

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  09D0208053	<b>(X3) Date Survey Completed</b>  04/27/2018
<b>Name of Provider or Supplier</b>  B & W Stat Laboratory	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5205</b>	<p>COMPLAINT INVESTIGATIONS CFR(s): 493.1233</p> <p>The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.</p> <p>This STANDARD is not met as evidenced by: Based on the review of records (final laboratory results and reports labeled as duplicate) and face-to-face interview with the complainant on April 11, 2018 at 11:00 AM and with the Laboratory Director (LD) via telephone on April 27, 2018 at approximately 11:00 AM, the laboratory failed to establish a complaint investigation mechanism. There was no evidence that the complaint regarding wrong patient name on a report was investigated for one (1) of the one (1) patient's toxicology result that was reported with wrong patient name (Patient with laboratory number 8047178). The findings included: 1. Review of final report dated 2/16/18 (obtained from the complainant) revealed a wrong name for a Patient with laboratory number (#) 8047178. According to an interview with the complainant, the clinic notified the laboratory on 2/16/18 that the report the laboratory sent on 2/16/18 was for a patient that was last seen in the clinic in 2015. Further interview revealed that the laboratory then issued a report labeled duplicate on 2/20/18 for the correct patient. 2. On April 27, 2018, the laboratory staff were asked how the error occurred. According to the staff, the clinic had issued two different patients same medical record number. The laboratory test order dated 4/25/15 and 2/15/18 revealed that two different patients have the same medical record number. On 2/16/18, the laboratory staff generated a specimen label for the patient seen on 4/25/15 instead of 2/15/18 resulting with a report for the wrong patient. It should be noted that the staff were unaware of the aforementioned error until the surveyor brought it to their attention. 3. Interview with the LD confirmed the lack of investigation regarding a report being generated for the wrong patient on 2/16/18.</p>

**D5821**

**TEST REPORT**

CFR(s): 493.1291(k)

When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report.

This STANDARD is not met as evidenced by:

Based on the review of records (final laboratory results and reports labeled as duplicate) and face to face interview with the complainant on April 11, 2018 at 11:00 AM and with the Laboratory Director (LD) via telephone on April 27, 2018 at approximately 11:00 AM, the laboratory failed to establish a record keeping mechanism to retain a copy of the incorrect report for one (1) of the one (1) patient's result that was reported with wrong patient name (Patient with laboratory number 8047178). The findings included: 1. Review of final report dated 2/16/18 (obtained from the complainant) revealed a wrong name for a Patient with laboratory number (#) 8047178. According to an interview with the complainant, the clinic notified the laboratory on 2/16/18 that the report the laboratory sent on 2/16/18 was for a patient that was last seen in the clinic in 2015. However, the laboratory had no copy of the initial report with the wrong patient name. The record was updated to reflect the correct name and a duplicate report generated. The laboratory had no mechanism to retain original reports. 2. According to interview with the LD, the laboratory's information system is unable to retain a copy of the original report. Note: this is a repeat citation from 5/3/2017 re-certification survey.

**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 the review of records (final laboratory results and reports labeled as duplicate) and face to face interview with the complainant on April 11, 2018 at 11:00 AM and with the Laboratory Director (LD) via telephone on April 27, 2018 at approximately 11:00 AM, the laboratory failed to establish a quality assessment protocol for the post analytic phase of testing to retain a copy of the incorrect report for one (1) of the one (1) patient's toxicology result that was reported with wrong patient name (Patient with laboratory number 8047178). Cross reference D5821  
NOTE: Repeat citation from 3/17/2009 and 5/3/2017 re-certification surveys.