

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D1038526	<b>(X3) Date Survey Completed</b>  07/17/2023
<b>Name of Provider or Supplier</b>  Ne Gastroenterology Associate Pc	<b>Street Address, City, State</b>  2812 Scranton-Carbondale Hwy, Blakely, PA	
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>D3009</b>	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor record review (Application for Exception to Section 5.22(f)) and interview with the laboratory director (LD) and testing personnel #2 (TP), the laboratory failed to ensure that the State of Pennsylvania (PA) regulations were met regarding having a supervisor on site during all normal scheduled working hours in which tests are being performed. Findings include: 1. The PA regulations (5.23 (b)(1)) states: "A general supervisor who meets all the requirements of subsection (a)(1), (2) or (3) and is on the laboratory premises during all normal scheduled working hours in which tests are being performed." 2. Review of the application for Exception to Section 5.22 (f) form signed by the laboratory director (LD) on 09/12/2021 states: " the laboratory director will appoint a qualified general supervisor for each laboratory who will be on-site to oversee laboratory operations during all hours in which testing is being performed and who will review quality control records on a weekly basis". 3. On the day of the survey, 07/17/2023 at 02:05 pm, during an interview, LD and TP #2 stated that the laboratory did not have a qualified supervisor onsite for every hour of patient testing as required by the State of PA.</p>