

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D1013263	(X3) Date Survey Completed 07/24/2019
Name of Provider or Supplier Men's Health Boston	Street Address, City, State 200 Boylston St Ste A309, Chestnut Hill, MA	
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
D0000	A CLIA recertification survey was conducted for the Men's Health Boston laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to verify at least twice annually procedures it performs that are not included in subpart I of this part as evidenced by the following: The laboratory is enrolled in American Proficiency Institute (API) proficiency testing (PT). A review of API PT records for calendar years 2019, 2018, and second event of 2017 (four testing events) on 7/24/19 revealed that the laboratory had received an unacceptable score of 67% for Sex hormone-binding globulin (SHBG) for the first and second testing events in 2018. Based on the two consecutive unacceptable scores, the laboratory had not demonstrated twice annual accuracy for SHBG in 2018. The technical consultant interviewed on 7/24/19 at 11:00 AM confirmed that the laboratory failed to verify accuracy of SHBG at least twice annually in 2018. The laboratory performs 1789 SHBG tests annually.</p>