Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2016578	03/30/2022
Name of Provider or Supplier	**Street Address, City, State**	
Northlake Pathology Llc	16061 Doctors Blvd, Hammond, 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 on March 30, 2022 at Northlake Pathology, CLIA ID # 19D2016578. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the laboratory's records and interview with personnel, the laboratory failed to have documentation of the annual performance of preventative maintenance for Histopathology equipment for one (1) of two (2) years reviewed. Findings: 1. Review of the laboratory's 2020 and 2021 records revealed the laboratory did not have documentation of performance of preventative maintenance for the Histopathology equipment for 2020. 2. In interview on March 30, 2022 at 12:07 pm the Testing Personnel confirmed the laboratory did not have documentation of the annual preventative maintenance for the Histopathology equipment for 2020.
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:

	Based on review of temperature logs and interview with personnel, the laboratory failed to perform and document corrective actions when the water bath temperature was outside of acceptable limits for twenty (20) of twenty two (22) days in March 2022. Findings: 1. Review of the laboratory "Monthly QC Log Work Stations" form revealed the following temperature requirements: a) "Water Bath: Daily temperature 41-44 degrees" b) "Embedding Center: Daily temperature 58-62 degrees" 2. Review of the "Monthly QC Log Work Stations" log for March 2022 revealed the water bath temperature was documented as outside of acceptable limits without corrective actions performed for the following twenty (20) days: Water Bath # 2: March 2, 2022: documented 61 degrees March 3, 2022: documented 61 degrees March 4, 2022: documented 61 degrees March 7, 2022: documented 62 degrees March 8, 2022: documented 61 degrees March 9, 2022: documented 61 degrees March 10, 2022: documented 61 degrees March 11, 2022: documented 61 degrees March 14, 2022: documented 62 degrees March 15, 2022: documented 62 degrees March 16, 2022: documented 61 degrees March 17, 2022: documented 61 degrees March 18, 2022: documented 61 degrees March 21, 2022: documented 62 degrees March 22, 2022: documented 62 degrees March 23, 2022: documented 62 degrees March 24, 2022: documented 61 degrees March 25, 2022: documented 61 degrees March 28, 2022: documented 62 degrees March 29, 2022: documented 62 degrees 3. In interview on March 30, 2022 at 10:40 am the Testing Personnel stated the water bath temperatures documented were accidental. The Testing Personnel confirmed the identified water bath temperatures were documented as outside of acceptable limits without corrective action.
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: Based on review of patient final reports, test menu, and interview with personnel, the laboratory failed to ensure patient final test reports included the name of the reference laboratory that performed the professional interpretation of histopathology testing. Findings: 1. Review of random selection of histopathology patient final test reports revealed the laboratory did not include the name of the reference laboratory that performed the professional interpretation for the following seven (7) patients: N20-610 N20-5124 N20-2475 N21-712 N21-3626 N22-410 N22-1004 2. In interview on March 30, 2022 at 11:47 am, the Testing Personnel confirmed the laboratory did not include the name of the reference laboratory that performed the professional interpretation. 3. Review of the laboratory's test menu revealed the laboratory perform 59, 259 Histopathology tests annually.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6)

	The laboratory director must 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 maintained to ensure acceptable levels of test performance. Refer to D5429.
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 laboratory's policies occurred. Refer to D5785.
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 Director failed to ensure patient final reports included required information. Refer to D5805.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must 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 policies and procedures for assessing personnel competency were maintained. Refer to D6128.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)

	The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, personnel records, and interview with personnel, the Technical Supervisor failed to perform competency annually for one (1) of one (1) testing personnel reviewed. Findings: 1. Review of the laboratory's "Personnel Competency Evaluation" policy revealed "All new employees will be evaluated twice during the first year of employment and then once a year thereafter. 2. Review of personnel records for the Testing Personnel revealed the laboratory did not have documentation of an annual competency assessment for 2020. 3. In interview on March 30, 2022 at 12:07 pm, the Testing Personnel stated she could not find her 2020 competency assessment. The Testing Personnel confirmed the laboratory did not have documentation of performance of her annual competency assessment for 2020.