

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2016578	(X3) Date Survey Completed 01/16/2018
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 Certification Survey was conducted on January 16, 2018 at Northlake Pathology, LLC-CLIA ID # 19D2016578. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard deficiencies were cited.
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with personnel, the laboratory failed to ensure dyes have not exceeded their expiration date. Findings: 1. Observation by surveyor during the laboratory tour on January 16, 2018 revealed the following expired items: a) Cancer Diagnostics Sample Tissue Marking Red Dye, 0.5 ounces, Quantity: 1 bottle, Lot # 5272, Expiration date: March 2017 b) Cancer Diagnostics Sample Tissue Marking Blue Dye, 0.5 ounces, Quantity: 1 bottle, Lot # 6028, Expiration date: July 2017 c) Cancer Diagnostics Sample Tissue Marking Green Dye, 0.5 ounces, Quantity: 1 bottle, Lot # 5272, Expiration date: March 2017 c) Cancer Diagnostics Sample Tissue Marking Black Dye, 0.5 ounces, Quantity: 1 bottle, Lot # 6039, Expiration date: July 2017 d) Tissue Marking Yellow Dye, Quantity: 1 bottle, Batch code # 4363, Expiration date: June 2016 e) Tissue Marking Blue Dye, Quantity: 1 bottle, Lot # 5217, Expiration date: February 2017 2. In interview on January 16, 2018 at 9:21 am, Personnel 2 stated the laboratory does not use the identified dyes. Personnel 2 confirmed the identified dyes were expired.</p>
D6087	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii)</p>

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 and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required. Refer to D5417.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to provide a written job description for all Laboratory Personnel. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a written job description for the Laboratory Director that included responsibilities specific to the laboratory. 2. Review of the laboratory's CMS 209 (Personnel) form revealed the Laboratory Director also serves as the Clinical Consultant, Technical Supervisor, General Supervisor and Testing Personnel. 3. In interview on January 16,2018 at 11:00 am, Personnel 2 confirmed the laboratory did not have a written job description for the Laboratory Director.