Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	09D0208053	12/14/2018
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
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 the review of test requisition slips and confirmation by interview with the Laboratory Director (LD) and the Technical Consultant (TC), the laboratory failed to ensure that each test requisition included the test to be performed for two (2) of the two (2) test requisition slips randomly selected for review (Accession number 439136 and 439137). The findings included: 1. Review of the test requisition slips for Accession numbers 439136 and 439137 revealed that the requisition slips did indicate what test is requested.The laboratory uses a manual test requisition slip that accompany each urine specimen. Note: The laboratory has a contractual agreement with a drug treatment center to perform urine drug screen that included (Amphetamine, Benzodiazepine, Cocaine, Methadone, Opiate, Phencyclidine, Marijuana, Buprenorphine, and 6 AM-heroin metabolite) for all specimens sent by the treatment center. 2. Interview with the LD and TC on December 14, 2018, at

	approximately, 12:45 PM confirmed that the test requisition slips did not include what test is requested. Further interview revealed that although each slip did not include the test, based on the contractual agreement the laboratory tests all specimens for the aforementioned drugs.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on the review of test requisition slips, and the laboratory's monthly quality assessment, and interview with the Laboratory Director (LD) and the Technical Consultant (TC), it was determined that the laboratory's pre-analytic system quality assessment failed to identify that test requisition slips lacked the test to be performed. Two (2) of the two (2) test requisition slips randomly selected for review lacked the test to be performed (Accession number 439136 and 439137). Cross-reference D5305.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of records (the laboratory's policies and procedures manual, manufacturer's instructions, and quality control data and Levey-Jennings charts); and interview with the Laboratory Director (LD) and Technical Consultant (TC), the laboratory failed to establish criteria for quality control (QC) acceptability for each drug included in the qualitative urine drug screen. Three (3) of the three (3) months of QC records randomly selected for review failed to provide evidence that the laboratory established criteria for control acceptability (July, August and September 2018). The findings included: 1. Review of the laboratory's policies and procedures for urine drug screen entitled "QUALITY CONTROL AND ASSESSMENT" revealed instructions to evaluate daily control acceptability by evaluating the Standard Deviations (SD). However, there was no procedure for developing the control acceptable limits. 2. Review of the BIO-RAD, manufacturer's package insert for Liquicheck (the qualitative urine toxicology control) did not reveal control ranges for the qualitative assays performed on the laboratory's analyzer (AU640). Further review

	of the insert revealed instructions for each laboratory to establish its own parameters. Note: The laboratory's drug screen profile included the following: Amphetamine, Benzodiazepine, Cocaine, Methadone, Opiate, Phencyclidine, Marijuana, Buprenorphine, and 6 AM-heroin metabolite. 3. The laboratory has programed the AU640 analyzer with QC acceptable ranges for the aforementioned drugs. However, there was no evidence that the ranges were established based on each lot of controls, for example, according to the review of Levey-Jennings (LJ) chart for Phencyclidine (PCP) and Amphetamine from July 1 through September 28, 2018, there was no evidence that the ranges were established for two different lots of the negative control. Lot Number (#) 70741 used in July 2018 and Lot #70751 used in August and September 2018. 4. Interview with the LD and the TC on December 14, 2018, at approximately, 12:00 Noon confirmed the lack of evidence for establishing control ranges.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: I. Based on the review of the laboratory's quality control (QC) log and Levey-Jennings (LJ) graph and the monthly analytic system quality assessment; and interview with the Laboratory Director (LD) and Technical Consultant (TC), the laboratory's post analytic system quality assessment failed to address QC values that were below Standard Deviations (SD) from July through September in 2018. Two (2) of the four (4) controls randomly selected for review were outside 2SD (positive QC for PCP and negative QC for Amphetamine). The findings included: A. Review of the laboratory's policies and procedures entitled "QUALITY CONTROL AND ASSESSMENT" revealed instructions to evaluate daily QC acceptability by evaluating the Standard Deviations. The policy further indicated that control value that exceeded the mean +/- 2SD but not +/-3SD is a warning sign that requires attention. B. Review of the LJ graph for Phencyclidine (PCP) and Amphetamine for July 1 through September 28, 2018 revealed that the positive QC for PCP and the negative QC for Amphetamine had readings outside 2SD for several days without any corrective actions as detailed below: 1. Review of the positive QC LJ graph for PCP revealed that the +/-2SD range for the control was 147-247 nanogram (ng) per milliliter (ml). According to the laboratory's QC log, the positive control for PCP was below 147 ng/ml on the following days: (a) 21 of the 21 days of testing in July 2018 7 /2/18; 7/3/18; 7/5/18; 7/6/18; 7/9/18; 7/10/18 ; 7/11/18; 7/12/18; 7/13/18; 7/16/18; 7/17 /18; 7/18/18; 7/19/18; 7/20/18; 7/23/18; 7/24/18; 7/25/18; 7/26/18; 7/27/18; 7/30/18; and 7/31/18. (b) 14 of the 23 days of testing in August 2018 8/1/18; 8/2/18; 8/6/18; 8/7 /18; 8/8/18; 8/9/18; 8/10/18; 8/14/18; 8/23/18; 8/27/18; 8/28/18; 8/29/18; 8/30/18; and 8/31/18. (c) 8 of the 18 days of testing in September 2018 9/4/18; 9/5/18; 9/6/18; 9/7 /18; 9/10/18; 9/11/18; 9/12/18; and 9/19/18. 2. Review of the negative QC LJ graph for Amphetamine revealed that the +/-2SD range for the control was 0-200 ng/ml. According to the laboratory's QC log, the negative control for Amphetamine was below zero (0) ng/ml on the following days: (a) 8 of the 21 days of testing in July 2018 7/10/18; 7/12/18; 7/17/18; 7/18/18; 7/19/18; 7/23/18; 7/24/18; and 7/21/18. (b) 9 of the 23 days of documented testing in August 2018 8/2/18; 8/3/18; 8/7/18; 8/14/18; 8

	/16/18; 8/20/18; 8/21/18; 8/22/18; and 8/24/18. (c) 10 of the 19 days of documented testing in September 2018 9/5/18; 9/6/18; 9/7/18; 9/10/18; 9/12/18; 9/13/18; 9/14/18; and 9/18/18; 9/20/18; and 9/21/18. C. Review of the laboratory's monthly quality assessment record for July through September revealed that there was -2SD to -3SD bias for both controls (positive QC for PCP and negative QC for Amphetamine). However, there was no evidence of investigation to address the stated bias. D. Interview with the LD and TC on December 14, 2018, at approximately, 12:30 PM confirmed that the monthly analytic system quality assessment did not address the control values that were below 2SD. II. Based on the review of records (the laboratory's policies and procedures, manufacturer's instructions, the laboratory's analytic system quality assessment records and quality control data and graphs) and interview with the Laboratory's Director (LD) and Technical Consultant (TC), the laboratory's analytic system quality assessment failed to identify the laboratory's failure to establish criteria for quality control acceptability. Three (3) of the three (3) months of control records randomly selected for review lacked evidence that the laboratory established criteria for quality control acceptability (July, August and September 2018) for each lot of controls used. Cross-reference D5469. NOTE: Repeat citation from 4/18/2007, 2/1/2013 and 5/3/2017 re-certification surveys
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of test reports, and the laboratory's monthly post analytic system quality assessment records, and interview with the Laboratory Director (LD) and the Technical Consultant (TC), the laboratory's post-analytic system quality assessment failed to identify the reporting error ("Cutoff "points referred as "Reference Range"). Two (2) of the two (2) urine drug screen reports randomly selected for review revealed that each urine drug screen result was reported with a "Reference Range" instead of a "Cutoff" point (Accession number 439136 and 439137). The findings included: 1. According to the review of the urine drug screen for Accession numbers 439136 and 439137, the laboratory reported each drug screen result with a "Reference Range" instead of a "Cutoff" point. The laboratory's drug screen included the following drugs: Amphetamine, Benzodiazepine, Cocaine, Methadone, Opiate, Phencyclidine, Marijuana, Buprenorphine, and 6 AM-heroin metabolite. Although the values reported for Accession numbers 439136 and 439137 were the correct cutoff points for each drug, the report identified the "Cutoff" point as "Reference Range". 2. Interview with the LD and TC on December 14, 2018, at approximately, 12:40 PM confirmed the reporting error. Further interview revealed that the error was a result of a software update to the laboratory's information system that replaced "Cutoff" with "Reference Range". 3. There was no documented evidence that the laboratory's monthly post-analytic system quality assessment identified the aforementioned error. NOTE: Repeat citation from 3/17/2009 and 5/3/2017 re-certification surveys
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control

	program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on the review of records (the laboratory's policies and procedures manual, manufacturer's instructions, and quality control data and Levey-Jennings charts); and interview with the Laboratory Director (LD) and Technical Consultant (TC), the TC failed to establish criteria for quality control (QC) acceptability for each drug included in the qualitative urine drug screen. Three (3) of the three (3) months of QC records randomly selected for review failed to provide evidence that the TC established criteria for control acceptability (July, August and September 2018). Cross-reference D5469. NOTE: Repeat citation from 5/3/2017 re-certification survey.