

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0710716	(X3) Date Survey Completed 09/18/2025
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (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 in three of six PT events reviewed. Findings: 1. The laboratory documented patient results for Gram stain and RPR testing in patient logbooks. 2. Records for RPR PT were reviewed for four events from 2024-2025. Results for RPR PT samples were not documented in the patient result logbook for two of four PT events. 3. Records for Gram stain PT were reviewed for two events in 2024. Results for Gram stain samples were not documented in the patient result logbook for one of two PT events. 4. During the exit interview on 09/18/2025 at 12:50 PM, the TC confirmed that PT results were not consistently documented in the Gram stain and RPR patient results logbooks.</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of proficiency testing (PT) records and interview with the technical consultant (TC), the laboratory failed to ensure that the testing personnel (TP) and laboratory director (LD) or designee consistently attested to the routine integration of PT samples into the patient workload using the laboratory's routine methods in three of six PT events reviewed. Findings: 1. Records for rapid plasma reagin PT were reviewed for four events from 2024-2025. The attestation form was not signed by the LD or designee in two of the four PT events. 2. Records for Gram stain PT were reviewed for two events in 2024. The attestation form was not signed by the TP or the LD or designee in one of two events 3. During the exit interview on 09/18/2025 at 12:50 PM, the TC confirmed that the TP and LD or designee did not consistently attest to the routine integration of PT samples into the patient workload using the laboratory's routine methods.

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 proficiency testing (PT) records 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 laboratory received an 80% for the D5-A 2024 Gram stain PT event. 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. The investigation did not address whether patient results were potentially affected by over-decolorizing the slides. 2. The laboratory received a 60% for Gram stain and morphology results for the D5-B 2024 Gram stain PT event. The PT records did not include an investigation into the unacceptable results. 3. During the exit interview on 09/18/2025 at 12:50 PM, the TC confirmed that the PT investigation for D5-A 2024 did not include an assessment of potential patient impact and there was no PT investigation for the unacceptable results from D5-B 2024 included with the PT records.

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 09/18/2025 at 12:50 PM, the TC confirmed that there was no consistent documentation that the laboratory self-evaluated ungraded Gram stain PT results.