

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2089996	(X3) Date Survey Completed 01/09/2019
Name of Provider or Supplier Microbiology Dx, Inc	Street Address, City, State 19a Crosby Dr, Bedford, 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 Microbiology DX, Inc. laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D6128	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview the technical supervisor failed to maintain documentation for annual competency assessments of testing personnel. A review of personnel records of the three testing personnel performing and/or supervising laboratory testing revealed the fact that competency assessments were not documented for calendar years 2017 and 2018. The laboratory director confirmed in an interview on 1/9/19 at 9:25 AM that competency assessments were performed but not documented for 2017 and 2018 . The laboratory performs approximately 37,000 bacteriology and mycology cultures annually.</p>