Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	09D0208053	07/29/2021
Name of Provider or Supplier	**Street Address, City, State**	
B & W Stat Laboratory	3104 Georgia Ave Nw, Washington, DC	

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
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on observation of the laboratory at 1:00 PM and interview with the testing person, the laboratory failed to report SARS-CoV-2 test results to the local health department as required by the Public Health Emergency for the detection of COVID-19. Findings: 1. The laboratory has been performing COVID-19 testing since March 2020. 2. The laboratory has not reported positive nor negative test results as required by the Public Health Emergency. 3. The testing person stated that he tried to report the results to the Health Dept but the spreadsheet on the website did not work. 4. During the interview the testing person was asked did the lab try to submit test results by email, fax, or mail. The testing person stated no. 5. The testing person stated that the Health Dept did not want to receive COVID-19 test results submitted any other way than by spreadsheet. 6. During the interview the testing person was asked to confirm the Health Dept did not want to receive test results any other way than by spreadsheet. The testing person was unable to confirm. 7. The testing person confirmed that the lab failed to report SARS-CoV-2 test results to the local health department as required by the Public Health Emergency for the detection of COVID-19.

D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on review of patient test requisitions and interview with the testing person(TP), the laboratory failed to acquire a written nor a electronic test request from an authorized person prior to performing patient testing. Findings: 1. The laboratory performs COVID-19, Toxicology, RPR, and Pregnancy testing on a patient walk in basis and test samples received from area facilities needing patient testing. 2. The laboratory did not receive an authorized test request from an authorized provider prior to performing testing. 3. The laboratory has an inhouse test requisition and an off site test requisition for performing testing. 4. Review of ten off site test requisitions during the year 2020-2021 for Toxicology testing showed that the authorized physician ordering the test did not sign nor date the requisition prior to the test being performed in the section for "Authorizing Physician" 5. Review of the inhouse test request did not show that an authorized request was received by an authorized provider prior to performing patient testing. 6. The TP stated that the lab has never required an authorized test request prior to performing any patient testing and that it was not needed.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on record review and interview with Testing Person #1, the laboratory did not ensure that medications, or other substances used by the patient were reported on the requisition and available for review prior to reporting patient test results for urine toxicology. Findings: 1. A patient urine specimen for toxicology testing collected on 4 /20/21 and reported 4/21/21 was interpreted as abnormal for the presence of buprenorphine. The requisition for the patient did not include a list of medications or substances the patient is taking; 2. During interview in the afternoon of the day of survey, Testing person #1 stated that the clinic that the patient is seen uses a medication to treat addiction, but this medication was not given on the requisition; and 3. The clinical consultant would not have a list of medications/substances the patient

	is taking to check for reactivity or cross reactivity in order to determine the result interpretation.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with the testing person and laboratory director, the laboratory failed to have written step by step procedures for all areas of the laboratory where patient testing was performed. Findings: I 1. The laboratory performs COVID-19, Toxicology, RPR, and Pregnancy testing on a patient walk in inhouse basis and test samples received from outside facilities needing patient testing. 2. The laboratory did not have a written procedure for collecting specimens and performing COVID-19 testing on the Centaur analyzer. 3. The laboratory did not have a written procedure for the review and release of Toxicology results. 4. The laboratory did not have a written procedure for how samples are distributed for testing after accessing was completed. 5. The laboratory did not have a written procedure for documenting the cooler temperature for samples that are transported and received from an outside facility. 6. The laboratory has a policy that the cooler temperature must be maintained within 2-8 Degree Celsius. 7. The laboratory did not have documentation that cooler temperatures were ever performed and documented. 8. The testing person confirmed that written step by step procedures for all areas of the laboratory where patient testing was performed was not available. II 1. The laboratory written procedure for RPR testing did not include instructions for performing titers and quality control for titers. The laboratory performed RPR titers for proficiency testing reported in 2019, and during interview with Testing Person #1 on the afternoon of the day of the survey, confirmed that there was no procedure for performing RPR titers. 2. The laboratory did not have a written procedure for performing serum HCG testing and did not have a written procedure for performing quality control for HCG testing each day a serum HCG test is performed.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on the review of the written procedure manual and interview with the testing person, the laboratory failed to provide all documents that were acquired during the COVID-19 antibody and antigen testing validation performed on the chemistry

	analyzer. Findings: 1. The laboratory has been performing COVID-19 testing since March 2020 on the Centaur analyzer. 2. The testing person stated that a validation was performed for COVID-19 testing on the Centaur analyzer. 3. The SARS-CoV-2 IgG comparison study showed that two results (specimen CR095 and CR096 did not agree with the results obtained by the established analyzer. There was no written discussion of these two discordant results. 4. The laboratory did not have a written procedure stating how the Covid-19 validation was performed, and the parameters for acceptability 5. The laboratory did not have records showing the directors review and approval of the Covid-19 validation studies.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with the testing person, the laboratory failed to perform calibration verification procures on the chemistry analyzer. Findings: 1. The laboratory has been performing COVID-19 testing since March 2020 on the Centaur analyzer. 2. The lab did not perform calibration verification procedures on the chemistry analyzer. 3. The testing person stated that calibration verification procedures were performed on the chemistry analyzer. 4. The testing person failed to provide the calibration verification procedures during the time of the survey.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic,

	and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with the testing persons, the laboratory director (LD) failed to ensure that written duties and responsibilities were available for all persons involved in laboratory testing. Findings: 1. The laboratory performs Toxicology testing. 2. The LD failed to specify in the written the duties and responsibilities who is responsible for reviewing and releasing Toxicology test results to the provider. 3. Testing person 1 stated that he does the review of the Toxicology results prior to the release to the provider. 4. Observation of testing person 2 at 1:30 PM showed that this person can also review and release Toxicology results to the provider. 5. Testing person 1 stated that he is always beside testing person 2 when she reviews Toxicology results and release to the provider. 6. Testing person 1 confirmed that written duties and responsibilities were not available for all persons involved in laboratory testing.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with the testing person, the technical consultant failed to have written step by step procedures for all areas of the laboratory where patient testing was performed. Findings: Refer to D5401
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on the review of the written procedure manual and interview with the testing person, the technical consultant failed to ensure that all documents acquired during the COVID-19 antibody and antigen test validation performed on the chemistry analyzer were available during the time of the survey. Findings: Refer to D5421 1. The laboratory has been performing COVID-19 testing since March 2020 on the Centaur analyzer. 2. The testing person stated that a validation was performed for COVID-19 testing on the Centaur analyzer. 3. The SARS-CoV-2 IgG comparison study showed that two results (specimen CR095 and CR096 did not agree with the results obtained by the established analyzer. There was no written discussion of these two discordant results. 4. The laboratory did not have a written procedure stating how the Covid-19

	validation was performed, and the parameters for acceptability 5. The laboratory did not have records showing the directors review and approval of the Covid-19 validation studies.
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 training and competency records and interview with the testing person, the technical consultant (TC) failed to provide training and competency checks when the lab started testing for COVID-19 antigens and antibodies. Findings: 1. The laboratory has been performing COVID-19 testing since March 2020 on the Centaur analyzer. 2. The TC failed to perform training and competency checks for lab personnel when the lab stated testing for COVID-19 antigens and antibodies. 3. The testing person confirmed that the TC failed to perform training and competency checks for lab personnel when the lab started testing for COVID-19 antigens and antibodies.