

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D2026264	<b>(X3) Date Survey Completed</b>  04/23/2024
<b>Name of Provider or Supplier</b>  Eastpath Diagnostics Llc	<b>Street Address, City, State</b>  136-16 31st Rd. 2b, Flushing, NY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	<p>An announced CLIA exempt-state validation survey was performed on April 23, 2024, by CMS Boston CLIA federal surveyor. The laboratory was surveyed under 42 CFR part 493 CLIA regulations. The laboratory was found to be in compliance with standard-level CLIA requirements. The findings were reviewed with clinical consultant #1/general supervisor #1 during an exit conference at the conclusion of the survey.</p>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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 record review, written laboratory policies and procedures, and interview with clinical consultant #1 (CC #1)/general supervisor #1 (GS #1) the laboratory failed to have a written clinical consultant competency policy and general supervisor competency policy based on the position responsibilities for one of two clinical consultants and one of two general supervisors. Findings include: 1. Record review on 04/23/2024 of the Laboratory Personnel Report (Form CMS-209) signed by the Laboratory Director on 04/12/2024 included two clinical consultants for the laboratory and two general supervisors. 2. Record review on 04/23/2024 of 2023 and 2024 personnel competency records revealed no evidence for one of two clinical consultant competency and one of two general supervisors competency based on job responsibilities. 3. Review of the laboratory's competency assessment policy on 04/23/2024 revealed no evidence of a written policy to assess the clinical consultant and general supervisor based on job responsibilities. 4. Interview on 04/23/2024 at 11:28 am with CC #1/GS #1 confirmed the findings above.</p>

**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 record review and interview with clinical consultant #1 (CC #1)/general supervisor #1 (GS #1), the laboratory director failed to document initial training for one of one testing persons performing high complexity testing. Findings include: 1. Record review on 04/23/2024 of the Laboratory Personnel Report (Forms CMS-209) signed by the laboratory director on 04/12/2024 included the following: a. Testing Person #4 (TP #4) - This person was hired to perform patient testing on 02/01/2024. 2. Record review on 04/23/2024 of personnel competency records revealed no documentation of initial training for TP #4. 3. Interview on 04/23/2024 at 12:15 pm with CC #1/GS #1 confirmed the findings above.