Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 01D0306320	**(X3) Date Survey Completed** 09/21/2021
Name of Provider or Supplier Pediatric Associates Of Auburn	**Street Address, City, State** 2901 Corporate Park Drive, Opelika, AL	
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**
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on a review of the CMS (Centers for Medicare and Medicaid Services) Casper reports, a review of the API (American Proficiency Institute) proficiency testing records, and a telephone interview with testing personnel, the surveyor determined the laboratory failed to successfully participate in Hematology testing for two consecutive testing events, Events #1 and #2, 2021. These failures resulted in an initial unsuccessful participation for the laboratory. The finding include: 1. A review of the CMS Casper reports revealed the laboratory failed to participate in Events #1 and #2, 2021, resulting in zero scores for Hematology [Complete Blood Count (CBC) testing]. 2. A review of the API proficiency testing confirmed the above noted findings. 3.

	During a telephone interview on 9/21/2021 at 8:20 AM, the testing personnel explained she was, at the time of testing Event #1, the only testing personnel to perform Proficiency Testing (PT), and was out of the office, due to a medical emergency. She further explained that while other testing personnel continued to run patient CBC specimens, they had not been trained to test proficiency samples. The surveyor discussed with the testing personnel the importance of rotating PT samples among all personnel who test patient specimens. The testing personnel stated this had also been explained by the surveyor, during her last on-site survey. The testing personnel stated the PT samples for Event #2 were tested late, one day past the submission deadline, simply because the PT was forgotten.
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on a review of the CMS (Centers for Medicare and Medicaid Services) Casper reports, a review of the API (American Proficiency Institute) proficiency testing records, and a telephone interview with testing personnel, the surveyor determined the laboratory failed to satisfactorily perform in Hematology testing for two consecutive testing events, Events #1 and #2, 2021. The laboratory did not participate in the proficiency testing, resulting in an initial unsuccessful participation for the laboratory. The finding include: 1. A review of the CMS Casper reports revealed the laboratory failed to participate in Events #1 and #2, 2021, resulting in zero scores for Hematology [Complete Blood Count (CBC) testing]. 2. A review of the API proficiency testing confirmed the above noted findings. 3. During a telephone interview on 9/21/2021 at 8:20 AM, the testing personnel explained she was, at the time of testing Event #1, the only testing personnel to perform Proficiency Testing (PT), and was out of the office, due to a medical emergency. She further explained that while other testing personnel continued to run patient CBC specimens, they had not been trained to test proficiency samples. The surveyor discussed with the testing personnel the importance of rotating PT samples among all personnel who test patient specimens. The testing personnel stated this had also been explained by the surveyor, during her last on-site survey. The testing personnel stated the PT samples for Event #2 were tested late, one day past the submission deadline, simply because the PT was forgotten.