

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2147425	(X3) Date Survey Completed 10/22/2019
Name of Provider or Supplier Arkansas Pediatric Clinic	Street Address, City, State 16115 St Vincent Way, Ste 320, Little Rock, AR	
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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Through a review of the package insert for the Beckman Coulter quality control material, a review of the Control Review Sheets, and interviews with laboratory staff, it was determined the laboratory failed to follow manufacturer's instructions for the use of the Beckman Coulter hematology controls. Survey findings include: A. A review of the package insert for the Beckman Coulter quality control material revealed the material can be used a maximum of 20 times within the 35 day open expiration period. B. Through a review of the Control Review Sheets for control lots #67900 (low), #77900 (normal), and #87900 (high) it was determined the bottles were used 31 times each during the period of 9/21/2019 through the date of the survey (10/22/2019). C. In an interview, at 11:20 a.m. on 10/22/2019, the technical consultant confirmed the quality controls had been tested more than 20 times before the new bottles were opened.</p>
D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The</p>

laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Through a review of the RBC/PLT Control Review sheets for April 2019, Patient RBC/PLT Review sheets, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to document corrective actions when the platelet controls were unacceptable on seven of eight days from April 9, 2019 through April 17, 2019. Survey findings include: A. A review of the RBC/PLT Control Review sheets for 4/9/19 through 4/17/19 revealed the platelet control was unacceptable for two of three controls on 4/9, 4/10, 4/11, 4/15, and 4/17 and unacceptable for three of three controls on 4/12, 4/13, and 4/16. No corrective actions were documented and no acceptable quality control was available on those days. B. Through a review of Patient RBC/PLT Review sheets it was determined thirteen patients had platelet results reported on 4/9/19, nine patients had platelet results reported on 4/10/19, eight patients had platelet results reported on 4/11/19, nine patients had platelet results reported on 4/12/19, twelve patients had platelet results reported on 4/15/19, and eight patients had platelet results reported on 4/16/19. Patient platelet results were reported on six of eight days when quality control was unacceptable between 4/9 and 4/17. C. In an interview at 11:06 on 10/22/2019, the technical consultant (as listed on the form CMS-209) confirmed that patients were reported on six days in April when platelet quality control was unacceptable.