Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0710716	(X3) Date Survey Completed 02/23/2024
Name of Provider or Supplier Baltimore City Health Dept Druid Sexual Health Cli	**Street Address, City, State** 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
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 02/23/2024 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), the laboratory's written policies and procedures failed to include accurate instructions for how gram stain specimens are collected and received in the laboratory 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 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 the lab does not use a sterilized loop when preparing the gram stain slide. The clinicians collect the specimen with a sterile swab and prepare the smear prior to bringing the slide to the lab for testing. 3. During the survey on 02/23/2024 at 12:30 PM, the TC confirmed that the "Gram-Stain Procedure" failed to include accurate instructions for how gram stain specimens were collected and received in the lab and how to stain the prepared slide.
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 02/23/2024 at 12:30 PM, the TC confirmed that the procedure had not been labeled with a discontinued date.
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 events. Each event included five educational challenges for PMN leukocytes. The laboratory's records available at the time of the survey did not include an evaluation of the educational challenges for the PMN leukocytes results to ensure the abilities of the testing personnel performing the test. 2. During a conversation 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.