

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2089996	(X3) Date Survey Completed 01/31/2023
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. Please refer to Conditions of Participation for Clinical Laboratories 42 CFR Part 493. .
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p> <p>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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory director failed to ensure that policies and procedures were established for individuals who conduct pre-analytical, analytical, and post analytical phases of testing to ensure their competency to process specimens, perform test procedures, and report test results promptly and proficiently as evidenced by the following: a) No documentation of competency assessments for calendar years 2021 and 2022 could be provided during the time of the survey for two (2) of two (2) testing personnel. b) A review of the laboratory's policy and procedure manual on 1/31/23 revealed that policies were not established on assessing the competency of individuals who conduct pre-analytical, analytical, and post analytical phases of testing. c) The laboratory director stated in an interview on 1/31/23 at 9:00</p>

AM that the personnel performing testing were evaluated solely through proficiency testing performance. .