Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0710717	02/26/2024
Name of Provider or Supplier	**Street Address, City, State**	
Baltimore City Hlth Dept Eastern Sexual Hlth Clini	1200 E Fayette St 1st 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the patient logbooks for syphilis serology and gram stain, proficiency testing (PT) records, and interview with the testing person (TP), the laboratory failed to document the PT samples along with the regular patient workload. Findings: 1. The syphilis serology and gram stain PT records from 2021 through 2023 were reviewed for a total of eight events for each speciality. 2. Review of the patient logbooks from 2021 through 2023 showed that the PT samples for all 16 events were not documented in the logbook in the same manner as the patients. The original test results were not documented and maintained in the same manner as the patients. 3. During the survey on 02/26/2024 at 11:45 AM, the TP confirmed that the PT results were not being documented in the patient logbooks in the same manner as the patients.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

	This STANDARD is not met as evidenced by: Based on review of the specimen collection procedure and interview with the technical consultant (TC), the laboratory failed to ensure that the policy included instructions for the collection and labeling of specimens for gram stain analysis. Findings: 1. The specimen collection procedure failed to include instructions for the collection and labeling of specimens for gram stain analysis collected by the clinicians. 2. The TC stated that the specimens are collected and processed by the clinicians and brought to the laboratory for staining and analysis. 3. During the survey on 02/26/2024 at 12:30 PM, the TC confirmed that the specimen collection procedure failed to include collection and labeling procedures of specimens for gram staining.
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 "Gram-Stain Procedure" and interview with the technical consultant (TC) and testing person (TP), the laboratory's written policies and procedures failed to include accurate instructions for how gram stain specimens are received in the lab, how quality control (QC) organisms are received in the lab and how to stain the prepared slide. Findings: 1. On page 2 the "Gram-Stain Procedure" states, "The smears should be left to air dry before being sent to the laboratory for fixation, staining, reading and interpretation." The procedure failed to define who prepares the smear and where it is prepared, how it is labeled, and how it is transported to the lab to ensure the identity of the specimen from collection to the lab. The TC explained that the clinicians collect the specimens, prepare and label the slide prior to sending it to the laboratory for further processing. 2. On page 4 of the "Gram-Stain Procedure" Section V. "Quality Control [QC]", the procedure states "Frozen stocks of all QC organisms will be maintained in T-soy broth with 10% glycerol at -70 C[Celsius] at the BDC lab. Fresh isolates will be supplied at the STAT labs at quarterly intervals" and "QC isolates will be sub-cultured at least every 48 hours on blood agar plates for use in checking the performance characteristics of the stain." The TP stated that the QC organisms are not stored at the clinic in T-soy broth and they do not sub-culture the organisms every 48 hours. The TP stated that the QC organisms

	are sent to the Eastern STD lab each Monday for weekly gram stain QC testing. 3. On page 4 of the "Gram-Stain Procedure" Section IV. "Procedure of Gram Staining" Smear preparation, the procedure requires the testing person to "Sterilize the inoculating loop on a flame of a Bunsen burner." The TC confirmed that they lab does not use a sterilized loop for preparing the smear on the slide. The clinicians collect the specimen with a sterile swab and prepare the smear prior to bringing the slide to the lab for testing. 4. During the survey on 02/26/2024 at 11:45 AM, the TC confirmed that the "Gram-Stain Procedure" failed to include accurate instructions for how gram stain specimens are received into the lab from the clinicians, how the QC specimens are labeled and transported from the Druid STD lab location to the Eastern STD lab location, and how the lab actually received the the smear on the slide for staining.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with technical consultant (TC), the laboratory failed to label the discontinued procedures in the procedure manual. Findings: 1. The written procedure manual included instructions for the binx io (Molecular Detection of Chlamydia and Gonorrhea) analyzer. 2. When interviewed the TC stated that the analyzer was no longer in use as of September 2023. 3. During the survey on 02/26/2024 at 11:45 AM, the TC confirmed that the procedure had not been labeled as discontinued.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the gram stain proficiency testing (PT) records and interview with the technical consultant (TC), the laboratory director failed to investigate PT results listed as educational challenge (26) for Polymorphonuclear (PMN) leukocytes during 2021 through 2023. Findings: 1. The gram stain PT records from 2021 through 2023 were reviewed. These records included eight event. Each event included five educational challenges for PMN leukocytes. The laboratory's records available at the time of the survey did not include and evaluation of the educational challenges for the PMN leukocytes results to ensure the abilities of the testing personnel performing the test. 2. During the exit interview on 02/26/2024 at 11:45 AM, the TC confirmed that the results of the educational challenges had not been reviewed using the PT summary provided by the PT organization for each event to ensure the accuracy of the testing personnel when evaluating PMN leukocytes.

D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on review of the RPR (rapid plasma reagin) quality control (QC) worksheets, and interview with the testing person (TP) and technical consultant (TC), the TP failed to document when RPR testing was not performed due to the room temperature (RT) not meeting the limits of acceptability. Findings: 1. The "RPR Card Test Quality Control" worksheet for September 2023 was reviewed. The acceptable RT listed on the worksheet is 23-29C[Celsius]. On 9 of 17 days that the laboratory was open for testing the RT value that was recorded was less than the lower limit of 23C. The TP stated that when the RT was unacceptable RPR testing was not performed. The TC stated that when testing is not performed, the TP is required to document that information on the "RPR Card Test Quality Control" worksheet. 2. During the exit interview on 02/26/2024 at 11:45 AM, the TC confirmed that the TP was not documenting when testing was not performed on the "RPR Card Test Quality Control" worksheet as required.