

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2090898	(X3) Date Survey Completed 08/11/2026
Name of Provider or Supplier Ochsner Northshore Dermatology Mohs Surgery	Street Address, City, State 900 Ochsner Blvd, Covington, 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 Validation survey was performed at Ochsner Northshore Dermatology Mohs Surgery, CLIA ID 19D2090898, on August 11, 2026. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the CMS 209 form, laboratory's policies, and interview with personnel, the laboratory failed to establish a complete written competency assessment policy for Testing Personnel. Findings: 1. Review of the laboratory's CMS 209 (Laboratory Personnel Report) form revealed the Laboratory Director serves as the Testing Personnel. 2. Review of the laboratory's policies revealed the laboratory did not include a competency assessment policy for personnel serving as Testing Personnel. 3. In interview on August 11, 2026 at the Histotechnician confirmed the laboratory did not include written competency assessment policies for Testing Personnel.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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 personnel, the laboratory failed to establish a complete policy and procedures manual. Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory did not include the following: Complete twice a year verification procedure: to include frequency of performance of audits with another dermatopathologist to verify the accuracy of the Mohs test performance. 2. In interview on August 11, 2026 at 11:19 am, the Histotechnician confirmed the laboratory did not include the frequency of test performance of audits to verify the accuracy of Mohs testing.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and interview with personnel, the laboratory failed to have complete test performance procedures for Mohs. Findings: 1. Review of the laboratory's Mohs policies revealed the laboratory did not include slide labeling procedures. 2. In interview on August 11, 2026 at 11:19 am, the Histotechnician confirmed the laboratory's Mohs test procedure did not include slide labeling.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) (b)(1)(i) 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. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section. This STANDARD is not met as evidenced by:

	I. Based on review of the laboratory's policies, maintenance records, and interview with personnel, the laboratory failed to perform stainer maintenance annually per laboratory policy for one (1) or three (3) years reviewed. Findings: 1. Review of the laboratory's "Stainer-Equipment Quality Control" policy revealed "The Stain Line is checked annually. The grounding check is monitored annually." 2. Review of the laboratory's maintenance logs revealed no documentation of performance of the identified annual maintenance tasks in 2025. 3. Review of an email provided by the laboratory's manager from the GE service representative stated the laboratory is on a 24-month preventative maintenance (PM) schedule. 4. In interview on August 11, 2026 at 1:00 pm, the Histotechnician stated the identified stainer maintenance should be performed annually. The Histotechnician confirmed the laboratory did not have the documentation of the annual stainer maintenance for 2025. II. Based on review of the laboratory's policies, maintenance records, and interview with personnel, the laboratory failed to perform microscope maintenance every six (6) months per laboratory policy in 2025. Findings: 1. Review of the laboratory's "Microscope-Equipment Quality Control" policy revealed "Microscope is serviced every 6 months." 2. Review of the laboratory's maintenance records revealed no documentation of the six (6) month microscope service due March 2025. 3. In interview on August 11, 2026 at 1:00 pm, the Manager and Histotechnician stated they needed to reach out to the service representative for documentation of the service. The laboratory was unable to provide documentation of the six (6) month service report for March 2025 at the time of the survey.
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 patient final reports and interview with personnel, the laboratory failed to include the address of the testing facility's location on the patient final reports for six (6) of six (6) randomly selected patients. Findings: 1. Review of the following six (6) randomly selected patient's revealed the laboratory did not include the address of the testing facility that performed the Mohs testing: January 27, 2025: Patient: 2836876 May 17, 2025: Patient 1169547 December 18, 2025: Patient 1710494 February 26, 2026: Patient 1963856 April 8, 2026: Patient 519735 June 4, 2026: Patient 768093 2. In interview on August 11, 2026 at 10:52 am, the Histotechnician stated the address is not included on the reports visible to them, only the facility's name. The Histotechnician stated patients would have to request their reports from Medical Records, not from their facility directly.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) (e)(6) 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 record review and interview with personnel, the Laboratory Director failed to ensure maintenance procedures were followed to ensure acceptable levels of test performance. Refer to D5433 I and II.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) (e)(8) Ensure that reports of test results include pertinent information required for interpretation; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D5805.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) (e)(13) 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 personnel, the Laboratory Director failed to ensure complete policies and procedures for assessing personnel competency were established. Refer to D5209.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) (e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Findings: 1. The laboratory failed to establish a complete policy and procedures manual. Refer to D5401. 2. The laboratory failed to have complete test performance procedures for Mohs. Refer to D5403.