Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1057816	07/13/2022
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Dermasurgery Associates	12222 Coit Road, Suite 101, Dallas, TX	

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
D0000	Laboratory representatives were present at the entrance conference. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas Health and Human Services Commission, Health Facility Compliance Arlington Group. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Southern Operations Branch-Dallas for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on direct observation, review of the manufacturer's instructions, laboratory environmental records, and staff interview, the laboratory failed to monitor the storage temperature for 3 of 3 McKesson Consult Diagnostics hCG Urine Tests Cassettes in 2021 and 2022 (11/2021-07/2022). The findings include: 1. During a tour of the Medical Assistant (MA) station on 07/13/2022 at 11:32 a.m, the surveyor observed an open box of McKesson Consult Diagnostics hCG Urine Tests Cassettes containing 3 test cassettes (lot# 1032002; expiration 02/28/2023). 2. Review of the manufacturer's

	instructions for the McKesson Consult Diagnostics hCG Urine Tests Cassettes revealed a storage temperature requirement of 36-86F/2-30C. 3. Review of laboratory environmental records from November 2021 through July 2022 revealed no documentation of temperature at the MA station. 4. During an interview with the Medical Assistant and Trainer on 07/13/2022 at 11:32 a.m, the surveyor asked if temperature was monitored at the MA station. The Medical Assistant and Trainer confirmed that temperature was not monitored.
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 review of the Center for Medicaid & Medicare Services (CMS)- 116 form, laboratory policy, proficiency testing records, and staff interview, the laboratory failed to have documentation of the laboratory director evaluating results of peer reviews to determine twice annual accuracy assessment accuracy for 5 of 5 events in 2021 and 2 of 2 events in 2022. The findings include: 1. Review of the CMS-116 form submitted at survey by the laboratory revealed the laboratory performed histopathology (Mohs) procedures. 2. Review of the laboratory policy titled "Quality Assurance Program" revealed the following, "-Comparison of Test Results ...Twice annually, slides from randomly chosen Mohs and in-house biopsy specimens will be sent to a dermatopathologist for evaluation of slide adequacy and second opinion of results from the Mohs surgery procedure. A request will be made for consulting slides to be returned ...and accompanying reports will be filed in the Mohs laboratory as part of the quality assurance record." 3. Review of the laboratory's twice annual accuracy assessments for 2021 and 2022 revealed the following: 04/30/2021 Peer review of Testing Person 3 performed by Testing Person 2 Thickness of the sections is appropriate to maximize the ability to interpret the slides. Processing artifact does not obscure the critical findings. Slide accession number: W21-0001, A1.1-1.2: No evidence of skin cancer Slide accession number: W21-0004, A1.1-1.3: No evidence of skin cancer Slide accession number: W21-0007, A1.1-1.2: No evidence of skin cancer The peer review was signed by Testing Person 2. There was no documentation of the results from the peer review being evaluated by the Laboratory Director. 05/17/2021 Peer review of Testing Person 2 performed by Testing Person 1 Thickness of the sections is appropriate to maximize the ability to interpret the slides. Processing artifact does not obscure the critical findings. Slide accession number: KS21-0014, A1. 1-1.2: No evidence of skin cancer Slide accession number: KS21-0060, A1.1-1.2: No evidence of skin cancer The peer review was signed by Testing Person 1. There was no documentation of the results from the peer review being evaluated by the Laboratory Director. 12/14/2021 Peer review of Testing Person 2 performed by Testing Person 1 Thickness of the sections is appropriate to maximize the ability to interpret the slides. Processing artifact does not obscure the critical findings. Slide accession number: KS21-0149, A1.1-1.2: No evidence of skin cancer Slide accession number: KS21-0214, A1.1-1.2: No evidence of skin cancer The peer review was signed by Testing Person 1. There was no documentation of the results from the peer review being evaluated by the Laboratory Director. 04/09/2021 Peer review of Testing Person 1 performed by Testing Person 2 Thickness of the sections is appropriate to maximize the ability to interpret the slides. Processing artifact does not obscure the critical findings. Slide accession number: P21-0026, A1.1-1.2: No evidence of skin

	cancer Slide accession number: P21-0307, A1.1-1.2: No evidence of skin cancer The peer review was signed by Testing Person 2. There was no documentation of the results from the peer review being evaluated by the Laboratory Director. 10/29/2021 Peer review of Testing Person 1 performed by Testing Person 2 Thickness of the sections is appropriate to maximize the ability to interpret the slides. Processing artifact does not obscure the critical findings. Slide accession number: P21-0610, A1. 1-1.2: No evidence of skin cancer Slide accession number: P21-0923, A1.1-1.2: No evidence of skin cancer The peer review was signed by Testing Person 2. There was no documentation of the results from the peer review being evaluated by the Laboratory Director. 07/05/2022 Peer review of Testing Person 2 performed by Testing Person 1 Case number: KS22-0154 Year: 2022 Diagnosis: n-residual tumor Report without error? No error Case number: KS22-0196 Year: 2022 Diagnosis: no residual tumor Report without error? No error The peer review cases above were signed by Testing Person 1. There was no documentation of the results from the peer reviews being evaluated by the Laboratory Director. 07/07/2022 Peer review of Testing Person 1 performed by Testing Person 2 Case number: P22-0461 Year: 2022 Diagnosis: no residual tumor Report without error? No error Case number: P22-0322 Diagnosis: no residual tumor Year: 2022 Report without error? No error The peer review cases above were signed by Testing Person 2. There was no documentation of the results from the peer reviews being evaluated by the Laboratory Director. 4. During an interview on 07/13/2022 at 11:00 a.m, the Office Manager, Trainer, and Histology Technician confirmed the above findings.