

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0710716	(X3) Date Survey Completed 03/19/2021
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: The laboratory failed to enroll in an approved proficiency testing (PT) program for Gram stain identification and rapid plasma reagin (RPR) testing during 2019 while testing was being performed (D2001). The cumulative effect of this deficiency has the potential to result in the laboratory's inability to ensure the accuracy and reliability of patient test results.</p>
D2001	<p>ENROLLMENT CFR(s): 493.801(a)(1)(2)(i)</p> <p>The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS;</p> <p>This STANDARD is not met as evidenced by:</p>

Based on remote record review of proficiency testing (PT) records and interview with the technical consultant and laboratory director (LD), the laboratory failed to enroll in an approved PT program during 2019 to verify the accuracy of the Gram stain identification and rapid plasma reagin (RPR) testing performed at the laboratory. Findings: 1. To meet the PT requirements, the laboratory is required to be enrolled in an approved PT program when performing patient testing. 2. The PT records that were submitted failed to include documentation for 2019. 3. During the remote survey phone interview on 03/19/2021 at 3:00 PM, the LD confirmed that the laboratory was unable to procure the funds to purchase the PT modules and reagents necessary for testing during 2019 and failed to ensure the accuracy and reliability of patient test results during 2019.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
Based on record review and interview, the laboratory director failed to ensure that the quality assurance program for the laboratory had been maintained and documented (D6021).

D6021

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 quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on remote survey record review and phone interview with the laboratory director (LD), the LD failed to ensure that "STAT Laboratory Surveys" records were performed and maintained, and that the "STAT Laboratory Surveys" failed to be performed after August 2019 as part of the quality assurance (QA) program. Findings: 1. The "STAT Laboratory Surveys" records from June 2018 through August 2019 were reviewed remotely. The records included a documented onsite review performed by the technical consultant (TC) at the Druid and Eastern STD clinics. 2. There were no monthly QA reports for August 2018, November 2018, March 2019, June 2019, and July 2019. The "STAT Laboratory Surveys" and investigation worksheets had not been completed since August 2019. 3. During the remote survey phone interview on 03/19/2021 at 3:00 PM, the LD stated that the missing "STAT Laboratory Surveys" records were due to the fact that the TC was not being paid and therefore did not come to the office and perform the required monthly reviews. According to the LD, since August 2019 no monthly reviews were performed and documented.