

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2172606	(X3) Date Survey Completed 08/19/2025
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	A Recertification survey was performed at Advanced Skincare (D/B/A New Orleans Aesthetics), CLIA ID 19D2172606, on August 19, 2025. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor and interview with personnel, the laboratory failed to ensure laboratory supplies had not exceeded their expiration dates. Findings: 1. Observation by surveyor during the laboratory tour on August 19, 2025 at 9:55 am revealed the following expired items: a) Avantik Tissue Marking Dye Yellow, lot 157388, Expiration Date: 2024-09-30, Quantity: one (1) bottle b) Avantik Tissue Marking Dye Red, lot 157387, Expiration Date: 2024-09-30, Quantity: one (1) bottle c) Avantik Tissue Marking Dye Blue, lot 157389, Expiration Date: 2024-09-30, Quantity: one (1) bottle d) Avantik Cover Mount 2, lot 158379, Expiration Date: 2024-08-31, Quantity: one (1) bottle e) Avantik Cover Mount, lot 156180, Expiration Date: 2024-08-31, Quantity: one (1) bottle f) EpreDia Neg-50 Yellow, lot 122673N, Expiration Date: 2025-02-27, Quantity: one (1) bottle 2. In interview on August 19, 2025 at 10:02 am, the Medical Assistant confirmed the identified items were expired.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>(a)(1) Maintenance as defined by the manufacturer and with at least the frequency</p>

specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on observation by surveyor, review of manufacturer's instrument manual, the laboratory's maintenance records, and interview with personnel, the laboratory failed to perform the preventative maintenance (PM) annually for the Leica cryostat for one (1) of two years reviewed. Findings: 1. Observation by surveyor during the laboratory tour on August 19, 2025 at 9:55 am revealed the laboratory utilizes the Leica CM 1860 cryostat. 2. Review of the Leica instrument manual under the "Cleaning and maintenance" section revealed "at least once a year have the instrument inspected by a qualified service engineer authorized by Leica." 3. Review of the laboratory's cryostat maintenance records revealed the 2024 annual preventative maintenance (PM) was not performed. 4. In interview on August 19, 2025 at 10:46 am, the Medical Assistant stated she was not able to locate the 2024 PM service records for the cryostat.

D5793

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (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 quality assessment forms, records, and interview with personnel, the laboratory failed to ensure their monitors identified issues within the analytic system. Findings: 1. Review of the laboratory's "Monthly Quality Assurance Checklist" revealed the laboratory monitors the following: a) "Patient Test Management" which includes, but not limited to, "Lab reports contain correct information" b) "Quality Control Policies" which includes, but not limited to, "All reagents, controls, kits, etc. that exceeded their expiration date were discarded" and "all instrument maintenance was performed and documented." c) "Laboratory Safety Policies" d) "Proficiency Testing Policies" e) "Quality Assurance Program" f) "Monthly Quality Control Slide Checklist" 2. Observation by surveyor, review of laboratory records, and interview with personnel revealed the laboratory's monitors did not identify the following issues within the analytic system: a) The laboratory failed to ensure laboratory supplies had not exceeded their expiration dates. Refer to D5417. b) The laboratory failed to perform the preventative maintenance (PM) annually for the Leica cryostat for one (1) of two years reviewed. Refer to D5429.

D5805

TEST REPORT

CFR(s): 493.1291(c)

(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 the laboratory's policies, patient test logs, patient slides, patient final reports, and interview with personnel, the laboratory failed to ensure the patient identifier used for the patient slide was included in the patient final report to ensure positive patient identification for four (4) of nine (9) randomly selected patients reviewed. Findings: 1. Review of the laboratory's policies revealed the laboratory labels the slides with the Mohs lab number, date of service, stage number, and quadrant. 2. Review of the laboratory's patient test logs, patient slides and patient final report (office notes) revealed the laboratory documented the Mohs lab number in the log book and on the patient slide; however, the patient final report did not include the Mohs lab number for the following four (4) patients: a) Patient M24.002 b) Patient M24.011 c) Patient M24.022 d) Patient M24.029 3. In interview on August 19, 2025 at 10:53 am, the Medical Assistant stated for cases in 2024 the Mohs lab number was not included on the patient reports, as she was unaware it was needed. The Medical Assistant further stated she was later informed to include the Mohs lab numbers on reports which were included for cases performed in 2025.

D5893

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(b)(c)

(b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's quality assessment forms, records, and interview with personnel, the laboratory failed to ensure their monitors identified issues within the postanalytic system. Findings: 1. Review of the laboratory's "Monthly Quality Assurance Checklist" revealed the laboratory monitors the following: a) "Patient Test Management" which includes, but not limited to, "Lab reports contain correct information" b) "Quality Control Policies" which includes, but not limited to, "All reagents, controls, kits, etc. that exceeded their expiration date were discarded" and "all instrument maintenance was performed and documented." c) "Laboratory Safety Policies" d) "Proficiency Testing Policies" e) "Quality Assurance Program" f) "Monthly Quality Control Slide Checklist" 2. Review of laboratory records and interview with personnel revealed the laboratory's monitors did not identify the following issues within the postanalytic system. Refer to D5805.