

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0714805	(X3) Date Survey Completed 04/28/2023
Name of Provider or Supplier Nephrology Associates Pc	Street Address, City, State 701 Greene Street, Suite 200, Augusta, GA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on April 28, 2023. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory policy and procedure manual (SOP) review and staff interview, the laboratory director failed to perform competency for 1 out of 2 Testing Personnel (TP) for 2022 and 2023. The Findings include: 1. Competency documents revealed the annual competencies were not performed for Testing Personnel #1(CMS-209) for 2022 and thus far 2023(January-April). 2. During an interview with the Testing Personnel #1 (CMS-209) on April 28, 2023 at 2:00 PM, in the laboratory confirmed that no competency was performed for the Testing Personnel TP #1(CMS-209) for 2022 and 2023.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p>

This STANDARD is not met as evidenced by:
Based on the Standard operating procedure (SOP) document review and staff interview, the laboratory failed to establish and follow a written policy for Quality Assessment. Findings include: 1. SOP document review revealed the laboratory failed to establish and follow a written policy for Quality Assessment for 2021, 2022, and thus far 2023. 2. During an interview with Testing Personnel #1 (CMS-209) on April 28, 2023 at 12:50 PM in the laboratory, confirmed the laboratory did not have a written policy for Quality Assessment for 2021, 2022, and thus far 2023.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory director (LD) failed to specify, in writing the duties and responsibilities of each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of laboratory testing. Findings include: 1. SOP review revealed the LD failed to specify in writing the duties and responsibilities of each person engaged in the performance of all phases of laboratory testing. 2. An interview with Testing Personnel #1 (CMS 209) in the laboratory on April 28, 2023 at 1:00 PM, in the laboratory, confirmed the SOP did not contain a duties and responsibilities policy and procedure.