Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0645245	05/03/2018
Name of Provider or Supplier	**Street Address, City, State**	
Brevard Community Pathology Services Llc	1555 Saxon Blvd Ste 502, Deltona, FL	

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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on record review and interview, the facility failed to assess and correct problems with verification of accuracy of C-reactive protein (CRP), Testosterone, and Human chorionic gonadotropin (HCG) for 2016-2017. The findings include: The record review of the 2016-2017 American Association of Bioanalysts (AAB) Proficiency Testing Service testing results for the laboratory showed the following unsatisfactory grades: The 3rd quarter AAB Chemistry 2016 analyte serum HCG showed a score of 20% with no corrective action documented. The 1st quarter AAB Chemistry analyte Testosterone showed a score of 0% due to being reported in the wrong unit of measurement. The 3rd quarter AAB Non-Chemistry 2017 analyte CRP scored 50%. The correction action showed this was due to clerical error. There was no documentation for any events to show training of staff or changes in procedure to prevent the failures from occurring in the future. The interview with the General Supervisor on 5/3/18 at 11:00am confirmed the lack of documentation to show training of staff or changes in procedure occurred as part of the correction action.
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 record review and staff interview, the facility failed to ensure quality control was performed each day of patient testing for two of two years reviewed (2016-2017) for the OSOM HCG Combo test kit. Findings include: 1. The record review of quality control (QC) records on 5/3/18 for the OSOM HCG Combo test showed QC was performed per manufacturer instructions which states "each new lot and with each untrained operator". The OSOM HCG Combo test is classified as "waived" for urine samples and "moderate complexity" for serum both of which are performed at the laboratory. (The manufacturer instructions for "moderate complexity" testing is less stringent than CLIA requirements). The interview with the general supervisor on 5/3 /18 at 11:00am confirmed that daily QC is not performed when a serum sample is tested.