

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2018531	(X3) Date Survey Completed 04/20/2022
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 Recertification survey was performed on April 20, 2022 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: Review of the laboratory's CMS 209 form, policies, personnel records, and interview with personnel revealed the laboratory failed to ensure the current Laboratory Director performed a competency assessment for four (4) of five (5) Clinical Consultants and Technical Supervisors. Findings: 1. In interview on April 20, 2022 at 9:20 am, the laboratory's Quality Assurance personnel stated the current Laboratory Director took over directorship in June 2021. 2. Review of the laboratory's CMS 209 form (Laboratory Personnel Report) revealed the laboratory had five (5) personnel, including the Laboratory Director, serving as Clinical Consultants and Technical Supervisors 3. Review of personnel records revealed the 2022 competency assessments for four (4) personnel for their duties as Clinical Consultants and Technical Supervisors were completed in March 2022; however, the current Laboratory Director did not perform the assessments. The Clinical Consultants and Technical Supervisors performed a competency assessment on each other. 4. In interview on April 20, 2022 at 9:20 am, the laboratory's Quality Assurance personnel confirmed the current Laboratory Director did not perform competency assessments for the four (4) personnel serving as Clinical Consultants and Technical Supervisors.</p>

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 D5209.

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 review of the laboratory's CMS 209 form, personnel records, and interview with personnel, the Laboratory Director failed to include written duties and responsibilities of the Cytology General Supervisor. Findings: 1. Review of the laboratory's CMS 209 form (Laboratory Personnel Report) revealed Clinical Consultant 2 also serves as the Cytology General Supervisor. 2. Review of the personnel records for Clinical Consultant 2 revealed the laboratory did not include a written job description related to duties of the Cytology General Supervisor. 3. In interview on April 20, 2022 at 9:36 am, the laboratory's Quality Assurance personnel stated the laboratory did not include a written job description of duties and responsibilities of the Cytology General Supervisor.