

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2016578	(X3) Date Survey Completed 10/22/2025
Name of Provider or Supplier Northlake Pathology Llc	Street Address, City, State 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 at Northlake Pathology, LLC, CLIA ID 19D2016578, on October 22, 2025. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the laboratory's policies, and interview with personnel, the laboratory failed to label stain solutions stored in ten (10) secondary containers with the identity of the contents, lot numbers, and expiration dates. Findings: 1. Observation by surveyor during the laboratory tour on October 22, 2025 at 9:07 am revealed three (3) secondary containers stored near the sink and one (1) secondary container stored in the refrigerator were not legibly labeled . Six (6) secondary containers were unlabeled with the identity of the contents, lot numbers, and expiration dates. 2. Review of the laboratory's "Anatomic Pathology-Accuracy of Analysis" policy revealed " Reagents must contain the following information: name of reagent, date of preparation, date of expiration, safety designations, and initials of technician/technologist preparing the solution." 3. In interview on October 22, 2025 at 9:17 am, Testing Personnel 2 stated the stickers for the identified secondary containers were not changed. Testing Personnel 2 confirmed the identified containers were not labeled with the identity of the contents, lot numbers, and expiration dates.</p>

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 the laboratory's temperature logs and interview with personnel, the laboratory failed to perform corrective actions when the embedding center temperature was outside of acceptable limits for 106 of 185 days reviewed. Findings: 1. Review of the laboratory's "Monthly QC Log Work Stations" revealed the following temperature requirement for the embedding center "daily temperatures 58-62 degrees." 2. Review of the laboratory's 2024 and January 2025 through October 2025 temperature logs revealed the embedding center temperature was outside acceptable limits without documentation of corrective actions for the following dates: July 2, 2024 documented temperature of 63 degrees July 3, 2024 documented temperature of 63 degrees July 8, 2024 documented temperature of 63 degrees July 22, 2024 documented temperature of 63 degrees July 24, 2024 documented temperature of 63 degrees July 25, 2024 documented temperature of 63 degrees July 26, 2024 documented temperature of 63 degrees July 29, 2024 documented temperature of 63 degrees July 31, 2024 documented temperature of 63 degrees September 2, 2024 documented temperature of 63 degrees September 3, 2024 documented temperature of 63 degrees September 12, 2024 documented temperature of 63 degrees September 18, 2024 documented temperature of 63 degrees September 24, 2024 documented temperature of 63 degrees September 25, 2024 documented temperature of 63 degrees September 26, 2024 documented temperature of 63 degrees September 27, 2024 documented temperature of 63 degrees September 30, 2024 documented temperature of 63 degrees October 1, 2024 documented temperature of 63 degrees October 4, 2024 documented temperature of 63 degrees October 7, 2024 documented temperature of 63 degrees October 14, 2024 documented temperature of 63 degrees October 15, 2024 documented temperature of 63 degrees October 16, 2024 documented temperature of 63 degrees October 17, 2024 documented temperature of 63 degrees October 21, 2024 documented temperature of 63 degrees October 24, 2024 documented temperature of 63 degrees October 25, 2024 documented temperature of 63 degrees October 28, 2024 documented temperature of 63 degrees October 31, 2024 documented temperature of 63 degrees November 5, 2024 documented temperature of 63 degrees November 7, 2024 documented temperature of 63 degrees November 11, 2024 documented temperature of 63 degrees November 12, 2024 documented temperature of 63 degrees November 14, 2024 documented temperature of 63 degrees November 15, 2024 documented temperature of 63 degrees November 18, 2024 documented temperature of 63 degrees December 1, 2024 documented temperature of 63 degrees December 4, 2024 documented temperature of 63 degrees December 5, 2024 documented temperature of 63 degrees December 10, 2024 documented temperature of 63 degrees December 11, 2024 documented temperature of 63 degrees December 12, 2024 documented temperature of 63 degrees December 13, 2024

documented temperature of 63 degrees December 17, 2024 documented temperature of 63 degrees December 18, 2024 documented temperature of 63 degrees December 19, 2024 documented temperature of 63 degrees December 23, 2024 documented temperature of 63 degrees December 27, 2024 documented temperature of 63 degrees December 30, 2024 documented temperature of 63 degrees March 10, 2025 documented temperature of 63 degrees March 13, 2024 documented temperature of 63 degrees March 14, 2025 documented temperature of 63 degrees March 17, 2025 documented temperature of 63 degrees March 19, 2025 documented temperature of 63 degrees March 20, 2025 documented temperature of 63 degrees March 21, 2025 documented temperature of 63 degrees March 24, 2025 documented temperature of 63 degrees March 25, 2025 documented temperature of 63 degrees March 26, 2025 documented temperature of 63 degrees March 27, 2025 documented temperature of 63 degrees March 28, 2025 documented temperature of 63 degrees March 31, 2025 documented temperature of 63 degrees May 1, 2025 documented temperature of 63 degrees May 2, 2025 documented temperature of 63 degrees May 5, 2025 documented temperature of 63 degrees May 6, 2025 documented temperature of 63 degrees May 13, 2025 documented temperature of 63 degrees May 14, 2025 documented temperature of 63 degrees May 15, 2025 documented temperature of 63 degrees May 21, 2025 documented temperature of 63 degrees May 22, 2025 documented temperature of 63 degrees May 23, 2025 documented temperature of 63 degrees May 27, 2025 documented temperature of 63 degrees May 28, 2025 documented temperature of 63 degrees May 29, 2025 documented temperature of 63 degrees May 30, 2025 documented temperature of 63 degrees June 2, 2025 documented temperature of 63 degrees June 3, 2025 documented temperature of 63 degrees June 4, 2025 documented temperature of 63 degrees June 5, 2025 documented temperature of 63 degrees June 6, 2025 documented temperature of 63 degrees June 9, 2025 documented temperature of 63 degrees June 10, 2025 documented temperature of 63 degrees June 11, 2025 documented temperature of 63 degrees June 13, 2025 documented temperature of 63 degrees June 16, 2025 documented temperature of 63 degrees June 17, 2025 documented temperature of 63 degrees June 18, 2025 documented temperature of 63 degrees June 19, 2025 documented temperature of 63 degrees June 20, 2025 documented temperature of 63 degrees June 25, 2025 documented temperature of 63 degrees June 26, 2025 documented temperature of 63 degrees June 27, 2025 documented temperature of 63 degrees June 30, 2025 documented temperature of 63 degrees July 1, 2025 documented temperature of 63 degrees July 2, 2025 documented temperature of 63 degrees July 3, 2025 documented temperature of 63 degrees July 7, 2025 documented temperature of 63 degrees July 14, 2025 documented temperature of 63 degrees July 15, 2025 documented temperature of 63 degrees July 16, 2025 documented temperature of 63 degrees July 17, 2025 documented temperature of 63 degrees July 18, 2025 documented temperature of 63 degrees July 23, 2025 documented temperature of 63 degrees July 24, 2025 documented temperature of 63 degrees 3. Further review of the laboratory's temperature logs revealed the General Supervisor and Laboratory Director reviewed the logs monthly. 4. In interview on October 22, 2025 at 10:28 am, the General Supervisor confirmed the laboratory did not perform corrective actions for temperatures outside of acceptable limits for the identified dates.

D5793

ANALYTIC SYSTEMS QUALITY ASSESSMENT
 CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems

	<p>quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, review of records, and interview with personnel, the laboratory failed to ensure their established monitors identified issues within the analytic system. Findings: 1. Observation by survey, review of records, and interview with personnel revealed the laboratory's monitors did not identify the following issues within the analytic system: a) The laboratory failed to label stain solutions stored in ten (10) secondary containers with the identity of the contents, lot numbers, and expiration dates. Refer to D5415. b) The laboratory failed to perform corrective actions when the embedding center temperature was outside of acceptable limits for 106 of 185 days reviewed. Refer to D5781.</p>
<p>D6087</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii)</p> <p>(e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;</p> <p>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 performed test methods as required. Refer D5415.</p>
<p>D6093</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;</p> <p>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 quality assessment programs were maintained to assure the quality of laboratory testing. Refer to D5793.</p>
<p>D6096</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7)</p> <p>(e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratorys established performance characteristics are identified, and</p> <p>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. Refer to D5781.</p>