

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2018531	(X3) Date Survey Completed 01/28/2020
Name of Provider or Supplier Pathology Laboratory, Inc, The	Street Address, City, State 2810 Ambassador Caffery Pkway, 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 on January 28, 2020 at The Pathology Laboratory, INC, CLIA ID # 19D2018531. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: I. Based on record review and interview with personnel, the laboratory failed to ensure written policies and procedures to address competency of Clinical Consultants, Technical Supervisors and General Supervisors were complete. Findings: 1. Review of the the laboratory's CMS-209 form (Laboratory Personnel Report) revealed the Laboratory Director and four (4) pathologists serve as Clinical Consultants, Technical Supervisors, and General Supervisors. 2. Review of the laboratory's "Competency Assessment" policy revealed the laboratory did not include competency assessment criteria or frequency for personal serving as Clinical Consultants, Technical Supervisors, and General Supervisors. 3. Review of personnel records revealed competency assessments were not performed for the four (4) personnel serving as Clinical Consultants, Technical Supervisors, and General Supervisors. 4. In interview on January 28, 2020 at 9:24 am, the compliance personnel stated the Laboratory Director did not perform competency assessments for the four (4) personnel serving as Clinical Consultants, Technical Supervisors, and General Supervisors. II. Based on record review and interview with personnel, the laboratory failed to follow written policies and procedures to assess competency for testing personnel. Findings: 1. Review of the laboratory's "Competency Assessment" policy revealed "Competency is</p>

documented for all employees at the following intervals: initial, six months post hire, twelve months post hire, and annually thereafter. The six elements are used, as applicable. Training and competency assessments for the Pathologists, Pathologist Assistant, Cytology General Supervisor (i.e. General Lab Supervisor of the Lafayette laboratory), and personnel who perform the task of grossing will be performed and documented by one of the Pathologists. The Laboratory Director will review all competency assessments for final approval." 2. Review of the the laboratory's CMS-209 form (Laboratory Personnel Report) revealed the Laboratory Director and four (4) pathologists serve as Testing Personnel. 3. In interview on January 28, 2020, the compliance personnel confirmed the laboratory did not have documentation of competency assessments for the five (5) personnel performing testing.

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 were maintained for assessing personnel competency. Refer to D5209 I and D5209 II.