

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D0417052	<b>(X3) Date Survey Completed</b>  08/08/2024
<b>Name of Provider or Supplier</b>  Quest Diagnostics Llc (II)	<b>Street Address, City, State</b>  1355 Mittel Blvd, Wood Dale, IL	
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>TECHNICAL SUPERVISOR RESPONSIBILITIES 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 direct observation, review of laboratory policy / procedure manuals, and interview with the General Supervisor (GS), the Technical Supervisor (TS) failed to identify and ensure five of six testing personnel (TP) had training for immunohematology testing on the Immucor Neo Iris analyzers put into use in February of 2024 prior to patient testing. Findings include: 1. Upon a tour of the laboratory on 08/08/2024, at 07:45 am, the surveyors identified three Immucor NEO Iris immunohematology analyzers (serial numbers: 100951, 100938, 100936). 2. An interview with the GS of immunohematology at 08:04 am, on 08/08/2024, confirmed the three Immucor NEO Iris immunohematology analyzers were implemented into the laboratory the last week of February 2024 for patient testing. 3. Review of the laboratory procedure, "Policy for Training Verification", stated the following in section 5.5.1: "Initial training must be performed when: A new procedure or test system is introduced in the department." 4. Review of training records found no documented training prior to patient testing for five of six TP (TP1, TP2, TP3, TP4, TP5) on the new Immucor NEO Iris immunohematology analyzers. 5. An interview, at 11:05 AM, on 08/08/2024 with the GS of immunohematology confirmed that no training was documented prior to patient testing on the Immucor Neo Iris test systems for five of six TP.</p>