Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2259522	(X3) Date Survey Completed 03/02/2023
Name of Provider or Supplier Progene Dx Llc	**Street Address, City, State** 19a Crosby Drive, 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	An initial CLIA certification survey was conducted for the Progene DX, LLC 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.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to indicate on the patient final test report the test report date as evidenced by the following: a) A review was performed of sixteen (16) final patient test reports issued between 1/7/22 and 2/6/23. The review revealed the fact that the report date field was not included for all sixteen (16) reports reviewed. a) The Technical Supervisor confirmed in an interview on 3/2/23 at 9:30 A.M. that the patient final test reports did not include a field for the test report date. The laboratory reports approximately 99,900 tests performed annually. .
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental

	conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on interview, the Laboratory Director failed to ensure that the physical plant and environmental conditions provided a safe environment in which employees were protected from physical, chemical, and biological hazards as evidenced by the following: Emergency Eyewash Station: On the day of the survey the maintenance records of the emergency eyewash were requested. The Laboratory Director interviewed on 3/2/23 at 10:55 AM confirmed that documentation was not maintained that the emergency eyewash was being routinely checked and maintained on a weekly basis .