Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0707368	01/16/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Partners Of Augusta Llc	411 Town Park Boulevard, Evans, GA	

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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on January 16, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following Condition level deficiency was cited:
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 review of the Quality Control Documents and staff interview the laboratory failed to monitor and evaluate the overall quality of the Reichert Unistat Bilirubinometer Analyzer for the analyte of Total Bilirubin. Reference: 5447
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 review of the Quality Control (QC) Data, the manufacturer's operation manual, and staff interview, the laboratory failed to perform QC for the Reichert Unistat Bilirubinometer. The findings include: 1. Based on review of the QC data, the laboratory failed to perform QC on the Reichert Unistat Bilirubinometer, from 05/7 /2018, installation date to January 16, 2019. 2. The operation manual for the Reichert Unistat Bilirubinometer states under 7.1 " Use of Commercial Serum Controls, that Analysis of at least a normal and abnormal level of a commercial serum control, assayed for total bilirubin, is recommended for checking performance of the Reichert Unistat Bilirubinometer." Under 7.2 "Quality Control Frequency, QC procedures should be performed before and after each sample run in response to questionable patient results and / or mandated by local regulations." 3. Interview with the Laboratory Director, Practice Administrator, and staff # 2, at 2:45 in the Conference Room on January 16, 2019, confirmed that they were not performing QC on each day of patient testing. It was agreed that they would stop testing until QC material was available.