

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D0231349	<b>(X3) Date Survey Completed</b> 12/13/2024
<b>Name of Provider or Supplier</b> Endocrinology Associates Inc	<b>Street Address, City, State</b> 3501 Colonial Green Circle, Roanoke, VA	
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>D0000</b>	An announced CLIA validation survey was conducted at Endocrinology Associates, INC on December 12, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The survey also included a follow up interview with the laboratory manager on 12/13/24. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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 a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), quality assessment (QA), proficiency testing (PT) and quality control (QC) documentation, personnel files, and interviews, the laboratory did not establish/follow a policy for technical consultant's (TC) competency assessment for one of two years reviewed (survey timeframe: December 12, 2022 to the date of the validation on December 12, 2024). Findings include: 1. During an interview with the laboratory manager on 12/12/24 at 10 AM while reviewing the CMS 209 personnel form, it was revealed that two personnel qualified and served as TC during the validation survey timeframe of 12/12/22 to 12/12/24. 2. During a review of the laboratory's QA, PT, and QC notebooks' documentation, the inspector noted that Personnel A reviewed and reported corrective actions as TC during December 2022 and calendar year 2023 and that the laboratory director (LD) served as TC in calendar 2024. See Personnel Code Sheet. 3. Review of the available personnel files revealed that the LD failed to document a competency assessment in calendar year 2023 for Personnel A for the role of TC. The inspector inquired regarding the TC competency. The laboratory manager stated on 12/12/24 at 12 noon:</p>

"That person served as laboratory manager prior to me and I do not recall that a TC competency was ever included in our protocols." 4. A follow up exit interview with the laboratory manager on 12/13/24 at 9:30 AM confirmed the above findings.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, lack of documentation, and interviews, the technical consultant (TC) failed to document hematology, chemistry, and microscopy competency assessments for two (2) of five (5) testing personnel (TP) in calendar year 2023. Findings include: 1. During an interview with the laboratory manager on 12/12/24 at 10 AM while reviewing the CMS 209 personnel form, it was revealed that 2 personnel qualified and served as TC during the validation survey timeframe of 12/12/22 to 12/12/24 (Personnel A in 2023 and laboratory director in 2024), and that 5 TP were identified as being responsible for performing non-waived hematology and chemistry patient testing utilizing Beckman Coulter Unicel DxH 690T Cellular Analysis System, Unicel DIX 800 Immunoassay System, and DxC 700 AU Clinical Chemistry analyzers and non-waived urine sediment microscopy during the timeframe of calendar year 2023. 2. Review of the available personnel records revealed no annual competency assessments by the TC for TP #1 and # 2 in calendar year 2023. See Personnel Code Sheet. 3. The inspector requested to review 2023 annual Beckman Coulter Unicel DxH 690T Cellular Analysis System, Unicel DIX 800 Immunoassay System, and DxC 700 AU Clinical Chemistry and microscopy competency assessment documentation for TP #1 and #2. The laboratory manager stated on 12/12/24 at 10:30 AM: "As of 2024, both techs are no longer working in the lab. One of them apparently took all of their records when they left and the other one has partial competency assessment and it is not signed by the TC." No additional records were made available for review. 4. A follow up exit interview with the laboratory manager on 12/13/24 at 9:30 AM confirmed the above findings.