:20 am that the laboratory did not retain the block requested. d. The laboratory reports performing approximately 1850 dermatopathology patient tests annually.
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 record review, the laboratory policies and interview of laboratory staff and the laboratory director on August 1, 2019, the laboratory failed to at least twice annually, verify the accuracy of Mohs and dermatopathology slide reviews. The findings included: a The laboratory contracts with a Mohs surgeon who performs Mohs surgeries and slide reviews on site. b. The laboratory had no documentation of twice annual verification of accuracy for the Mohs surgeon's slide review since April of 2017, (where they had performed one set of annual verification of accuracy on the previous Mohs surgeon). The laboratory had no documentation of accuracy for the current Mohs surgeon listed on the CMS-209 as testing personnel. c. The laboratory was cited on September 12, 2017 by the California state agency surveyor (D5217 "the laboratory failed to verify the accuracy of Mohs proceedures performed 2016-2017") for the same deficiency. The laboratory failed to provide documentation of correction for this deficiency on the date of recertification survey August 1, 2019. d. The laboratory has one dermatopathologist performing differential and special stain review for patient testing. The laboratory had no documentation of twice annual verification of accuracy for dermatopathology stain reviews since 2017. e. The laboratory director and laboratory staff confirmed by interview on August 1, 2019, at approximately 1:30 pm, that the laboratory had not performed twice annual verification of accuracy for the Mohs surgeon and did not have documentation of twice annual verification of accuracy for the dermatopathology testing. f. The laboratory reports performing approximately 350 Mohs patient slide reviews and 1500 dermatopathology patient slide reviews annually.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and interview with the laboratory staff on August 1, 2019, the laboratory failed to have a written procedure manual for all tests, assays, and examinations performed by the laboratory available to, and followed by, laboratory personnel. The findings included: a. The laboratory performs histopathology tissue grossing and Mohs surgical testing on site. b. On the day of survey the laboratory had no policy manual for the dermatopathology procedures performed for the tests and examinations performed by the laboratory. c. The laboratory staff confirmed by interview on August 1, 2019 at approximately 10:00 am, that the laboratory did not have a signed policy or procedure manual for the tests and procedures performed. d. The laboratory reports performing approximately 350 Mohs slide reviews, and 1500 Histopathology slide reviews annually.
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 observation of the laboratory reagent storage areas and interview of laboratory staff on August 1, 2019, the laboratory failed to ensure that reagents, solutions, and other supplies were not used when they had exceeded their expiration date, have deteriorated, or are of substandard quality. The findings included: a. The laboratory performs differential and special stains for histopathology slide review. 1. The refrigerator containing the differential and special stains revealed that two of the three reagent components for periodic acid-schiff (PAS) staining were expired: -Stat Lab Light Green Solution: Lot number 44998 expired 03-2019 -Schiff's Reagent: Lot number 067242 expired 06-2019 2. In the main laboratory storage area: -IMEB Inc. HCL/Formic Acid bone decalcifier: Lot number 14122 expired 05-2017 -Transform Spray Lot 11111534 expired 11-2012 b. The Mohs' technician had decanted the Hemotoxylin Eosin stains into unlabeled containers which were left in the laboratory storage cabinet with no expiration dates, or identification of contents. c. The laboratory staff confirmed by interview on August 1, 2019 at approximately 12:35 pm that the laboratory was using expired reagents and failed to relabel those containers which had been used to store diluted staining reagents.
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 records review and interview with the laboratory staff on August 1, 2019, the laboratory failed to 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. The findings included: a. The laboratory had no policies or procedures for documentation and performance of twice annual verification of accuracy for the Mohs surgeon, or the dermatopathologist performing histopathology slide review. See D5217. b. The laboratory had no policy or procedures for the processes performed by the contracted Mohs histotechnician. See D5401 c. The laboratory performs grossing of patient tissue for dermatopathology and histopathology slide review. The laboratory had no policies or procedures for the processes performed by the pathologists performing the patient testing. See D5401 d. The laboratory had no policy or procedure to ensure that slides and blocks sent to a referral laboratory for review were retrieved in a timely manner, and accurately accounted post referral laboratory report. See D3043 e. The laboratory had no policy or procedure to ensure that reagents are not used past their expiration date. See D3043. f. The laboratory director and the laboratory staff confirmed by interview on August 1, 2019 at approximately 1:30 pm that the laboratory did not have available an approved policy or procedure manual for laboratory personnel to follow. See D5401.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for

	monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory staff on August 1,2019, the laboratory director failed to ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. The findings included: a. The laboratory contracts the services of a Mohs surgeon for performing Mohs surgery and reading of the Mohs patient maps for clearing of abnormal skin growths. b. The laboratory had no documentation of training or competency assessments for the Mohs surgeon (testing personnel) since 2017 or the Mohs histotechnician who performs grossing at the facility. c. The laboratory had no documentation of competency (twice annual verification of accuracy) for the histopathology testing personnel.See D5217 d. The laboratory staff confirmed by interview on August 1, 2019, at approximately 1:30 pm, that the laboratory did not have documentation of competency for the testing personnel for histopathology testing. e. The laboratory reports performing approximately 1850 patient specimens annually.