

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D1073159	(X3) Date Survey Completed 06/27/2018
Name of Provider or Supplier Pathology Laboratory, Inc, The	Street Address, City, State 1810 Bertrand Drive, Lafayette, 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 performed at Reliopath LLC - CLIA # 19D1073159 on June 27, 2018. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level 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, record review, and interview with laboratory personnel, the laboratory failed to ensure that Immunohistochemical and Routine Staining Materials are not used beyond their expiration dates. Findings: 1. Observation by the surveyor during the tour of the laboratory on June 27, 2018 revealed the following expired items in place for patient testing: One (1)/ 7 milliliter (ml) bottle of Cell Marque CD31 (JC70) Immunohistochemical Material - lot 1516303A with an expiration date of 2018-05 One (1)/ 7 ml bottle of Cell Marque PSA (ER-PR8) Immunohistochemical Material - lot 1607709F with an expiration date of 2018-02 One (1)/ 100 ml bottle of American Master Tech 1% Potassium Permanganate (utilized in the reticulin stain) - lot 17120738 with an expiration date of 2018-06-07. 2. Review of a random selection of patient test records from March 21, 2018 through June 25, 2018 revealed the following patients were tested and reported utilizing the expired items cited above: a) Cell Marque CD31 (JC70) Immunohistochemical Material - lot 1516303A with an expiration date of 2018-05: Patient 25 reported on June 22, 2018. b) Cell Marque PSA (ER-PR8) Immunohistochemical Material - lot 1607709F with an expiration date of 2018-02: Patient 26 reported on March 26, 2018. Patient 27 reported on May 10, 2018. Patient 28 reported on May 15, 2018. Patient 29 reported on June 18, 2018. c) American Master Tech 1% Potassium Permanganate (utilized in the reticulin stain) -</p>

lot 17120738 with an expiration date of 2018-06-07: Patient 30 reported on June 19, 2018. Patient 31 reported on June 22, 2018. Patient 32 reported on June 27, 2018. 3. Interview with personnel 6 on June 27, 2018 confirmed the laboratory tested and reported patient test results utilizing the expired items cited above.

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 record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required for accurate and reliable results. Findings: 1. The laboratory failed to ensure that Immunohistochemical and Routine Staining Materials are not used beyond their expiration dates. Refer to D5417. 2. Interview with personnel 6 on June 27, 2018 confirmed the laboratory tested and reported patient test results utilizing the expired items cited above.