

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2072399	(X3) Date Survey Completed 03/27/2018
Name of Provider or Supplier 1st Choice Pediatrics	Street Address, City, State 1205 North 6th Street, Longview, TX	
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
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> <p>This STANDARD is not met as evidenced by: . Based on review of American Proficiency Institute (API) proficiency testing (PT) documentation for 2016 and 2017, confirmed by staff interview, the laboratory failed to test PT samples using personnel who routinely perform hematology testing using the Sysmex XP-300 analyzer. Findings: 1. API PT attestation documentation for 2016 and 2017 was reviewed. Attestation statements for hematology testing in the second and third events of 2016 and the first event of 2017 were signed by the clinic manager (testing person 6, CMS form 209) as the person performing the tests. No other testing personnel signatures were found. 2. In an interview at the site on 03-27-2018, the clinic manager stated she had performed the testing herself and was at the time unaware of the requirement to test PT samples using personnel who routinely perform patient testing. .</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: . Based on review of American Proficiency Institute (API) proficiency testing (PT)</p>

documentation for 2016 and 2017, confirmed by staff interview, the laboratory director failed to attest to the routine integration of hematology PT samples into the patient workload using the laboratory's routine methods using the Sysmex XP-300 analyzer. Findings: 1. API PT attestation documentation for 2016 and 2017 was reviewed. Attestation statements for hematology testing in the second and third events of 2016 and the first event of 2017 were signed by the clinic manager as the lab director or designee. The clinic manager was not qualified by education or training to serve as director or designee. 2. In an interview at the site on 03-27-2018, the clinic manager stated she had signed the attestation forms herself and was at the time unaware of the regulatory requirements for delegation of signatory authority. .

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
. Based on review of personnel competency and training documentation for 2018, confirmed by staff interview, the laboratory technical consultant failed to evaluate the competency of 7 of 7 testing personnel using the required criteria. Findings: 1. Personnel training and competency documentation was reviewed. For 6 of 7 testing personnel listed on CMS form 209, competency documentation consisted of a "Nurse Skill Check-off" sheet listing tests and procedures performed by clinic staff, including a single entry for "CBC machine." No check-off sheet was found for the clinic manager. 2. The forms for testing personnel 2 and 4 were initialed by the clinic manager. The forms for testing personnel 1, 3, 5 and 6 were initialed by testing person 2. None of the forms were signed by the technical consultant. 3. None of the forms indicated that competency had been evaluated using the required criteria. In an interview at the site on 03-27-2018, the clinic manager identified her own initials and those of testing person 2, and stated the required methods of verifying competency for testing personnel had not been documented. .