Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2140887	01/09/2019
Name of Provider or Supplier	**Street Address, City, State**	
Ethel Diagnostic Laboratory	4 Ethel Road, Edison, NJ	

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
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation of the manual Staining Station and interview with the owner, the laboratory failed to label all staining jars used for manual Hematoxylin and Eosin staining from October 2018 to the date of the survey. The owner confirmed on 1 /9/19 at 11:15 am that the staining jars were not labeled.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the Procedure Manual (PM), the laboratory records, tour of the laboratory and interview with the owner, the Laboratory Director (LD) failed to provide overall management, oversight and direction to the owner for laboratory testing. The findings include: 1. The LD failed to ensure that performance verifiation was performed on laboratory information system. Cross refer to D6086. 2. The LD failed to ensure that personnel had education and experience to perform patient

	testing. Cross Refer to D6102. 3. The LD failed to ensure that PM was approved. Cross Refer to D6106.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records and interview with the owner, the Laboratory Director (LD) failed to ensure that Laboratory Information System (LIS) was verified from October 2018 to the day of survey. The owner confirmed on 1/9/19 at 10:40 am that the LD did not ensure LIS was verified.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on lack of Personnel Records (PR) and interview with the owner, the laboratory director failed to ensure that education and experience records of each personnel were available from October 2018 to the date of survey. The owner confirmed on 1/9/19 at 10:20 am that education and experience was not documented for personnel performing testing.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the owner, the current laboratory director failed to have an approved procedure manual from July 2018 to the date of the survey. The findings include: 1. On the day of survey the owner stated that the laboratory director was changed in July 2018 but there was no update sent to CLIA program. 2. The PM included procedures not performed in the laboartory such as Cytology procedures, proficiency testing guidelines. 3. The owner confirmed on 1/9/19 at 10:00 am that the current director did not approve PM.