

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D1073788	(X3) Date Survey Completed 02/27/2020
Name of Provider or Supplier Wake Forest Pediatric Associates, PLLC	Street Address, City, State 6845 Knightdale Boulevard, Suite 100, Knightdale, NC	
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
D6051	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies, review of 2018 and 2019 American Proficiency Institute (API) proficiency testing (PT) records, review of 2018 and 2019 testing personnel (TP) competency records, and interview with TP #5 and TP #7 2/27/20, the technical consultant (laboratory director) failed to ensure the TP competency assessments included a yearly assessment of TP test performance through the testing of previously analyzed specimens, internal blind testing samples or external PT samples for all TP. Findings: Review of laboratory policy "Laboratory Quality Assurance Policy and Procedure" revealed "The assessment of competency of testing personnel will include the following methods: ...Assessing test performance through previously analyzed specimens or through the use of internal blind testing or external proficiency testing." Review of 2018 and 2019 API PT records revealed of the 6 Hematology/Coagulation events participated in only 3 of the 11 current TP had participated in the PT events in a 2 year time period. Review of TP 2018 and 2019 competency records revealed no documentation that TP who had not participated in the PT events yearly had been assessed either by testing of previously analyzed specimens or internal blind testing as required for yearly competency assessments. Exit interview with TP #5 and TP #7 at approximately 2:00 p.m. confirmed the TP had not participated yearly in either PT events, internal blind testing of samples or testing of previously analyzed specimens as required. They stated they thought if each PT event was rotated through TP that the requirement was met.</p>

D6052

TECHNICAL CONSULTANT RESPONSIBILITIES

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

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, review of 2018 and 2019 TP competency records and interview with TP #5 2/27/20, the technical consultant (laboratory director) failed to ensure the procedure for the assessment of problem solving skills was established and TP were assessed for problem solving skills yearly. Findings: Review of laboratory policy "Laboratory Quality Assurance Policy and Procedure" revealed "The assessment of competency of testing personnel will include the following methods: ...Assessing problem solving skills." The policy fails to state how problem solving skills are assessed. Review of 2018 and 2019 TP competency records revealed a statement that problem solving skills were assessed, but failed to document how and what problem solving skills were assessed. Interview with TP #5 at approximately 1:00 p.m. confirmed the laboratory has not established a competency procedure for the assessment of problem solving skills. She stated she asks questions of the TP, but there was not an actual problem solving assessment and no documentation of the assessment of problem solving skills in the TP competency records.