Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0666165	04/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
Wv Office Of Laboratory Services	167 11th Avenue, South Charleston, WV	

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 review of records and interview with staff, the laboratory failed to establish written policies and procedures for verification of accuracy of tests being performed that are not included in subpart I as required at 493.1236(c). Findings include: 1. Testing person #7 stated during interview at 11:10 am on 4/4/2018 that there had been no proficiency testing challenges for the Zika ELISA (enzyme-linked immunosorbent assay). 2. Review of Zika IgM Capture ELISA records revealed no written policy in place for twice yearly verification of accuracy of the Zika ELISA test. 3. Technical supervisors #1 and #4 stated during interview at 10:40 am on April 5, 2018 that there had been no proficiency challenges for the Eastern Equine Encephalitis (EEE) test during 2016 or 2017. 4. Review of EEE records revealed no written policy in place for twice yearly verification of accuracy of the EEE test.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results.

	(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the Serodia-TP-PA (Treponema pallidum particle agglutination) procedure approved by the director on 6/1/2013 and interview with technical supervisor #2 at 2:00 pm on April 5, 2018, the laboratory procedure did not include the corrective action to take if the State Lab Positive or State Lab Negative control failed to perform as expected.
D5789	TEST RECORDS CFR(s): 493.1283(b) Records of patient testing including, if applicable, instrument printouts, must be retained. This STANDARD is not met as evidenced by: Based on review of Zika ELISA testing records and interview with staff, the laboratory failed to retain all records of patient testing that took place on 2 of 3 reviewed dates. Findings include: 1. Record review revealed that sample E17M016032 was reported on 8/14/2017. The testing records did not include the plate map record showing patient location on testing plate. 2. Record review revealed that sample E17M031404 was reported on 12/14/2017. The plate reader records showed that a sample was tested in duplicate but the sample identification was not recorded. 3. Testing person #7 confirmed during interview at 10:15 am on 4/4/2018 that the patient identification records were not present.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation, review of the BD MGIT 960 Operating Procedure approved by the director on 2/11/2015, mycobacteriology test records from December 2017 and January 2018, and interview with staff; the laboratory did not document the quality assessment activities undertaken when the MGIT instrument malfunctioned. Findings

	include: 1. During a tour of the mycobacteriology laboratory at approximately 9:30 am on 4/5/2018, the surveyor noted that 1 of 3 drawers on the MGIT instrument had an exclamation point illuminated. Technical supervisor #4 stated that drawer B was not currently working. 2. The MGIT 960 Inventory Report for 12/7/2017 showed that 35 samples were present in drawer B. 3. A notation that manual readings were taken appeared on the MGIT 960 Inventory Report for the following dates: 12/30/17, 1/5 /18, 1/12/18 and 1/19/18. 4. Technical supervisors #1 and #4 and testing person #4 stated during interview at 9:50 am on 4/5/2018 that revised procedures were not in place describing the manual reading backup method. 5. Technical supervisor #1 stated during interview at approximately 9:55 am that the laboratory was intending to replace the instrument but that the corrective action and intermediate steps being taken currently were not being documented as quality assessment activities.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on review of verification documentation and interview, the laboratory director did not ensure that the report summarizing the results of verification testing of the In Bios Zika IgM Capture ELISA reflected the data actually generated. Findings include: 1. The surveyor reviewed the verification study approved on 6/26/2017 by the technical supervisor at the time and by the current laboratory director on 6/28/2017 entitled In Bios Zika Detect IgM Capture ELISA Establishment and Verification of Performance Specifications. 2. The verification record stated that the laboratory had achieved 96.15% accuracy and 100% precision, and that the assay, "...performs as per the manufacturer's specifications in the hands of the OLS technologists." 3. Appendix B of the verification study included manufacturer data summarized as having positive percent agreement for Zika 100%. 4. The laboratory data in Appendix A of the verification study showed 96.15% accuracy was obtained due to 2 of 25 tests expecting to be positive yielding negative results. 5. The laboratory data in Appendix A of the verification study showing 100% precision did not account for the 2 tests that did not yield expected results. 6. There was no discussion in the verification study of the 2 outlier results. 7. During interview at 2:50 pm on 4/5/2018 the laboratory director confirmed that the precision summary did not match the data obtained.