

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2140887	(X3) Date Survey Completed 01/25/2022
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Competency Assessment (CA) records and interview with the Testing Personnel (TP) the laboratory failed to follow its policies and procedures for assessing the competency of TP who perform Histopathology testing from 1/9/19 to the date of survey. The findings include: 1. The CA was not performed on two out of two TP in the calendar years 2019, 2020, and 2021. 2. The laboratory CA policy stated that testing personnel are evaluated annually. 3. The TP confirmed on 1/25/22 at 1:20 pm the laboratory did not follow the CA procedure.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of Biannual Assessment (BA) records and interview with the Testing Personnel (TP), the laboratory failed to verify the accuracy of Histopathology tests testing twice annually from 1/9/19 to the date of survey. The TP confirmed on 1/25/22 at 1:45 pm the laboratory did not perform BA twice annually.</p>
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual and interview with the Testing Personnel (TP), the laboratory failed to establish a written procedure for Biannual Assessment (BA) from 1/9/19 to the date of survey. The TP confirmed on 1/25/22 at 1:45 pm that a BA procedure was not established.

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 surveyor review of Personnel Records (PR) and interview with the Testing Personnel (TP), the Laboratory Director failed to ensure that the education records were available on the date of the survey. The finding includes: 1. Education records were not available for one of two TP. 2. The TP confirmed on 1/25/22 at 1:30 pm that education records were not available.