

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D0943414	<b>(X3) Date Survey Completed</b>  07/20/2023
<b>Name of Provider or Supplier</b>  Northeast Gastroenterology Center	<b>Street Address, City, State</b>  10 Park Place, Hazleton, 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>D8103</b>	<p><b>BASIC INSPECTION REQUIREMENTS</b> CFR(s): 493.1773(b)(c)(d)</p> <p>(b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the laboratory director (LD), the laboratory failed to have the required records accessible during the course of the laboratory survey performed on 07/20/2023. Findings Include: 1. On the day of the survey, 07/20/2023 at 10:15 am, the laboratory could not provide the quality control records from 12/28/2021 to 07/20/2023. 2. It is stated on the Stain Assessment by Pathologist Policy that "All quality assessment sheets will be stored for a two-year period at Keystone Medical Labs." 3. LD confirmed the findings above on 07/20/2023 around 10:30 am.</p>