Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2197164	(X3) Date Survey Completed 06/15/2023
Name of Provider or Supplier Mcdaniel Dermatology And Skin Surgery Institute	**Street Address, City, State** 222 Hwy 21, Madisonville, 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 Certification survey was performed on June 15, 2023 at McDaniel Dermatology and Skin Surgery Institute, CLIA ID # 19D2197164. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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 policies, records, and interview with personnel, the laboratory failed to retain quality assurance and twice a year verification records for at least two (2) years as required. Findings: 1. Review of the laboratory's "Proficiency Testing" policy stated "Results of each Proficiency Test will be entered in a log and kept in the laboratory management manual, as part of its permanent records." 2. Review of the laboratory's records revealed the laboratory did not retain the following: a) "Monthly Patient Quality Assurance Checklist" for January 2022 b) Twice year verification records (laboratory refers to as proficiency testing) for the first half of 2022 3. In interview on June 15, 2023 at 11:32 am, the Office Manager confirmed the laboratory did not retain the identified documents for at least two (2) years.
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 laboratory's policies, personnel records, and interview with personnel, the laboratory failed to follow established competency assessment policies for one (1) physician performing potassium hydroxide (KOH) prep testing. Findings: 1. In interview on June 15, 2023 at 10:02 am the Office Manager and Laboratory Director stated Testing Personnel 1 performed KOH prep testing. 2. Review of the laboratory's "Competency and CLIA competency assessment" policy revealed "Evaluation and documenting competency of personnel responsible for testing is required at least semi-annually during the first year the individual sees patient specimens. After the first year, competency must be performed at least annually. The following procedures are requirements for assessment of competency for all personnel performing laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting or test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills." " Competency assessment, which includes the procedures, must be performed for testing personnel for each test that the individual is approved by the laboratory director to perform. Results of each Competency Test will be entered in a log and kept in the laboratory management manual, as part of its permanent records." 3. Review of personnel records for Testing Personnel 1 revealed the laboratory did not have documentation of a competency assessment performed for KOH testing for 2022. 4. In interview on June 15, 2023 at , the Laboratory Director confirmed a 2022 competency assessment was not performed on Testing Personnel 1 for KOH testing .
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, test menu, records, and interview with personnel, the laboratory failed to verify the accuracy of potassium hydroxide (KOH) prep testing at least twice annually in 2022. Findings: 1. Review of the laboratory's test menu revealed the laboratory performs KOH prep testing. 2. Review of the laboratory's policies and records revealed the laboratory did not have a policy and documentation of verification of the accuracy of KOH testing at least twice annually for 2022. 3. In interview on June 15, 2023 at 11:38 am, the Laboratory Director confirmed the laboratory did not verify the accuracy of KOH prep testing at least semi annually in 2022.
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 review of the laboratory's policies and interview with personnel, the laboratory failed to follow their established policy related to the review of the policy manual. Findings: 1. Review of the laboratory's "Formal Policy Statement" revealed "This procedure manual is reviewed by the Laboratory Director annually and at other times as required by major changes in procedure or other circumstances affecting laboratory performance of the test." 2. Review of the laboratory's policy manual revealed the Laboratory Director did not review the policies in 2022. 3. In interview on June 15, 2023 at 10:30 am, the office manager confirmed the Laboratory Director did not review/sign the policies annually per laboratory policy for 2022. II. Based on review of the laboratory's policies, manufacturer's instructions, 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) Twice year verification (referred to as proficiency testing by the laboratory): specific number of cases to send semi-annually to a Board Certified dermatopathologist b) Maintenance for cryostat: updated frequency of performance of maintenance tasks per manufacturer's requirements for current cryostat in use 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 Dermatopathologist." 3. Review of the laboratory's "Quality Assurance Program" policy, which differed from the "Proficiency Testing" policy, revealed "Proficiency testing is required for this service provided by our physician. It is suggested to submit 3 cases every 6 months to an outside Pathologist." 4. Review of the laboratory's cryostat log and policy revealed " The machines are wiped out daily with dry gauze, to collect waste material. Then wiped with gauze containing 100% isopropyl alcohol, to disinfect. Wiped again with a dry gauze and ready for the next day. According to manufacturer's instructions, lab personnel should oil weekly, grease monthly, and/or perform necessary maintenance. There is a service contract" 5. Review of the Leica 1950 cryostat manual revealed "The microtome is virtually maintenance-free. To ensure a smooth operation of the instrument over several years we recommend the following: at least once a year have the instrument inspected by a qualified service engineer authorized by Leica, enter into a service contract at the end of the warranty period, and clean the instrument daily." 6. In interview on June 15, 2023 at 10:47 am, the Office Manager stated the Leica 1950 cryostat is a loaner. The Office Manager confirmed the laboratory's cryostat maintenance policy and log were not updated to the manufacturer's requirements. 7. In further interview on June 15, 2023 at 11:38 am, the Office Manager stated the laboratory sends six to eight cases to another dermatopathologist for proficiency testing. The Office Manager confirmed the laboratory's policies for proficiency testing did not correspond with what was in practice.
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 by surveyor and interview with personnel, the laboratory failed to ensure supplies and reagents did not exceed expiration dates. Findings: 1. Observation by surveyor during the laboratory tour on June 15, 2023 at 9:54 am revealed the following expired items: a) KOH 10% 50 mL solution, Lot 21286302, Expiration date: 2022-10-12, Quantity: one (1) bottle b) Tissue Marking Dye Red, Lot 110104, Expiration date: 2022-09-30, Quantity: one (1) bottle c) Tissue Marking Dye Yellow, Lot 125197, Expiration date: 2023-04-30, Quantity: one (1) bottle d) Tissue Marking Dye Black, Lot number was illegible, Expiration date: 2022-10-31, Quantity: one (1) bottle e) DermPath Diagnostics Buffered 10% Formalin, Lot 25118, Expiration date: 2023-06-01, Quantity: ten (10) bottles f) Michel's Solution, Lot 133061, Expiration date: 2023-01-31, Quantity: seven (7) bottles 2. In interview on June 15, 2023 at 10:02 am, the office manager confirmed the identified items were expired.
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, quality control records, and interview with personnel, the laboratory failed to ensure Testing Personnel documented the stain quality for Hematoxylin and Eosin (H&E) stains for 2022 eighteen (18) months reviewed. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed the Laboratory Director serves as the Testing Personnel for Mohs (Histopathology). 2. Review of the laboratory's quality control logs for 2022 and January 2023 through June 14, 2023 revealed the Testing Personnel (who also serves as the Laboratory Director) did not document her review of the slide stain quality. 3. In interview on June 15, 2023 at 10:47 am, the Office Manager confirmed the Laboratory Director did not document her review of the stain quality of slides for the identified months.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policies, temperature logs, and interview with personnel, the laboratory failed to document corrective actions performed when the cryostat temperature was not maintained within acceptable limits per laboratory policy for one (1) of eighty one (81) days reviewed in 2023. Findings: 1. Review of the laboratory's cryostat temperature logs revealed the acceptable temperature range as -20 to -30 degrees Celsius. 2. Review of the laboratory's "Cryostat Maintenance" policy revealed "The cryostat should be maintained at -21 C to no colder than -30 C

for best Mohs sectioning. Any variance out range will be recorded and reported to the supervisor immediately If the range variance cannot be repaired, the console will not be used until serviced." 3. Review of the laboratory's cryostat temperature log for 2023 revealed the cryostat temperature was documented as outside of acceptable limits without corrective actions for the following day: June 14, 2023 documented temperature at -20 Celsius 4. In interview on June 15, 2023 at 10:47 am, the Office Manager confirmed the laboratory did not have documentation of corrective action for the identified cryostat temperature that was outside of acceptable limits. II. Based on review of the laboratory's room temperature log and interview with personnel, the laboratory failed to document corrective actions performed when the room temperature was not maintained within acceptable limits per laboratory policy for 132 of 164 days reviewed. Findings: 1. Review of the laboratory's room temperature logs revealed the acceptable room temperature range as 68 to 76 degrees Fahrenheit. 2. Review of the laboratory's room temperature logs for 2022 and 2023 revealed the room temperature was documented as outside of acceptable limits without corrective actions for the following 132 days: April 24, 2022 documented temperature of 51 degrees May 25, 2022 documented temperature of 47 degrees May 31, 2022 documented temperature of 53 degrees June 7, 2022 documented temperature of 44 degrees June 8, 2022 documented temperature of 45 degrees June 14, 2022 documented temperature of 48 degrees June 15, 2022 documented temperature of 55 degrees June 21, 2022 documented temperature of 58 degrees June 22, 2022 documented temperature of 59 degrees June 28, 2022 documented temperature of 58 degrees June 29, 2022 documented temperature of 57 degrees July 6, 2022 documented temperature of 54 degrees July 7, 2022 documented temperature of 53 degrees July 12, 2022 documented temperature of 56 degrees July 18, 2022 documented temperature of 60 degrees July 26, 2022 documented temperature of 60 degrees July 27, 2022 documented temperature of 57 degrees August 2, 2022 documented temperature of 51 degrees August 3, 2022 documented temperature of 55 degrees August 9, 2022 documented temperature of 60 degrees August 10, 2022 documented temperature of 57 degrees (illegible) August 16, 2022 documented temperature of 58 degrees August 17, 2022 documented temperature of 57 degrees August 23, 2022 documented temperature of 59 degrees August 30, 2022 documented temperature of 59 degrees August 31, 2022 documented temperature of 58 degrees September 6, 2022 documented temperature of 56 degrees September 13, 2022 documented temperature of 60 degrees September 14, 2022 documented temperature of 52 degrees September 20, 2022 documented temperature of 54 degrees September 27, 2022 documented temperature of 54 degrees September 28, 2022 documented temperature of 42 degrees October 4, 2022 documented temperature of 52 degrees October 11, 2022 documented temperature of 48 degrees October 12, 2022 documented temperature of 57 degrees October 18, 2022 documented temperature of 62 degrees October 25, 2022 documented temperature of 64 degrees October 26, 2022 documented temperature of 59 degrees November 1, 2022 documented temperature of 59 degrees November 2, 2022 documented temperature of 55 degrees November 15, 2022 documented temperature of 46 degrees November 16, 2022 documented temperature of 50 degrees November 22, 2022 documented temperature of 52 degrees (illegible) November 28, 2022 documented temperature of 60 degrees December 6, 2022 documented temperature of 66 degrees December 13, 2022 documented temperature of 59 degrees December 14, 2022 documented temperature of 59 degrees December 20, 2022 documented temperature of 35 degrees December 21, 2022 documented temperature of 42 degrees December 27, 2022 documented temperature of 44 degrees January 2, 2023 documented temperature of 63 degrees January 4, 2023 documented temperature of 64 degrees January 10, 2023 documented temperature of 50 degrees January 17, 2023 documented temperature of 58 degrees January 24, 2023

documented temperature of 66 degrees January 31, 2023 documented temperature of 54 degrees February 1, 2023 documented temperature of 61 degrees February 7, 2023 documented temperature of 42 degrees February 8, 2023 documented temperature of 61 degrees February 14, 2023 documented temperature of 49 degrees February 15, 2023 documented temperature of 48 degrees February 22, 2023 documented temperature of 51 degrees February 28, 2023 documented temperature of 61 degrees February 29, 2023 documented temperature of 60 degrees March 3, 2023 documented temperature of 61 degrees March 7, 2023 documented temperature of 60 degrees March 8, 2023 documented temperature of 61 degrees March 14, 2023 documented temperature of 60 degrees March 15, 2023 documented temperature of 62 degrees March 21, 2023 documented temperature of 52 degrees March 22, 2023 documented temperature of 40 degrees March 28, 2023 documented temperature of 61 degrees March 29, 2023 documented temperature of 62 degrees March 29, 2023 documented temperature of 60 degrees March 30, 2023 documented temperature of 61 degrees March 31, 2023 documented temperature of 61 degrees April 1, 2023 documented temperature of 60 degrees April 2, 2023 documented temperature of 61 degrees April 3, 2023 documented temperature of 61 degrees April 4, 2023 documented temperature of 60 degrees April 5, 2023 documented temperature of 60 degrees April 6, 2023 documented temperature of 61 degrees April 7, 2023 documented temperature of 62 degrees April 10, 2023 documented temperature of 61 degrees April 11, 2023 documented temperature of 54 degrees April 12, 2023 documented temperature of 55 degrees April 13, 2023 documented temperature of 52 degrees April 14, 2023 documented temperature of 61 degrees April 17, 2023 documented temperature of 50 degrees April 18, 2023 documented temperature of 51 degrees April 19, 2023 documented temperature of 51 degrees April 20, 2023 documented temperature of 52 degrees April 21, 2023 documented temperature of 52 degrees April 24, 2023 documented temperature of 51 degrees April 25, 2023 documented temperature of 51 degrees April 26, 2023 documented temperature of 50 degrees April 27, 2023 documented temperature of 50 degrees April 28, 2023 documented temperature of 51 degrees May 1, 2023 documented temperature of 51 degrees May 2, 2023 documented temperature of 52 degrees May 3, 2023 documented temperature of 52 degrees May 4, 2023 documented temperature of 54 degrees May 5, 2023 documented temperature of 55 degrees May 8, 2023 documented temperature of 53 degrees May 9, 2023 documented temperature of 54 degrees May 10, 2023 documented temperature of 56 degrees May 11, 2023 documented temperature of 55 degrees May 12, 2023 documented temperature of 56 degrees May 15, 2023 documented temperature of 52 degrees May 16, 2023 documented temperature of 51 degrees May 17, 2023 documented temperature of 50 degrees May 18, 2023 documented temperature of 51 degrees May 19, 2023 documented temperature of 52 degrees May 22, 2023 documented temperature of 53 degrees May 23, 2023 documented temperature of 53 degrees May 24, 2023 documented temperature of 52 degrees May 25, 2023 documented temperature of 53 degrees May 26, 2023 documented temperature of 51 degrees May 29, 2023 documented temperature of 57 degrees May 30, 2023 documented temperature of 59 degrees May 31, 2023 documented temperature of 50 degrees June 1, 2023 documented temperature of 52 degrees June 2, 2023 documented temperature of 52 degrees June 5, 2023 documented temperature of 51 degrees June 6, 2023 documented temperature of 53 degrees June 7, 2023 documented temperature of 52 degrees June 8, 2023 documented temperature of 51 degrees June 9, 2023 documented temperature of 51 degrees June 12, 2023 documented temperature of 55 degrees June 13, 2023 documented temperature of 51 degrees June 14, 2023 documented temperature of 50 degrees June 15, 2023 documented temperature of 51 degrees 3. In interview on June 15, 2023 at 10:47 am, the Office Manager confirmed the laboratory did not have documentation of corrective action for the identified room

	temperatures that were outside of acceptable limits. III. Based on review of the laboratory's room temperature/humidity log and interview with personnel, the laboratory failed to document corrective actions performed when the room's humidity was not maintained within acceptable limits per laboratory policy for twenty six (26) of 164 days reviewed. Findings: 1. Review of the laboratory's temperature logs revealed the acceptable humidity range as greater than 60 % ("60 % >"). 2. Review of the laboratory's room temperature/humidity logs for 2022 and 2023 revealed the humidity was documented as outside of acceptable limits without corrective actions for the following twenty six (26) dates: January 4, 2022 documented humidity of 35 % January 5, 2022 documented humidity of 40 % January 11, 2022 documented humidity of 36 % January 12, 2022 documented humidity of 36 % January 13, 2022 documented humidity of 37 % January 18, 2022 documented humidity of 37 % January 19, 2022 documented humidity of 38 % January 25, 2022 documented humidity of 38 % February 22, 2022 documented humidity of 50% February 24, 2022 documented humidity of 48 % March 8, 2022 documented humidity of 46 % March 9, 2022 documented humidity of 42 % March 15, 2022 documented humidity of 44 % March 16, 2022 documented humidity of 45 % March 22, 2022 documented humidity of 45 % March 23, 2022 documented humidity of 45 % March 28, 2022 documented humidity of 45 % March 29, 2022 documented humidity of 45 % April 5, 2022 documented humidity of 46 % April 11, 2022 documented humidity of 47 % April 12, 2022 documented humidity of 44 % April 19, 2022 documented humidity of 45 % May 3, 2022 documented humidity of 48 % May 4, 2022 documented humidity of 46 % June 1, 2022 documented humidity of 59 % July 13, 2022 documented humidity of 58 % 3. In interview on June 15, 2023 at 10:47 am, the Office Manager confirmed the laboratory did not have documentation of corrective action for the identified room humidity readings that were outside of acceptable limits.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation by surveyor 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 potassium hydroxide (KOH) prep testing at least twice annually in 2022. Refer to D5217. 2. The laboratory failed to ensure supplies and reagents did not exceed expiration dates. Refer to D5417.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) 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.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) 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 record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5401 I.
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 observation by surveyor and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to retain quality assurance and twice a year verification records for at least two (2) years as required. Refer to D3031. 2. The laboratory failed to ensure supplies and reagents did not exceed expiration dates. Refer to D5417.
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.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Findings: 1. The laboratory failed to document corrective actions performed when the cryostat temperature was not maintained within acceptable limits per laboratory policy for one (1) of eighty one (81) days reviewed in 2023. Refer to D5785 I. 2. The laboratory failed to document corrective actions performed when the room temperature was not maintained within acceptable limits per laboratory policy for 132 of 164 days reviewed. Refer to D5785 II. 3. The laboratory failed to document corrective actions performed when the room's humidity was not maintained within acceptable limits per laboratory policy for twenty six (26) of 164 days reviewed. Refer to D5785 III.
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 record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Findings: 1. The laboratory failed to follow their established policy related to the review of the policy manual. Refer to D5401 I. 2. The laboratory failed to have complete policies and procedures. Refer to D5401 II.