Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0219525	11/08/2018
Name of Provider or Supplier	**Street Address, City, State**	
David Oneil Md Pa	17 Fontana Lane Suite 201, Baltimore, 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
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the written procedure and interview with the technical consultant (TC), the laboratory did not establish an Individualized Quality Control Plan (IQCP) for performing serum HCG testing. Findings: 1. The laboratory did not establish IQCP for performing serum HCG testing. 2. The laboratory did not perform quality control procedures with a positive and negative external control 3. The laboratory did not perform an IQCP that included a risk assessment, quality control plan, and a quality assessment plan. 4. The TC stated that they may run a serum HCG once a year. When performed they run a external positive and negative control.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

	This STANDARD is not met as evidenced by: Based on review of competency procedures , educational requirements for performing moderately complex testing , and interview with the technical consultant (TC), the TC did not ensure all testing persons (TP) education requirements for performing red cell antigen and serum HCG testing. Findings: 1. Four out of the five TP performing moderate complex patent testing had a diploma available on the day of the survey. 2. The TP that did not have a diploma had competency procedures performed by TC during the year 2017 and 2018. 3. On the day of the survey the TC stated that the TP would get the diploma and forward. As of the time of this report the diploma has not been received.