

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0664387	(X3) Date Survey Completed 01/04/2019
Name of Provider or Supplier Pediatric Care Center,The	Street Address, City, State 5612 Spruce Tree Ave, Bethesda, MD	
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
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record and patient sample log review and interview with the technical consultant (TC), the laboratory did not handle hematology and chemistry PT specimens in the same manner as patient samples. Findings: 1. All patient samples which enter the laboratory are recorded on a patient log. 2. A review of patient logs from January, 2017 to December, 2018 showed that hematology PT samples were not documented on the patient log along with patient specimens in 6 of 6 PT events; and 3. The chemistry PT specimen for the 1st event of 2017 was not logged on the bilirubin patient log. 4. During an interview on 1/4/19 at 2:15 PM, the TC confirmed that PT samples were not handled in the same manner as patient specimens.</p>
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p>

This STANDARD is not met as evidenced by:

Based on proficiency testing (PT) record review and interview with the technical consultant (TC), the laboratory did not ensure that all the testing personnel who tested patient samples performed the PT. Findings: 1. The laboratory currently has 3 testing personnel listed on the "Laboratory Personnel Report (CMS-209)" who perform hematology and chemistry testing. 2. A review of hematology PT attestation worksheets from 2017 and 2018 showed that PT was performed by the same testing person in 4 of 6 events; and 3. A review of chemistry PT attestation worksheets from 2017 and 2018 showed that PT was performed by the same testing person in 5 of 6 events. 4. During an interview on 1/4/19 at 2:15 PM, the TC confirmed that PT samples were not tested each year by all the staff who perform patient testing to ensure accurate and reliable patient test results.