Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D0690692	01/21/2020
Name of Provider or Supplier	**Street Address, City, State**	
Tufts University Health Service Clinical	124 Professors Row, Medford, 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 Tufts University Health Service laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D5503	BACTERIOLOGY CFR(s): 493.1261(a)(2) (a) The laboratory must check the following for positive and negative reactivity using control organisms: (a)(2) Each week of use for gram stains. This STANDARD is not met as evidenced by: Based on quality control (QC) record review and confirmed through interview, the laboratory failed to check for positive and negative reactivity using control organisms for each week of use for gram stains as evidenced by the following: The surveyor asked to review QC records for gram stains for calendar years 2018 and 2019. Testing Person 1 (TP1) stated that the volume of gram stains is low and QC is not performed and documented. TP1 confirmed in an interview on 1/21/2020 at 2:00 PM that the laboratory failed to check and document positive and negative reactivity using control organisms for each week of use for gram stains. The laboratory performs 5 gram stains annually.