Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0710716	05/02/2018
Name of Provider or Supplier	**Street Address, City, State**	
Baltimore City Health Dept Druid Sexual Health Cli	1515 W North Avenue/2nd Floor, Baltimore, MD	

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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on record review, the lab director did not sign attestation statements to document proficiency testing samples were tested in the same manner as patient specimens. Findings: 1. The lab director did not sign the attestation for event D5-A 2016 (Gram stain); 2. The lab director did not sign the attestation for event RHCVW-A 2016; 3. The lab director did not sign the attestation for event RHCVW-B 2016; 4. The lab director did not sign the attestation for event D5-A 2017 and the lab did not have handling, preparation, processing, examination, and reporting records for this event; 5. The lab director did not sign the attestation for event VM-A 2017; 6. The lab director did not sign the attestation for event VM-B 2017; and 7. The lab director did not sign the attestation for event RHCVW-B 2017 and the lab did not have handling, preparation, processing, examination, and reporting records for this event.
D3011	FACILITIES CFR(s): 493.1101(d)

	Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on record review and interview with lab staff on the day of survey, the lab manager and lab director did not review and sign the "MSDS Acknowledgement Roster" in the written procedure, to show that this training was conducted.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on record review and interview with lab staff, the lab did not review and provide documentation to show that it evaluated proficiency test performance for RPR titers. Findings: 1. In 2017 all three events (identified as events A, B and C) were given a code 11 by the proficiency test provider. The code means the lab was unable to perform the RPR titer and the proficiency test provider states that the lab will provide documentation to show that it was unable to perform the tests; 2. The lab did not prepare a statement or provide documentation showing why the lab failed to participate in each event; and 3. Lab staff stated, during interview on the day of survey, that the lab discontinued RPR titers. The labs written procedure for performing RPR titers was not retired and still in the procedure manual.
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 record review and interview with lab staff, the lab did not update the written procedures to ensure they were current. Findings: 1. The lab has a chart (procedure) to document temperatures of a bacteriology incubator. Lab staff stated, during interview on the day of survey, that the incubator procedures are no longer performed by the lab; 2. The RPR worksheet (procedure) used by the lab is not labeled with the labs identification information (name, address); and 3. The daily gram stain quality control record (procedure) is not labeled with the labs identification information (name, address).
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 written procedures and interview with lab staff, the labs written procedures were not up to date for the immunology, bacteriology and serology testing performed. Findings: 1. The RPR titer procedure was not retired from the written procedure, even though lab staff stated that the procedure was no longer performed, in addition the procedure did not include quality control testing for the titers; 2. The Gram stain procedure was not updated and still includes procedures for preparing stains and staining reagents by weighing dry powders and mixing them with liquid reagent, even though the lab uses already prepared stain reagents; 3. The laboratorys written procedure for choice of specimen for rapid HIV testing was not specific to ensure the lab was using the intended specimen. The lab uses the Alere Determine HIV-1/2 Ag/Ab Combo test kit for HIV testing. Lab staff stated that the test is performed on blood collected in a white stoppered tube containing silicone, but the written procedure states that the lab uses blood from a skin puncture. lab staff stated that the HIV test is waived and the manufacturer states that the test is waived only if the lab uses fingerstick capillary blood but is moderate complexity for serum and venous whole blood. The labs written procedure states that the white stoppered gel tube is used for the collection of blood that will be submitted to the reference lab for confirmatory HIV testing. 4. The laboratorys written procedure for choice of specimen for the Ora quick HCV rapid antibody test was not specific to ensure the lab was using the intended specimen. The lab uses the Ora quick HCV rapid antibody test. Lab staff stated that the test is performed on blood collected in a white stoppered tube containing silicone, the labs written procedure does not specify the specimen type. lab staff stated that the test is waived but the manufacturer states that it is only waived if the lab uses fingerstick capillary blood or venous whole blood collected in an appropriate anticoagulant preservative, and moderate complexity for serum and other specimens. The labs written procedure states that the white stoppered gel tube is used for the collection of blood that will be submitted to the reference lab for confirmatory testing. 5. The labs written procedure did not include instructions to check patient identification prior to collection of capillary and venous blood, the procedures did not state the type of identification required to positively identify patients for blood collection; and 6. The labs written procedure for specimen labels on page 6 states to label specimens appropriately, but is not specific in describing what appropriate labeling is.
D5407	PROCEDURE MANUAL

	CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the labs written procedures, the lab did not ensure that procedures and changes in procedures are approved, signed and dated by the lab director. Findings: 1. The current lab director has not approved, signed and dated the labs written procedures; and 2. The Alere package insert for HIV testing was not approved, signed and dated by the lab director. The test kit replaced other manufacturer test kits and this change of methods for HIV testing was not documented in the labs procedures.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on record review and interview with lab staff, the lab did not document the manufacturer name, lot numbers and expiration dates of test kits and stain reagents to ensure they were not used past expiration. Findings: 1. The lab did not document the lot number and expiration date of the Oraquick HCV test kits on the testing records; and 2. The lab did not document the manufacturer, lot number and expiration dates of crystal violet, Gram iodine, Gram safranin used for Gram stain testing from May to December of 2016.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interview with lab staff, the lab did not ensure that quality control programs were maintained for accurate and reliable testing of patient specimens. Findings: 1. The quality control records for the HIV testing for April 16, 23 and 30, 2018 were incomplete, the lab did not indicate if the positive AB HIV-1 AB control passed or failed in 4 of 18 tests performed; 2. The quality control records for the HIV testing for April 23 and 30, 2018 were incomplete, the lab did not indicate if the positive AB HIV-2 AB control passed or failed in 3 of 18 tests performed; and 1. The quality control records for the HIV testing for April 16, 23 and 30, 2018 were incomplete, the lab did not indicate if the positive Ag HIV-/2 p24 antigen (ag) control

	passed or failed in 4 of 18 tests performed; and 1. The quality control records for the HIV testing for April 16, 23 and 30, 2018 were incomplete, the lab did not indicate if the negative control passed or failed in 4 of 18 tests performed.