Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0311863	10/10/2018
Name of Provider or Supplier	**Street Address, City, State**	
Newport Pediatrics Pc	1829 Crowe Lane, Newport, TN	

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	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 a review of the hematology analyzer troubleshooting section, a review of patient summaries reported monthly, and interview with testing personnel, the laboratory failed to follow instructions for checking fingerstick samples and proceeding to zap the aperture when results appear unsatisfactory during 2018. Findings include: 1. A review of manufacturer instructions for troubleshooting questionable sample results requires the samples be checked for clots, mix samples prior to analysis, and allow samples to sit 3-5 minutes before analysis and before proceeding to zap aperture. 2. A review of patient summaries for the past six months showed each time questionable results were obtained, the testing person proceeded to zap apertures. 3. Interviews with testing personnel at 11:00 AM on October 10, 2018 confirmed manufacturer instructions were not followed for checking sample integrity prior to instrument intervention.
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 a review of competency checks for four testing personnel 2017 and 2018 and interview with the office managerr, the technical consultant failed to follow the 6 elements of competency required by the Centers for Medicare and Medicaid Services (CMS). Findings include: 1. Four of four testing personnel evaluated during 2017 and 2018 were not evaluated using the 6 elements of competency required by CMS. 2. An interview witht the office manager at 11:30 AM on October 10, 2018 confirmed four of four testing personnel evaluated during 2017 and 2018 were not evaluated using the 6 elements of competency required by CMS.