

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D0245748	<b>(X3) Date Survey Completed</b>  04/03/2024
<b>Name of Provider or Supplier</b>  Eastern Nephrology Associates	<b>Street Address, City, State</b>  1302 Medical Center Drive, Wilmington, NC	
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>D6030</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(12)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, the absence of personnel competency records, interview with technical consultant (TC), and interview with testing personnel (TP #1) 04/03/24, the laboratory director (LD) failed to ensure policies and procedures were followed for performing annual competency evaluations for 1 of 2 TP (TP #1) for 2020, 2021, 2022, and 2023. Findings: Review of "Personnel Training &amp; Competency Assessment" policy/procedure revealed "b. After the first year of employment, competency assessment will be done and documented annually." Review of "Laboratory Director Responsibilities" policy/procedure, revealed "Ensure that policies and procedures are established for monitoring individuals...verify that they maintain competency to: - process specimens, - perform test procedure, and - report test results promptly and proficiently." No competency evaluation records available to review for TP #1 for 2020, 2021, 2022 and 2023. Interview with TC at approximately 3:57 p.m. confirmed no competency evaluation records available for TP #1 for 2020, 2021, 2022, and 2023. TC stated she took over October 02, 2023, and she could not find competency documentation for TP #1 for 2020, 2021, 2022 and 2023.</p>

TC stated the prior TC either didn't do it or lost the paperwork. Interview with TP #1 at approximately 3:58 p.m. confirmed prior TC did not complete her competency evaluation documentation for 2020, 2021, 2022, and 2023. During interview at approximately 4:20 pm, TP #1 provided 2020 and 2021 competency records for review by the surveyor. The records were not signed by TP #1, the TC, or the LD to indicate review and approval.