Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0665745	01/16/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Associates Mont County	14955 Shady Grove Road Ste 380, Rockville, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of competency check evaluations and interview, the laboratory (lab) did not perform competency checks for the technical consultant. Findings: 1. The competency check assessments performed by the labs technical consultant were reviewed and these records did not include the directors assessment of the technical consultant: and 2. During interview on the morning of the day of survey, the technical consultant stated that the lab director did not perform competency assessments for her duties as technical consultant.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on record review and interview, the lab did not perform parallel quality control checks prior to placing a new lot number of control reagent in use in order to verify the manufacturer's stated values for each level of control (low, normal and high) when tested alongside the previous lot number of control reagent. Findings: 1. The test lab

	records did not include parallel quality control testing; and 2. The technical consultant stated that the lab did not perform parallel quality control checks.