

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0999066	(X3) Date Survey Completed 07/11/2019
Name of Provider or Supplier Pontchartrain Pediatrics	Street Address, City, State 4405 Highway 190 E Service Road, Covington, 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 July 11, 2019 at Pontchartrain Pediatrics, CLIA ID # 19D0999066. 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: Based on record review and interview with personnel, the laboratory failed to ensure written policies and procedures to assess competency for one (1) of (2) Technical Consultants were complete. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed the Laboratory Director and another physician serve as Technical Consultants. 2. Review of the laboratory's policies and procedures revealed the laboratory did not have a policy for competency assessment of Technical Consultant, including frequency of performance. 3. Review of personnel records for the additional physician serving as Technical Consultant revealed a competency assessment for duties as Technical Consultant was not performed. 4. In interview on July 11, 2019 at 10:14 am, Testing Personnel 1 stated the Laboratory Director did not perform a competency assessment on the additional physician serving as Technical Consultant.</p>
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform</p>

test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) 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 established for assessing personnel competency. Findings: 1. The laboratory failed to ensure written policies and procedures to assess competency for one (1) of (2) Technical Consultants were complete. Refer to D5209. 2. The Technical Consultants failed to ensure all testing personnel were assessed through testing previously analyzed specimens, internal blind samples or external proficiency samples. Refer to D6051.

D6051

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Technical Consultants failed to ensure all testing personnel were assessed through testing previously analyzed specimens, internal blind samples or external proficiency samples. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) form revealed the following testing personnel: Testing Personnel 1 Testing Personnel 2 Testing Personnel 3 Testing Personnel 4 Testing Personnel 5 Testing Personnel 6 Testing Personnel 7; Hired June 17, 2019 2. Review of the laboratory's "Competency Assessment Documentation Form" revealed "Performs required Proficiency testing with less than 10% failure on evaluation" as a task examined through direct observation and policy review. 3. Review of the laboratory's American Proficiency Institute (API) proficiency records for 2018 revealed the following testing personnel did not perform proficiency testing: Testing Personnel 3 Testing Personnel 4 Testing Personnel 6 4. In interview on July 11, 2019 at 10:01 am, Testing Personnel 1 stated currently all staff review the proficiency testing policy for the competency requirement. Testing Personnel 1 confirmed all testing personnel did not perform external proficiency samples, internal blind samples, or previously analyzed samples in 2018.