Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D1039182	05/17/2018
Name of Provider or Supplier	**Street Address, City, State**	
Annapolis Pediatrics	877 Baltimore Annapolis Blvd Ste 208, Severna Park, MD	

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
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the laboratory staff, the laboratory did not ensure that a copy of all PT documents were maintained by the laboratory for a minimum of two years from the date of the PT testing event. Findings: 1. PT records were reviewed from event 2, 2016 to event 1, 2018. Record review showed that for event 3, 2016 in Hematology and event 2, 2017 in Microbiology, the signed attestation statements, testing records, and PT results and scores were not present at the time of the survey; and 2. Original testing records and instrument print outs were not available for event 3, 2016 and event 3, 2017 in Microbiology and event 1, 2017 in Hematology. 3. During an interview on 5/17/18 at 12:15 PM, the laboratory staff confirmed that PT documents were missing for the above listed PT events.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory staff, the laboratory did not ensure that postanalytical quality assurance (QA) was performed to monitor, assess,

	and correct problems when they occur. Findings: 1. Patient records were reviewed and 3 were selected for postanalytical review. Upon review, it was found that 1 of 3 patients showed transcription errors. 2. Patient #1's hemoglobin was reported as 3.9 in the electronic medical record, but was listed as 11.3 on the instrument print out and on the hand written patient log. 3. During an interview on 5/17/18 at 12:15 PM, laboratory staff confirmed that Patient #1's hemoglobin was reported incorrectly.
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 review of quality assurance (QA) records and interview with laboratory staff, the laboratory director (LD) did not ensure that the QA program was maintained to identify failures and corrective actions taken when failures are identified. Findings: 1. The laboratory performs an annual "CBC Correlation" by running 2 blood specimens on the hematology analyzers at each of their 4 offices as well as sending it to a reference laboratory. The technical consultant (TC) indicates on the "CBC Correlations" form if the correlation is acceptable by marking "Y/N" and also signs their initials. 2. A review of "CBC Correlations" forms from 2016-2017 showed that the correlation performed in October, 2017 was not evaluated by the TC and determined to be acceptable. 3. During an interview on 5/17/18 at 12:15 PM, the laboratory staff confirmed that the laboratory's QA plan was not maintained to identify failures in quality as they occur.