Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0681418	08/10/2020
Name of Provider or Supplier	**Street Address, City, State**	
Anniston Pediatrics Inc	1001 Leighton Avenue, Anniston, 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 CMS Casper reports (#153/#155) and a telephone interview with laboratory staff on 8/10/2020 at 1:07 PM, the surveyor determined the laboratory failed to successfully participate in proficiency testing for Hematocrit (HCT) for two of three consecutive events, Event #3, 2019 and Event #2, 2020. These failures resulted in an initial unsuccessful proficiency testing participation for the laboratory. The findings include: 1. A review of the Casper reports revealed the laboratory failed HCT testing for two of three testing events, as follows: a) The laboratory scored sixty percent (60 %) for Hct on Hematology testing Event #3, 2019. b) The laboratory scored zero percent (0 %) for Hct for Event #2, 2020. 2. In a telephone interview on 8

	/10/2020 at 1:07 PM, the laboratory staff stated the proficiency testing was overlooked for Event #2, 2020, due to the current pandemic activities and remodeling at the facility. The staff further stated the proficiency testing has been done, and the laboratory is currently awaiting a report from CLIA. The laboratory continued patient testing during the time of the missed proficiency testing.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a review of CMS Casper reports (#153/#155) and a telephone interview with laboratory staff on 8/10/2020 at 1:07 PM, the surveyor determined the laboratory failed to perform satisfactorily in proficiency testing for Hematocrit (HCT) for two of three consecutive events, Event #3, 2019 and Event #2, 2020. These failures resulted in an initial unsuccessful proficiency testing participation for the laboratory (D2016). The findings include: Refer to D2016.