

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2047065	(X3) Date Survey Completed 08/23/2018
Name of Provider or Supplier B Pediatrics	Street Address, City, State 4503 Texas Boulevard, Texarkana, 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
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) documentation for 2016 and 2017 and staff interview, the laboratory director failed to attest to the integration of PT samples into the patient workload using the laboratory's routine methods. Findings: 1. API PT documentation for 2016, 2017 and 2018 was reviewed. Attestation forms stating: "The undersigned certify that, as closely as possible, these proficiency testing samples were tested in the same manner as patient specimens" were included. Forms for the 3rd event 2016 and 1st, 2nd and 3rd events 2017 were signed by testing person 1 (CMS form 209) as the person performing the tests. The forms were not signed by the laboratory director. In an interview at the site on 08-23-18, testing person 1 confirmed that the laboratory director had failed to sign the attestation forms. .</p>
D2121	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: . Based on review of API PT documentation for hematology testing using the QBC Autoread analyzer in the second event 2018, confirmed by staff interview, the</p>

laboratory failed to attain satisfactory scores in 4 of 6 analytes tested in the specialty of hematology. Findings: 1. API PT documentation for the second testing event of 2018 were reviewed. The following analytes received scores below 80%. Hematocrit (%) Sample Reported Expected Grade QBC-06 28 31-36 Unacceptable QBC-07 34 33-38 Acceptable QBC-08 23 21-25 Acceptable QBC-09 32 31-36 Acceptable QBC-10 32 26-30 Unacceptable Cumulative score: 60% Hemoglobin (g/dL) Sample Reported Expected Grade QBC-06 9.7 10.6-12.3 Unacceptable QBC-07 12.4 11.4-13.2 Acceptable QBC-08 7.9 7.3-8.6 Acceptable QBC-09 11.3 10.7-12.4 Acceptable QBC-10 11.4 9.1-10.6 Unacceptable Cumulative score: 60% Platelet Count (X10⁹/L) Sample Reported Expected Grade QBC-06 322 76-128 Unacceptable QBC-07 169 80-135 Unacceptable QBC-08 614 426-712 Acceptable QBC-09 129 76-127 Acceptable QBC-10 142 201-336 Unacceptable Cumulative score: 40% White Cell Count (X10⁹/L) Sample Reported Expected Grade QBC-06 6.5 9.7-13.3 Unacceptable QBC-07 11.3 12.7-17.2 Unacceptable QBC-08 6.1 4.9-6.8 Acceptable QBC-09 11.3 9.8-13.4 Acceptable QBC-10 11.0 5.3-7.3 Unacceptable Cumulative score:40% 2. In an interview at the site on 08-23-2018, testing person 1 stated she had verified that the values obtained in testing had been entered correctly and was in the process of investigating the issue. .

D5411

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)**

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:
 . Based on review of daily logs for hematology testing using the QBC Autoread analyzer from 2016, 2017 and 2018, confirmed by staff interview, the laboratory failed to perform system checks according to manufacturer's instructions. Findings: 1. The operator's manual for the QBC Autoread hematology analyzer states: "The Calibration Check Rod should be tested daily following the startup self-check procedures." (QBC Autoread Operator's Manual, Rev. A, p. 4-7, 4.5.1) 2. Review of daily logs for hematology revealed that, since the time of the previous survey, the calibration check had been performed on the following dates: 07-13-2016 08-16-2016 09-09-2016 03-09-2017 06-22-2018 3. In an interview at the site on 08-23-2018, testing person 1 stated that calibration checks were not routinely performed, and that the dates shown on the log were representative of the laboratory's performance of the procedure.