Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0689175	11/08/2021
Name of Provider or Supplier	**Street Address, City, State**	
Duke Neal Medical, Llc	12 Professional Dr, Houma, 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 Duke Neal Medical, LLC-CLIA ID 19D0689175 on November 8, 2021. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on review of the laboratory's test menu and interview with personnel, the laboratory failed to report one hundred eight (108) SARS COV-2 results to the state as required. Findings: 1. Review of the laboratory's test menu revealed the laboratory utilized the BD Veritor System for SARS COV-2 testing with an annual volume of 108. 2. In interview on November 8, 2021 at 10:05 am, laboratory personnel 1 stated the laboratory began utilizing the BD Veritor System for SARS COV-2 testing on October 1, 2020. 3. In further interview on November 8, 2021 at 10:13 am, laboratory personnel 2 stated no results (positive or negative) have been reported to the state.
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 random selection of patient test records, patient microscope slides, and interview with personnel, the laboratory failed to retain technical reports for at least two (2) years as required for four (4) of nine (9) patients reviewed. Findings: 1. Review of random selection of patient test records and microscope slides from 2019, 2020, and 2021 revealed in 2020 slides are labeled with the patient's name and accession number from a technical report that is generated from the laboratory that performs the technical (processing) of patient samples. 2. Further review of random selection of patient test records revealed the laboratory did not retain copies of the technical reports for the following four (4) patients: Patient ID: IRJO0000 Patient ID: WARO0003 Patient ID: MUAU0000 Patient ID: JOMC0030 3. In interview on November 8, 2021 at 11:52 am, laboratory personnel 1 stated the technical reports for patient samples prior to March 2021 were destroyed by the hurricane in August 2021. Laboratory personnel 1 stated the laboratory kept paper copies of the technical reports.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of the laboratory's polices, proficiency testing records, and interview with personnel, the laboratory failed to perform an assessment for one (1) of eight (8) proficiency testing (PT) events per laboratory policy. Findings: 1. Review of the laboratory's "Quality Assurance for Testing Personnel Histopathology and KOH" policy under the "KOH" section revealed "Three times a year a CLIA approved lab sends the testing personnel a KOH skin prep to read. If the findings are ever inconsistent with the testing personnel's findings it will be discussed with testing personnel and retested if deemed necessary. Any corrections will be noted on a corrective action form and filed." 2. Review of the laboratory's 2019, 2020 and 2021 American Association of Bioanalysts (AAB) proficiency testing results revealed the laboratory received the following unacceptable result: QC Chemistry 2021: Clinical Microscopy: KOH Skin Prep: Reported value: Negative; Intended Result: Positive 3. Further review of the laboratory's proficiency testing records revealed the laboratory did not have documentation of an assessment/corrective action performed. 4. In interview on November 8, 2021 at 11:10 am, laboratory personnel 1 confirmed the laboratory did not have documentation of an assessment performed for the identified KOH proficiency event.
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: Based on review of the laboratory's policies and procedures and interview with personnel, the laboratory failed to establish written policies for reporting SARS COV-2 results. Findings: 1. In interview on November 8, 2021 at 10:05 am, laboratory personnel 1 stated the laboratory began utilizing the BD Veritor System for SARS COV-2 testing on October 1, 2020. 2. Review of the laboratory's policies and procedures revealed the laboratory did not have written procedures for reporting SARS COV-2 results, to include, but not limited to who is responsible, and frequency of reporting. 3. In interview on November 8, 2021 at 10:13 am, laboratory personnel 2 confirmed the laboratory did not have a written policy for the reporting of positive and negative SARS COV-2 results to the state.
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, record review, and interview with personnel, the laboratory failed to monitor the room temperature of storage room where supplies are stored per manufacturer requirements. Findings: 1. Observation by surveyor during the laboratory tour on November 8, 2021 at 10:50 am revealed the laboratory did not monitor the room where the following supplies were located: a) BD Vacutainer SST blood collection tubes, Lot # 1102116, Quantity: one (1) pack b) BD Vacutainer UA Preservative Tubes, Lot # 0258285, Quantity: one (1) pack c) BD Vacutainer K2EDTA blood collection tubes, Lot # 1137395, Quantity: one (1) pack d) BD Vacutainer C and S Preservative Urine tubes, Lot # 0301589, Quantity: one (1) pack e) BD Veritor Flu A and B kits, Quantity: two (2) boxes f) SARS Quickvue, Lot # 706600, Quantity one (1) box g) Consult Diagnostics Influenza A and B, Lot # 440B11, Quantity: one (1) box h) Consult Diagnostics Strep A, Lot STA0052026, Quantity: one (1) box 2. Review of manufacturer storage requirements for the identified supplies revealed the following: a) BD Vacutainer collection tubes: storage requirement 4-25 degrees Celsius b) BD Veritor kits: storage requirement 2-30 degrees Celsius c) SARS Quickvue kit: storage requirement 15-30 degrees Celsius d) Consult Diagnostics kits: storage requirement 2-30 degrees Celsius 3. In interview on November 8, 2021 at 10:50 am, laboratory personnel 1 and 2 confirmed the temperature of the room where supplies are stored was not monitored.
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, policies and procedures, test menu, and interview with personnel, the laboratory failed to ensure testing personnel documented the stain quality for Hematoxylin and Eosin (H&E) stains. 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 "Risk assessment (RA) for specimen sent for slide or interpretation" policy revealed "Upon arrival of slides, they are checked for quality control as to staining and placement of specimen. Any discrepancies are noted and corrective action is obtained. A corrective action form is filled out if needed. The date and time of arrival along with the person's initials checking them in are placed on the copy of the log sheet. Physician views slides under microscope for a diagnosis. A path report is then generated and recorded. " 3. In interview on November 8, 2021 at 11:49 am, laboratory personnel 1 stated the physician (Laboratory Director) does not document the quality control (stain quality) for histopathology testing. 4. Review of the laboratory's test menu revealed the laboratory performs 769 histopathology tests annually.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of random selection of patient test reports, patient slides, and interview with personnel, the laboratory failed to maintain a labeling system to ensure positive identification of patient samples. Findings: 1. Review of random selection of patient test records and microscope slides from 2019, 2020, and 2021 revealed in 2020 slides are labeled with the patient's name and accession number from technical report that is generated from the laboratory that performs the technical (processing) of patient samples. 2. In interview on November 8, 2021 at 11:52 am, laboratory personnel 1 stated the technical reports for patient samples prior to March 2021 were destroyed by the hurricane in August 2021. Laboratory personnel 1 stated the laboratory kept paper copies of the technical reports. 3. Review of random selection of 2020 and 2021 patient final test reports revealed the technical report number was not indicated on the patient's final report. The laboratory included a patient ID number on patient final test reports that did not match the accession number on slides and technical report. The laboratory utilized the patient's name as an identifier to link the slide. 4. Further review of random selection of 2020 and 2021 patient final test reports revealed the laboratory failed to maintain a labeling system for the following patients: March 12, 2020 Patient ID: IRJO0000 July 16, 2020 Patient ID: WARO0003 November 30, 2020 Patient ID: MUAU0000 February 3, 2021 Patient ID: JOMC0030 May 13, 2021 Patient ID: SYGI0000 October 12, 2021 Patient ID: JOMA006

D5805	TEST REPORT CFR(s): 493.1291(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: Review of patient final reports, test menu, and interview with personnel, the laboratory failed to include their current address on patient final reports. Findings: 1. In interview on November 8, 2021 at 10:05 am, laboratory personnel 1 stated the laboratory moved to their current location due to hurricane damage to their previous location. 2. Review of the following random selection of patient final test reports revealed the laboratory included the hurricane damaged location's address, not the current address where testing is performed: October 29, 2021: Patient JOMA0006 November 2, 2021: Patient 1068 3. In interview on November 8, 2021 at 12:32 pm, laboratory personnel 1 confirmed the laboratory did not include the current address of the laboratory on patient final reports. 4. Review of the laboratory's test menu revealed the laboratory performs the following tests annually: thirty eight (38) KOH preps, 769 histopathology and 108 SARS COV-2 tests.
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 review of the laboratory's test menu and interview with personnel, the Laboratory Director failed to provide overall management and direction. Refer to D6082.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

	This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to provide overall management and direction to the laboratory. Refer to D3031.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu and interview with personnel, the Laboratory Director failed to ensure the laboratory reported SARS COV-2 results as required. Refer to D3000.
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, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel were performing test methods as required. Findings: 1. The laboratory failed to monitor the room temperature of storage room where supplies are stored per manufacturer requirements. Refer to D5413. 2. The laboratory failed to maintain a labeling system to ensure positive identification of patient samples. Refer to D5787.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure corrective action was performed when proficiency results were unacceptable. Refer to D5221.
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.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of patient final reports, test menu, and interview with personnel, the laboratory failed to include the laboratory's address on patient final reports for Histopathology testing. Refer to D5805.
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 review of the laboratory's policies and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D5401.