

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2140887	(X3) Date Survey Completed 03/25/2019
Name of Provider or Supplier Ethel Diagnostic Laboratory	Street Address, City, State 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Final Reports (FR) and interview with the owner, the laboratory failed to follow Document # HIS-004 procedure from March 2019 to the date of a revisit survey. The finding includes: 1. Procedure section, step # 3 stated 'The benchmark measure for routine specimens is 24-72 hours from receipt of specimen' but the review of 30 out of 30 FR revealed that the laboratory reported after 100 hours. 2. The owner confirmed on 3/25/19 at 11:00 am that the laboratory did not follow HIS-004 procedure. b) Based on surveyor review of the PM, observation of flammable cabinet and interview with the owner, the laboratory failed to follow Document # HIS-040 procedure from March 2019 to the date of a revisit survey. The finding includes: 1. Section # III, step # 3 stated 'All reagents are labeled with the date received' but the observation of Eosin-Y, Harris Hematoxylin and Rapid Pap counter stain did not have receive date on them. 2. The owner confirmed on 3/25/19 at 12:15 pm that reagents were not labeled. c) Based on surveyor review of the PM and interview with the owner, the laboratory failed to follow Document # HIS-034 procedure on 3/9/19 and 3/18/19. The finding includes: 1. Section III, step # 4 stated 'the driver logs are documented on the Daily Delivery Log Sheet' but there was no evidence of log sheets for 3/9/19 and 3/18/19. d) Based on surveyor review of the PM and interview with the owner, the laboratory failed to have a detail Document # HIS-025 procedure on the date of a revisit survey. The</p>

finding includes: 1. The procedure did not mention the use of tools to assess competency assessment. 2. The owner confirmed on 3/25/19 at 10:30 am that the procedure was not complete.

D5433

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:
Based on surveyor review of the laboratory records, procedure manual and interview with the owner, the laboratory failed to establish a maintenance protocol for Microscope when protocols were not provided by the manufacturer from March 2019 to the date of a revisit survey. The owner confirmed on 3/25/19 at 10:30 am that the laboratory did not establish maintenance protocol.

D5601

HISTOPATHOLOGY
CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on surveyor review of Quality Control (QC) records and interview with the owner, the laboratory failed to perform Hematoxylin and Eosin (H&E) stain Quality Control (QC) slide on March 9 and 18 of 2019. The owner confirmed on 3/25/19 at 11:25 am that the laboratory did not prepare H&E stain QC slide.

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 surveyor review of the Final Report (FR) and interview with the owner, the laboratory failed to ensure that the FR included the name of the laboratory where testing was performed from March 2019 to the date of a revisit survey. The owner confirmed on 3/25/19 at 11:50 pm that FR did not have all the required information.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Procedure Manual and interview with the owner, the Laboratory Director (LD) failed to ensure a Quality Assurance (QA) program was established to assure quality of laboratory services provided from October 2018 to the date of a revisit survey. The owner confirmed on 3/25/19 at 10:45 am the LD did not establish a QA program.