Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1106323	10/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Southern Pediatrics Pllc	740 Cool Springs Blvd, Suite 140, Franklin, 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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview with the laboratory director it was determined the laboratory failed to have 2 levels of acceptable controls for the Complete Blood Count Analyzer (CBC), (See D5447) and failed to take corrective action for quality control data that failed to meet the established limits, (See D5783) resulting in Immediate Jeopardy.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review of the Complete Blood Count (CBC) analyzer quality control printouts and interview with the lead testing person (TP) the laboratory failed to

	ensure 2 levels of quality control were run and in acceptable limits before reporting patients in 2017 and 2018 resulting in Immediate Jeopardy. Findings include: 1. Review of the CBC analyzer quality control printouts the laboratory failed to ensure 2 levels of quality control were run and in acceptable limits before reporting patients on September 1, 2017, August 23, 24, 29, 30, September 3, 17,18, 19, October 22, 23, 24, 25 in 2018. 2. Interview with the lead TP on October 30, 2018 at 11:30 am confirmed the laboratory failed to ensure 2 levels of quality control were run and in acceptable limits before reporting patients on September 1, 2017, August 23, 24, 29, 30, September 3, 17,18,19, October 22, 23, 24, 25 in 2018.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (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 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: Based on record review of the CBC analyzer quality control printouts, Out-of-Control policy and interview with the lead testing person(TP) the laboratory failed to perform corrective action for controls that failed to meet the established criteria from the manufacturer on patient testing in 2017 and 2018 resulting in immediate jeopardy. The findings include: 1. Review of the CBC analyzer quality control printouts the laboratory failed to perform corrective actions for controls that failed to meet the established criteria from the manufacturer on the following days of patient testing: a) 3 of 3 levels of control December 21, 2017 for Hemoglobin (HGB) and 2 out of 3 levels for Red Blood Cells (RBC) b) 2 of 3 levels of control December 28, 2017 for RBC and HGB c) 2 of 3 levels of control August 27, 2018 for White Blood Cells (WBC), RBC, HGB. d) 2 of 3 levels of control September 10, 2018 for WBC, RBC, HGB. 2. Review of the laboratory Out-of-Control policy indicate to: 1) Reanalyze the same control immediately, but do not report patients results. 2) Record both control values if the reanalyzed control now falls within acceptable limits. A note is made in the corrective action column of the quality control log. 3. Interview with the lead TP on October 30, 2018 at 1:00 pm confirmed the laboratory failed to follow Out-of - Control policy and document corrective actions for controls that failed to meet the established criteria from the manufacturer in 2017 and 2018.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview with the lead testing person, it was determined that the Laboratory Director failed to identify failures in Quality Assurance (See

	D6022) and failed to ensure that testing personnel have documented initial training, semi-annual competencies in 2018 (See D6029) resulting in Immediate Jeopardy.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a review of hematology instrument quality control printouts for September - December 2017 and August - October 2018, lack of quality control corrective actions, and an interview with the laboratory director, the laboratory director failed to provide appropriate monitoring and evaluation of the hematology quality control during the above period resulting in Immediate Jeopardy. Findings include: 1. Review of the hematology instrument quality control printouts from September - December 2017 and August - October 30, 2018 the laboratory director failed to monitor and evaluate the hematology quality control that exceeded the acceptable limits for the above dates. 2. Corrective action forms were unavailable for review for hematology controls that exceeded the acceptable limits from September - December 2017 and August - October 30, 2018 3. Interview with the laboratory director on October 30, 2018 at 1: 30 pm indicated she was unaware of out of range quality control or that quality control was not performed on days of patient testing during the above dates.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on lack of initial and semi-annual competency records and interview with the lead testing person it was determined the Laboratory Director failed to document initial training and semi-annual competencies for performing Complete Blood Count (CBC) on the CBC analyzer in 2018 resulting in Immediate Jeopardy. The findings include: 1. Documented initial training records for performing CBC's on the CBC analyzer were not available for review for testing personnel #1 and #2 in 2018. 2. Documented semi-annual competency records for performing CBC's on the CBC analyzer were not available for review for testing person #1 in 2018. 3. Interview with

	the lead testing person on October 30, 2018 at 1:30 pm confirmed the Laboratory Director failed to perform initial and semi-annual competencies for 2 out of 2 testing personnel that perform CBC's in 2018.