

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D1047391	<b>(X3) Date Survey Completed</b>  05/25/2022
<b>Name of Provider or Supplier</b>  Neodiagnostix, Inc	<b>Street Address, City, State</b>  910 Clopper Road, Suite 240 South, Gaithersburg, MD	
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>D6120</b>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b> CFR(s): 493.1451(b)(7)(8)</p> <p>(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p> <p>This STANDARD is not met as evidenced by: Based on review of the personnel report and competency assessment records and interview with the associate lab director (ALD), the technical supervisor failed to ensure that testing personnel were not self-evaluated for competency. Findings: 1. The laboratory personnel report (form CMS-209) listed three general supervisors (GS) all of whom were delegated and qualified to perform competency assessments. 2. The ALD stated that as part of the annual competency assessments, one GS would compile a collection of images from previous cases for evaluation by all testing personnel (TP). The TP evaluation results would be reviewed and signed off by the GS who compiled the images. The ALD stated that the three GS would rotate who compiled the images each year. 3. Records showed that in 2021 GS #3 performed a self-evaluation of competency. 4. During the survey on 05/25/2022 at 12:30 pm, the ALD confirmed that in 2021 GS #3 compiled the collection of images, evaluated the images, then performed a self-evaluation of competency.</p>