Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2265804	05/16/2023
Name of Provider or Supplier	**Street Address, City, State**	
The Nueline Clinic Of Mckinney, Pllc	2740 Virginia Pkwy Suite 100, Mckinney, TX	

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 entrance conference was held with the laboratory representatives. The survey process was discussed, and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be NOT in compliance with the CLIA conditions for specialties /subspecialties surveyed for 42 CFR 493.1403 Laboratory Director, (moderate complexity). 493.1409 Technical Consultant Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals

	(normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 laboratory policies, quality control (QC) records, and procedures and confirmed in interview, the laboratory failed to have a policy in place for corrective actions taken when control results fail to meet laboratory's criteria for acceptability. Findings Included: 1. Review of laboratory policies and procedures determined the laboratory failed to have a corrective action policy in place to document actions taken when control results fail to meet laboratory's criteria for acceptability. 2. Review of Abbott Architect QC records revealed the laboratory failed to document corrective actions for QC failures in April 2021 on the following dates and times: Multichem IA Plus Assayed Quality Control Level 1,2,3 QC Lot Number: 35006210; Expiration: 09 /30/2023 04/18/2023 Level 1 Control 09:11 QC FAILED for FSH; 10:42 QC FAILED for FSH; 13:37 QC repeated and passed 09:19 QC FAILED for LH; 10:44 QC repeated and passed 09:21 QC FAILED for Prolactin; 10:45 QC FAILED for Prolactin; 13:32 QC repeated and passed 09:26 QC FAILED for Total T4; 10:46 QC FAILED for Total T4; 13:33 QC repeated and passed 04/19/2023 Level 1 Control 10: 08 QC FAILED for Progesterone; No repeat of QC documented 04/24/2023 14:31 QC FAILED for Anti-Tg; 15:20 QC repeated and passed The laboratory failed to document corrective action for the above QC failures in April 2023. 3. During an interview on 05/16/2023, at 11:45 a.m., in the conference room, Testing Person 2 (TP-2) was asked to provide the laboratory's corrective action policy. No policy was provided. This confirmed the above findings.
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: I. Based on direct observation, review of manufacturer's instructions, laboratory environmental records, and confirmed in staff interview, the laboratory failed to ensure relative humidity ranges were within manufacturer's specifications for the Abbott Architect IS1000 prior to patient testing. Findings Included: 1. During a tour of the laboratory on 05/16/2023 at 01:40 p.m., the inspector observed an Abbott Architect IS1000 Immunoassay Analyzer (Serial Number: G3452139522) in the patient processing area. 2. Review of the Architect System Operations Manual (Version:01-26-2023) revealed the following: "Environmental specifications and requirements Humidity: 10%-85% (non-condensing) RH (Relative Humidity)" 3. Review of laboratory environmental logs revealed the laboratory failed to record the humidity in the patient processing area. 4. During an interview on 05/16/2023 at 01:45

	p.m., in the laboratory, TP-2 was asked if humidity was documented in the patient processing area. TP-2 stated humidity was NOT documented. This confirmed the above findings. II. Based on direct observation, manufacturer's instructions, laboratory environmental logs, and confirmed in staff interview, the laboratory failed to ensure temperature ranges were within manufacturer's specifications for Multichem IA (Immunoassay) Plus Quality Control (QC). Findings Included: 1. During a tour of the laboratory on 05/16/2023 at 01:40 p.m., the inspector observed an Abbott Architect IS1000 Immunoassay Analyzer (Serial Number: G3452139522) in the patient processing area. 2. Review of manufacturer's instructions for the Multichem IA Plus QC revealed the following: "Procedure for use: Allow the control to stand at room temperature (18 to 25 C) for half an hour or until completely thawed." 3. Review of laboratory environmental logs revealed the laboratory failed to record the room temperature in the patient processing area. 4. During an interview on 05/16/2023 at 01: 45 p.m., in the laboratory, TP-2 was asked if temperature was documented in the patient processing area. TP-2 stated room temperature was NOT documented. This confirmed the above findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of verification studies for the Abbott Architect analyzer, laboratory records, and confirmed in interview, the laboratory failed to ensure the reportable range for analytes were verified by the laboratory's studies. Findings Included: 1. Review of verification studies, revealed the laboratory started performing patient analyses on the Abbott Architect on 03/09/2023. 2. Further review of verification studies for the Abbott Architect analyzer revealed the laboratory's verified reportable range listed in the analyzer did not coincide with the reportable ranges obtained in the verification studies for analytes as required by 493.1253 as follows: Reportable range from verification study: FSH: 0.16-127.00 Reportable range in analyzer: FSH: 0.05-150.00 Reportable range from verification study: LH: 0.18-240.25 Reportable range in analyzer: LH: 0.05-150.00 Reportable range from verification study: Prolactin: 0.85-174.61 Reportable range in analyzer: Prolactin: 0.60-200.00 Reportable range from verification study: Progesterone: 0.40-36.0 Reportable range in analyzer: Progesterone: 0.10-40.00 The laboratory's reportable range input in the analyzer did not coincide with the reportable range obtained in the verification studies for all the above analytes. 3. Review of laboratory records revealed the laboratory performed an estimated 3,120 tests annually. 4. During an interview on 05/16/2023, at 01:30 p.m., with TP-1, TP-1 was asked to provide the reportable ranges of the above analytes on the analyzer. TP-1 produced the above ranges on the Abbott Architect analyzer. This confirmed the above findings.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)

	Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory policies, manufacturer's instructions, Multichem IA Quality Control (QC) records, and staff interview, it was revealed the laboratory failed to verify the criteria for acceptability of all control materials prior to placing into use, for 1 of 1 lot used in 2023. Findings Included: 1. A review of laboratory policies revealed the laboratory did NOT have a policy for verifying the criteria for acceptability of all control materials. 2. Random review of reagent package inserts revealed the following: "Architect LH Ref: 2P40-25 Quality Control Procedures: When using commercially available controls, each laboratory should establish its own concentration ranges for new control lots at each clinically relevant control level. This can be accomplished by assaying a minimum of 20 replicates over several (3-5) days." 3.Review of the Multichem IA Quality Control (QC) records from 2023, revealed the following quality control lot number was placed into service and failed to be verified by the laboratory: Level 1,2,3 QC Lot Number: 35006210; Expiration: 09/30/2023 3. During an interview on 05/16/2023 at 01:45 p.m., in the laboratory, TP-2 confirmed the laboratory failed to verify the criteria for acceptability of the control material prior to placing into use.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of laboratory policy, manufacturer's instructions, quality control (QC) records, and confirmed in interview, the laboratory failed to document corrective actions for 3 of 15 runs that included failures in April 2023. Findings Included: 1. Review of the laboratory policies revealed the laboratory did not have a policy for documenting corrective actions for QC failures for analytes tested on the

	Abbott Architect IS1000 analyzer. 2. A sampling review of individual analyte package inserts revealed the following: "Architect Progesterone Ref: 7K77-20 Quality Control ..If the quality control procedures in your laboratory require more frequent use of controls to verify test results, follow your laboratory-specific procedures. Ensure that assay control values are within the concentration ranges specified in the control package insert." "Architect Prolactin Ref: 7K76-25 Quality Control ..If the quality control procedures in your laboratory require more frequent use of controls to verify test results, follow your laboratory-specific procedures. Ensure that assay control values are within the concentration ranges specified in the control package insert." "Architect LH Ref: 2P40-25 Quality Control Each laboratory should establish control ranges to monitor the acceptable performance of the assay. If a control is out of its specified range, the associated sample results are invalid, and the samples must be restested." "Architect FSH Ref: 7K75-25 Quality Control ..If the quality control procedures in your laboratory require more frequent use of controls to verify test results, follow your laboratory-specific procedures. Ensure that assay control values are within the concentration ranges specified in the control package insert." 3. Review of Abbott Architect QC records revealed the laboratory failed to document corrective actions for QC failures in April 2021 on the following dates and times: Multichem IA Plus Assayed Quality Control Level 1,2,3 QC Lot Number: 35006210; Expiration: 09 /30/2023 04/18/2023 Level 1 Control 09:11 QC FAILED for FSH; 10:42 QC FAILED for FSH; 13:37 QC repeated and passed 09:19 QC FAILED for LH; 10:44 QC repeated and passed 09:21 QC FAILED for Prolactin; 10:45 QC FAILED for Prolactin; 13:32 QC repeated and passed 09:26 QC FAILED for Total T4; 10:46 QC FAILED for Total T4; 13:33 QC repeated and passed 04/19/2023 Level 1 Control 10: 08 QC FAILED for Progesterone; No repeat of QC documented 04/24/2023 14:31 QC FAILED for Anti-Tg; 15:20 QC repeated and passed The laboratory failed to document corrective action for the above QC failures in April 2023. 4. During an interview on 05/16/2023, at 12:35 p.m., in the conference room, TP-1 stated the laboratory repeated out of range QC by repeat testing with fresh QC, but no corrective actions for QC failures were documented. This confirmed the above findings. Word Key Anti-Tg- Antithyroglobulin Total T4- Thyroxine FSH- Follicle-stimulating Hormone LH- Luteinizing Hormone
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of Centers for Medicare and Medicaid Services (CMS)-116 form, laboratory records and confirmed by staff interview, the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6004.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory

	director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, 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 review of CMS 209 form, personnel records and confirmed in interview, the laboratory failed to employ one or more individuals who were qualified by education to provide technical consultation for each of the specialties of service in which the laboratory performs moderate complexity tests. Findings Included: 1. Review of Centers for Medicare and Medicaid Services (CMS) -209 form, submitted at time of survey (05/16/2023), revealed 1 of 1 technical consultant (TC-1; Also the Laboratory Director) listed as overseeing moderate complexity testing. 2. Review of laboratory personnel records revealed no qualifying educational documentation for TC-1. 3. During an interview with testing person 1 (TP-1), on 05/16/2023 at 11:15 a.m. in the conference room, TP-1 was asked to provide documentation of TC-1 qualifying educational requirements for moderate complexity testing. No documentation was provided. This confirmed The laboratory did not employ one or more individuals who were qualified by education to provide technical consultation for each of the specialties of service in which the laboratory performs moderate complexity tests.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) 209 form, personnel records, and in interview with staff, the laboratory failed to have a technical consultant who meets the qualification requirements of 493.1411 of this subpart. The laboratory failed to ensure the individual employed met the minimum educational requirements to qualify as a technical consultant. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for

	example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) -209 form, laboratory personnel records and staff interview, the laboratory failed to provide documentation that 1 of 1 individual met the educational requirements to qualify as a technical consultant (TC-1). Findings Included: 1. Review of Centers for Medicare and Medicaid Services (CMS) -209 form, submitted at time of survey (05/16/2023), revealed 1 of 1 technical consultant (TC-1) listed as overseeing moderate complexity testing. 2. Review of laboratory personnel records revealed no qualifying educational documentation for TC-1. 3. During an interview with testing person 1 (TP-1), on 05/16 /2023 at 11:15 a.m. in the conference room, TP-1 was asked to provide documentation of TC-1 qualifying educational requirements for moderate complexity testing. No documentation was provided. This confirmed the above findings.