Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0710717	09/17/2025
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) (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: *This is a repeat deficiency. The laboratory was cited during the initial survey completed on 02/26/2024 for not documenting proficiency testing (PT) results in the patient testing logbooks. The laboratory's plan of correction stated this would be corrected by 04/01/2024. Based on review of PT records, review of patient testing logbooks, and interview with the technical consultant (TC), the laboratory failed to document Gram stain and rapid plasma reagin (RPR) PT results in the same manner as patient results. Findings: 1. The laboratory documented patient results for Gram stain and RPR testing in patient logbooks. 2. Records for RPR PT were reviewed for five events from 2024-2025. Results for RPR PT samples were not documented in the patient result logbook for two of five PT events. 3. Records for Gram stain PT were reviewed for two events in 2024. Results for Gram stain PT samples were not documented in the patient result logbook for one of two PT events. 4. During the exit interview on 09/17/2025 at 1:45 PM, the TC confirmed that PT results were not consistently documented in the Gram stain and RPR patient results logbooks.
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 observation and interview with the technical consultant (TC), laboratory staff did not follow established safety procedures to ensure protection from physical, chemical, biochemical, and biohazardous materials. Findings: 1. During a tour of the laboratory at 2:00 PM, an open drink container was observed on the counter in the laboratory testing area. 2. The Occupational Safety and Health Administration (OSHA) and Environmental Protection Agency (EPA) provide guidelines for laboratory safety. Good laboratory practices state that there should be no eating, drinking, or application of cosmetics in the laboratory. 3. During an interview on 09/17 /2025 at 2:00 PM, the TC confirmed that laboratory staff did not follow established safety procedures to ensure protection from physical, chemical, biochemical, and biohazardous materials.
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 review of the standard operating procedure manual (SOPM), proficiency testing (PT) records, and the patient results logbook, and interview with the technical consultant (TC), the laboratory failed to ensure all unacceptable PT results were evaluated and potential patient impact was assessed. Findings: 1. The SOPM included a form titled "Investigation of Proficiency Testing Results" to be used to investigate any unacceptable PT results. 2. For the D5-A 2024 Gram stain event: a. The laboratory received a 60% for Gram stain results. b. The investigation stated that "it appeared that staff may have decolorized the slides for too long resulting in the incorrect response." Retraining for Gram stain testing was documented on 07/11 /2024. c. The investigation did not address whether patient results were potentially affected by over-decolorizing the slides. 3. For the D5-B 2024 Gram stain event: a. The laboratory received a 60% for Gram stain results. The laboratory reported two PT samples as Gram-positive when the intended response was Gram- negative. The investigation stated the laboratory reported the samples as Gram-negative when the intended results were Gram-positive. b. The laboratory received a 60% for morphology results. The investigation did not address the unacceptable PT results for morphology. c. The investigation stated that "it appeared that the staff may have decolorized the slides for too long resulting in the incorrect response." Gram stain testing was suspended until retraining occurred. d. The investigation did not address whether patient results were potentially affected by over-decolorizing the slides. 4. The "Investigation of Proficiency Testing Results" form included in the SOPM was not used for any investigation of unacceptable PT results. 5. During the exit interview on 09/17/2025 at 1:45 PM, the TC confirmed that the PT investigations did not include an assessment of potential patient impact, did not address all unacceptable results, and were not investigated using the approved "Investigation of Proficiency Testing Results" form.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty

	assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the technical consultant (TC), the laboratory failed to perform a self-evaluation of scores that were ungraded by the PT provider. Findings: 1. The laboratory was enrolled in PT for Gram stains with College of American Pathologists (CAP). 2. The following codes were used when a PT sample was not graded by CAP with the following instructions from the "Actions Laboratories Should Take when a PT Result is Not Graded" section included in CAP's participant summary: a. "[26] Educational Challenge:" "Review participant summary for comparative results and document performance accordingly. Evaluation criteria are not established for educational challenges. Laboratories should determine their own evaluation criteria approved by their laboratory director for self-evaluation." b. "[27] Lack of participant or referee consensus:" "Document that the laboratory performed a self-evaluation and compared its results to the intended response when provided in the participant summary. If comparison is not available, perform and document alternative assessment (ie, split samples) for the period that commercial PT reached non-consensus to the same level and extent that would have been tested." 3. The 2024 1st PT event included two morphology results not graded due to code [27] and four "PMN Leukocytes" results not graded due to code [26]. The laboratory investigation only included an assessment for one of the four results coded [26]. 4. The 2024 2nd PT event included one morphology result not graded due to code [27] and five "PMN Leukocytes" results not graded due to code [26]. There was no documentation that the laboratory self-evaluated the ungraded PT results. 5. During the exit interview on 09/17/2025 at 1:45 PM, the TC confirmed that there was no consistent documentation that the laboratory self-evaluated ungraded Gram stain PT results.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of temperature records and interview with the technical consultant (TC), the laboratory failed to document corrective actions when refrigerator temperature values were out of acceptable range in two of 18 months reviewed. Findings: 1. During a tour of the laboratory at 2:00 PM, the TC stated that the quality control reagents for the rapid plasma reagin assay were stored in the refrigerator with the freezer. 2. The acceptable refrigerator temperature range was listed on the log as 2-8 Celsius (C). 3. Temperature records were reviewed from 01/2024-06/2025. 4. The refrigerator temperature was documented as -5 C on one of 22 days in 07/2024 and -6 C on 5 of 22 days in 08/2024. 5. No corrective actions were documented for the out-of-range temperatures. 6. During the exit interview on 09/17/2025 at 1:45 PM, the TC confirmed that corrective actions were not documented when the refrigerator temperatures were outside acceptable range.

D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratorys established performance specifications are identified, and that patient test results are reported only when the system is functioning properly; This STANDARD is not met as evidenced by: Based on review of the procedure manual, quality control (QC) logs, and patient results logbooks, and interview with the technical consultant (TC), the laboratory reported patient Gram stain results when QC was not tested and reported patient rapid plasma reagin (RPR) results when room temperature was outside acceptable range. Findings: 1. The procedure manual stated that Gram stain QC was to be tested each day patients were tested. Gram stain logs showed that QC for Gram stain testing was last performed on 10/18/2024. The Gram stain patient logbook showed that a patient was tested on 12/13/2024. 2. The RPR QC log stated that acceptable room temperature for patient testing was 23-29 Celsius (C). At 1:37 PM on 09/17/2025, the TC confirmed that patient testing should not be performed when room temperature was outside acceptable range. The room temperature was documented as 21 C for the month of 09/2024. The RPR patient logbooks showed that a patient was tested on 09 /19/2024 and 09/24/2024. 3. During the exit interview on 09/17/2025 at 1:45 PM, the TC confirmed that a patient was documented as tested in the Gram stain logbook when QC was not tested and two patients were documented as tested in the RPR logbook when room temperature was outside acceptable range.