Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0645245	08/13/2019
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
D0000	A recertification survey was conducted on August 13, 2019 at Medical Arts Laboratory of Deltona. The facility was not in compliance with CFR 493, Requirements for Laboratories.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory was not enrolled in proficiency testing (PT) for the first event in 2019 for the specialty of Chemistry, and subspecialties of Endocrinology and Toxicology. The findings include: Review of PT records and interview with the General Supervisor at 11:00 a. m. on August 13, 2019 revealed that the laboratory did not have documentation to indicate that PT had been performed for the specialities of Chemistry, Endocrinology, and Toxicology for the first event of 2019. Testing performed under this specialty includes: Alanine Aminotransferase, Albumin, Alkaline Phosphatase, Amylase, Aspartate Aminotransferase (AST), Total Bilirubin, Total Calcium, Chloride, Cholesterol, High Density Lipoprotein Total Cholesterol, Creatine Kinase, Creatinine, Glucose, Total Iron, Magnesium, Potassium, Sodium, Total Protein, Triglycerides,

	Urea Nitrogen, Uric Acid, Free Thyroxine, Human Chorionic Gonadotropin, Triiodothyronine, Thyroid-Stimulating Hormone, Thyroxine, Carbamazepine, Digoxin, Phenobarbital, Phenytoin, Theophylline, and Valproic Acid. .
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on record review of American Association of Bioanalysts (AAB) Proficiency Testing Hematology proficiency testing and interview with the General Supervisor, the laboratory failed to score at least 80% for the analyte Partial Thromboplastin Time in the 3rd event of 2018. The findings include: Review of AAB proficiency testing showed a score of 0% in the 3rd testing event of 2018 for the following test: Partial Thromboplastin Time. During an interview on 8/13/19 at 11:03am the General Supervisor confirmed the failed proficiency testing score. .
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to perform preventative maintenance on the microscope and centrifuge for 2 out of 2 (2018-2019) years reviewed and the facility failed to perform and document all weekly and monthly maintenance for the Sysmex XS 1000i for 2 of 2 years reviewed (2018-2019). The findings include: 1. Review of the maintenance sticker on the Nikon microscope showed maintenance was performed on 8/2017, and next maintenance was due on 8/18. No documentation of yearly preventative maintenance for the microscope was provided. Review of the maintenance sticker on the Power Spin Fx and LW Scientific C5 Centrifuge showed the last service was on 2/18, and service was due on 2/19. No documentation of yearly preventative maintenance for the centrifuges was provided. During an interview on 08/13/19 at 12:00 PM the General Supervisor confirmed that there was no documentation of preventative maintenance being performed. 2. The record review on 8/13/19 of the Sysmex XS 1000i maintenance records showed no weekly maintenance was performed from April 2018 through July 2019. No monthly maintenance was performed from December 2018 through July 2019. The interview with the General Supervisor on 8/13/19 at 11:30am confirmed the weekly and monthly maintenance documentation was missing. .
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or

	specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to perform calibrations every 6 months on the Sysmex XS 1000i and the ACL Coagulation instrument for two of two years reviewed (2018-2019). The findings include: Review of calibration records for the Sysmex XS 1000i showed calibrations were performed 9/29/2017 and 9/26/2018. Calibration records for the ACL showed calibrations were performed on 3/2018, 1/2019, and 3/2019. During an interview on 8/13/2019 at 11:40am with the General Supervisor, it was confirmed the every 6 month calibrations were missing for each instrument. .
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of AAB proficiency testing records and staff interview, the Laboratory Director failed to recognize that the laboratory was not enrolled in proficiency testing (PT) for the first testing event of 2019. The findings include: Review of the CASPER Report 0096D showed blank Event Score for the 1st testing event of 2019 for the specialty of Chemistry and subspecialties of Endocrinology and Toxicology. Review of proficiency testing records at the laboratory on 8/14/19 showed no record of PT being performed for the specialty of Chemistry and subspecialties of Endocrinology and Toxicology. During an interview on 8/13/19 at 11:15am, the General Supervisor was unable to locate test scores for the 1st event of 2019 and stated the fee was not paid on time for enrollment.