Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2172606	(X3) Date Survey Completed 10/06/2023
Name of Provider or Supplier Advanced Skincare	**Street Address, City, State** 3434 Prytania Street #420, New Orleans, LA	

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	An Initial survey was performed at Advanced Skincare (D/B/A New Orleans Aesthetics), CLIA ID 19D2172606, on October 6, 2023. New Orleans Aesthetics was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1219 CONDITION: Histopathology 42 CFR 493.1441 CONDITION: Laboratories performing high complexity testing; Laboratory Director
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory's patient test logs, records, and interview with personnel, the laboratory failed to retain maintenance and temperature logs for at least two (2) years. Findings: 1. Review of the laboratory's Mohs patient test logs revealed patient testing began on December 5, 2022. The laboratory performed testing on December 5, 2022 and December 6, 2022. 2. Review of the laboratory's records revealed the laboratory did not retain the cryostat temperature and daily routine maintenance logs from December 2022. 3. In interview on October 6, 2023 at 2:07 pm, the Medical Assistant confirmed the laboratory did not keep the December 2022 cryostat temperature and daily routine maintenance logs.
D5028	HISTOPATHOLOGY CFR(s): 493.1219 If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1273, and 493.1281 through 493.1299.

	This CONDITION is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to ensure the quality of testing in the specialty of Histopathology. Findings: 1. The laboratory failed to verify the accuracy of Histopathology testing in 2023 at least one (1) out of two (2) times annually as required. Refer to D5217. 2. The laboratory failed to follow their established slide labeling policies. Refer to D5401 I. 3. The laboratory failed to follow their established policies for use of the Mohs log book for eighteen (18) of eighteen (18) patients reviewed. Refer to D5401 II. 4. The laboratory failed to have complete policies and procedures. Refer to D5401 III. 5. The laboratory failed to monitor the room temperature and humidity where the cryostat was located per the manufacturer's requirements. Refer to D5413. 6. The laboratory failed to establish maintenance procedures for the microscope utilized for Histopathology testing. Refer to D5433. 7. The laboratory failed to ensure testing personnel documented the stain quality for Hematoxylin and Eosin (H&E) stains for ten (10) of twelve (12) days. Refer to D5609. 8. The laboratory failed to perform monthly quality assurance per their laboratory policy for six (6) of six (6) months reviewed. Refer to D5791.
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 laboratory's policies, records, patient test log, and interview with personnel, the laboratory failed to verify the accuracy of Histopathology testing in 2023 at least one (1) out of two (2) times annually as required. Findings: 1. Review of the laboratory's patient test log revealed the laboratory began patient testing on December 5, 2022. 2. Review of the laboratory's "Proficiency Testing" policy revealed "Semi-annually, the tech or Risk Manager will send two cases containing the original slides, label it with only the surgical case number, and send it our {sic} for a microscopic examination by a Board Certified Dermatopatholigst." 3. Review of the laboratory's records revealed the laboratory did not have documentation of verification of the accuracy of Histopathology testing for the first half of 2023. 4. In interview on October 6, 2023 at 2:10 pm, the Laboratory Director confirmed the laboratory did not verify the accuracy of Histopathology testing during the first half of 2023.
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: I. Based on observation by surveyor, review of the laboratory's procedures, and

	interview with personnel, the laboratory failed to follow their established slide labeling procedures. Findings: 1. Review of the laboratory's procedures revealed "The tech labels the slides, the slide will be labeled with the patient name, accession #, stage # and quadrant #." 2. Observation by surveyor on October 6, 2023 at 1:53 pm, revealed the laboratory labels the patient slides with accession number, date, stage number, and quadrant number. 3. In interview on October 6, 2023 at 1:53 pm, the Medical Assistant confirmed the laboratory did not label the patient slides per policy. II. Based on observation by surveyor, review of the laboratory's policies, and interview with personnel, the laboratory failed to follow their established policies for use of the Mohs log book for eighteen (18) of eighteen (18) patients reviewed. Findings: 1. Review of the laboratory's policies revealed "The specimen is given an accession number and logged in the Mohs logbook. Patient name, date, site, diagnosis, stage or layer and number of quadrants per specimen layer." 2. Review of the laboratory's "Mohs Log" revealed the laboratory did not document the site, stage, number of quadrants, and/or diagnosis per the laboratory's policy for the following eighteen (18) patients: a) Patient M22-001: site was not documented b) Patient M22-002: site was not documented c) Patient M22-003: site was not documented d) Patient M22-004: site was not documented e) Patient M23-001: site was not documented f) Patient M23-002: site, stage and number of quadrants were not documented g) Patient M23-003: site, stage and number of quadrants were not documented h) Patient M23-004: site, diagnosis, stage and number of quadrants were not documented i) Patient M23-005: site and diagnosis were not documented j) Patient M23-006: site and diagnosis were not documented k) Patient M23-008: site, diagnosis, stage and number of quadrants were not documented l) Patient M23-009: site, diagnosis, stage and number of quadrants were not documented m) Patient M23-010: site, diagnosis, stage and number of quadrants were not documented n) Patient M23-011: site, diagnosis, stage and number of quadrants were not documented o) Patient M23-012: site, diagnosis, stage and number of quadrants were not documented p) Patient M23-013: site, diagnosis, stage and number of quadrants were not documented q) Patient M23-014: site, diagnosis, stage and number of quadrants were not documented r) Patient M23-015: site, diagnosis, stage and number of quadrants were not documented 3. In interview on October 6, 2023 at 2:07 pm, the Medical Assistant confirmed the laboratory did not follow their policy for use of the Mohs log. III. Based on review of the laboratory's policies and interview with personnel, the laboratory failed to have complete policies and procedures. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory failed to include the following: a) Maintenance procedures for laboratory equipment, including logs in use b) Record retention, to include, but not limited to slides, quality control logs, patient test reports, maintenance and temperature logs. c) Complaint 2. In interview on October 6, 2023 at 2:31 pm, the Laboratory Director confirmed the laboratory did not include the identified policies in their procedure manual.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: Based on observation by surveyor, review of manufacturer's requirements, and interview with personnel, the laboratory failed to monitor the room temperature and humidity where the cryostat was located per the manufacturer's requirements. Findings: 1. Observation by surveyor during the laboratory tour on October 6, 2023 at 1:45 pm revealed the laboratory utilizes the Leica CM 1860 cryostat for Histopathology testing. 2. Further observation by surveyor during the laboratory tour on October 6, 2023 at 1:45 pm revealed the laboratory did not monitor the room temperature or humidity where the cryostat was located. 3. Review of the manufacturer's manual under "Installing the Instrument" section revealed the following requirements: a) "Room temperature consistently 18 degrees C-35 degrees C" b) "Relative humidity, maximum 60% (non-condensing)" 4. In interview on October 6, 2023 at 1:55 pm, the Medical Assistant confirmed the laboratory did not monitor the room temperature or humidity of the room the cryostat was located in.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, records, and interview with personnel, the laboratory failed to establish maintenance procedures for the microscope utilized for Histopathology testing. Findings: 1. Review of the laboratory's policies revealed the laboratory did not have a written policy related to maintenance of equipment. 2. Further review of the laboratory's policies revealed the laboratory had a "2023 Microscope (see procedure manual)" log that included the following tasks: a) "The microscope should be covered at the close of every day" b) "Take extra care to keep stage of the microscope clean" c) "Wipe eye pieces and lenses with lens cloth" d) "Change bulbs as needed and have regular service contracts performed" e) "Document daily, monthly care" 3. Further review of the laboratory's "2023 Microscope" log revealed the laboratory did not complete/document performance. 4. In interview on October 6, 2023 at 2:10 pm the Laboratory Director stated the laboratory does not use the microscope maintenance log identified.
D5609	HISTOPATHOLOGY CFR(s): 493.1273(e)(f) (e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS 209 form (Laboratory Personnel Report),

	policies, quality control logs, patient test logs, and interview with personnel, the laboratory failed to ensure testing personnel documented the stain quality for Hematoxylin and Eosin (H&E) stains for ten (10) of twelve (12) days. Findings: 1. Review of the laboratory's CMS 209 form (Laboratory Personnel Report) revealed the Laboratory Director serves as the testing personnel. 2. Review of the laboratory's "Quality Assurance for Routine Stains" policy revealed "The lab director will determine whether the stain is acceptable for the day. Each QC will be logged on the stain QC chart." 3. Review of the laboratory's "Mohs Log" and "Mohs Quality Control sheet" revealed the laboratory did not document the quality control for the following ten (10) days of patient testing: a) April 19, 2023 b) April 25, 2023 c) April 26, 2023 d) June 13, 2023 e) June 14, 2023 f) June 28, 2023 g) July 5, 2023 h) August 2, 2023 i) August 9, 2023 j) September 20, 2023 4. Further review of the "Mohs Log" revealed the following fourteen (14) patients were tested on the identified dates: a) April 19, 2023: Patient M23-001 b) April 25, 2023: Patient M23-002; Patient M23-003 c) April 26, 2023: Patient M23-004 d) June 13, 2023: Patient M23-005 e) June 14, 2023: Patient M23-006 f) June 28, 2023: Patient M23-008 g) July 5, 2023: Patient M23-009; Patient M23-010; Patient M23-011 h) August 2, 2023: Patient M23-012 i) August 9, 2023: Patient M23-013 j) September 20, 2023: Patient M23-014; Patient M23-015 5. In interview on October 6, 2023 at 2:05 pm, the Laboratory Director confirmed the H&E stain quality was not documented for the identified dates of patient testing.
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 observation by surveyor, review of the laboratory's policies, records, and interview with personnel, the laboratory failed to perform monthly quality assurance per their laboratory policy for six (6) of six (6) months reviewed. Findings: 1. Review of the laboratory's "Quality Assurance for Routine Stains" policy revealed "Monthly the nurse or tech will check off the Monthly Quality Assurance Checklist. This will cover the quality assessment program for procedures used in this office. This checklist is used to evaluate General Laboratory Systems, Pre-analytic Systems, Analytic Systems, and Post-analytic Systems. The lab director will also review and sign off the checklist monthly." 2. Review of the laboratory's records revealed the laboratory did not perform monthly quality assurance for six (6) months of patient testing reviewed. 3. Observation by surveyor, review of the laboratory's policies, and records revealed the laboratory did not identify the following issues within the analytic system: a) The laboratory failed to follow their established slide labeling policies. Refer to D5401 I. b) The laboratory failed to follow their established policies for use of the Mohs log book for eighteen (18) of eighteen (18) patients reviewed. Refer to D5401 II. c) The laboratory failed to have complete policies and procedures. Refer to D5401 III. d) The laboratory failed to monitor the room temperature and humidity where the cryostat was located per the manufacturer's requirements. Refer to D5413. e) The laboratory failed to establish maintenance procedures for the microscope utilized for Histopathology testing. Refer to D5433. f) The laboratory failed to ensure testing personnel documented the stain quality for Hematoxylin and Eosin (H&E) stains for

	ten (10) of twelve (12) days. Refer to D5609. 4. In interview on October 6, 2023 at 2: 07 pm, the Medical Assistant and Laboratory Director confirmed the laboratory did not perform monthly quality assessment for the six (6) months of patient testing.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D6087. 2. The Laboratory Director failed to ensure that a quality control program was maintained to assure the quality of laboratory testing. Refer to D6093. 3. The Laboratory Director failed to ensure that a quality assessment (QA) program was followed to assure the quality of laboratory services provided. Refer to D6094. 4. The Laboratory Director failed to ensure maintenance procedures were established to ensure acceptable levels of test performance. Refer to D6095. 5. The Laboratory Director failed to ensure that an approved procedure manual was available. Refer to D6106. 6. The Laboratory Director failed to include written description of duties and responsibilities of personnel involved in all phases of testing. Refer to D6107.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to verify the accuracy of Histopathology testing in 2023 at least one (1) out of two (2) times annually as required. Refer to D5217. 2. The laboratory failed to monitor the room temperature and humidity where the cryostat was located per the manufacturer's requirements. Refer to D5413.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by:

	Based on record review and interview with personnel, the Laboratory Director failed to ensure that a quality control program was maintained to assure the quality of laboratory testing. Refer to D5609.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was followed to assure the quality of laboratory services provided. Refer to D5791.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on review of records and interview with personnel, the Laboratory Director failed to ensure maintenance procedures were established to ensure acceptable levels of test performance. Refer to D5433.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available. Findings: 1. The laboratory failed to follow their established slide labeling policies. Refer to D5401 I. 2. The laboratory failed to follow their established policies for use of the Mohs log book for eighteen (18) of eighteen (18) patients reviewed. Refer to D5401 II. 3. The laboratory failed to have complete policies and procedures. Refer to D5401 III.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting

	and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, personnel records, and interview with personnel, the Laboratory Director failed to include written description of duties and responsibilities of personnel involved in all phases of testing. Findings: 1. Review of the laboratory's policies and personnel records revealed the laboratory did not have written job responsibilities for the following: Laboratory Director Clinical Consultant Technical Supervisor General Supervisor Testing Personnel 2. In interview on October 6, 2023 at 2:31 pm, the Laboratory Director confirmed the laboratory did not have written job descriptions and responsibilities for the identified personnel roles.