

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0659180	(X3) Date Survey Completed 05/11/2026
Name of Provider or Supplier East Tennessee Reproductive Endocrine Lab	Street Address, City, State Dogwood Ave, Bldg 119, Rm 328, Mountain Home, TN	
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
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: Citation One Based on a review of the laboratory procedure manual and staff interviews, the laboratory failed to ensure its competency assessment policy was in compliance with Subpart M of the Clinical Laboratory Improvement Amendments (CLIA) regulations when it did not include a requirement for reassessment of competency if test methods changed and did not include the six required elements defined in Subpart M. The findings include: 1. A review of the laboratory policy titled " Quality Assurance" revealed the policy did not include a requirement for reassessment of competency if test methods change, and did not include the six required elements for A) Direct observation of patient testing, B) Monitoring the recording and reporting of test results, C) Record review, D)Direct observation of instrument and maintenance function checks, E) Blind testing, and F) Evaluation of problem solving, as defined in Subpart M of the CLIA regulations. 2. An interview with the Laboratory Lead on 05.11.2026 at 2:00 p.m. confirmed the survey findings. Citation Two Based on a review of the submitted Centers for Medicare & Medicaid Services Laboratory Personnel Report (CLIA) (FORM CMS-209), laboratory's procedure, personnel records, and staff interview, revealed the laboratory's competency assessment policy failed to include assessment of the regulatory responsibilities for the general supervisor (GS) as required in Subpart M of the State Operations Manual (SOM) Appendix C, and failed to have documentation of GS competencies for two of three GS in 2024 and 2025 on the survey day, 05.11.2026 Findings included: 1. A review of the submitted FORM CMS-209 listed three GS</p>

(GS1, GS2, GS3) for high complexity testing. 2. A review of the laboratory's policy titled "Quality Assurance" revealed that the policy failed to include competency assessments for the GS for high complexity testing. 3. A review of laboratory personnel records revealed the following: -No documented GS competency assessments for GS2 and GS3 for 2024 and 2025. 4. An interview with the Laboratory Lead on 05.11.2026 at 2:00 p.m. confirmed the above survey findings.

D6013

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(3)(ii)

(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

This STANDARD is not met as evidenced by:
Based on observations in the laboratory, a review of validation records, and staff interviews, the laboratory director failed to approve validation studies for the ALCOR iSED Automated Erythrocyte Sedimentation Rate (ESR) analyzer before the start of patient testing on 08.11.2025. A total of 6,840 patients were tested from 08.11.2025 through survey day, 05.11.2026. The findings include: 1. Observation of the laboratory on 05.11.2026 at 11:00 a.m. revealed an ALCOR iSED Automated ESR analyzer (serial #6107) used for Erythrocyte Sedimentation Rate (ESR) patient testing. 2. Review of the validation studies for the ALCOR iSED Automated ESR analyzer revealed that the validation studies had not been approved by the laboratory director before the start of patient testing on 08.11.2025, on the survey day, 05.11.2026. 3. Interview with the Laboratory Lead on 05.11.2026, at 2:00 p.m. confirmed the above survey findings. Subsequent electronic interview with Laboratory Lead on 05.22.2026 at 11:28 a.m. confirmed 6,840 patient testing performed from 08.11.2025 through the survey day of 05.11.2026.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(12)

(e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

This STANDARD is not met as evidenced by:
Based on a review of the Department of Health and Human Services Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), review of personnel records and staff interview, the laboratory director failed to ensure testing personnel four (TP4) with a date of hire 01.27.2026, had documented training and demonstration of accuracy before performing testing for the specialties /subspecialties of Bacteriology, Mycology, Parasitology, Virology, Syphilis Serology, General Immunology, Routine Chemistry, Urinalysis, Endocrinology, and Hematology, on the survey day, 05.11.2026. The findings include: 1. Review of the Form CMS-209 revealed TP4 listed on the personnel report for high complexity testing. 2. A review of personnel records revealed no evidence that TP4 had documented training or demonstration of accuracy before performing testing in the specialties/subspecialties of Bacteriology, Mycology, Parasitology, Virology, Syphilis Serology, General Immunology, Routine Chemistry, Urinalysis,

Endocrinology, and Hematology on the survey day, 05.11.2026 3. Interview with Laboratory Lead on 05.11.2026 at 2:00 p.m. confirmed the hire date of 01.27.2026 for TP4. Additionally, it confirmed that TP4 was actively performing testing across all specialties/subspecialties and that no documented training or demonstration of accuracy was available on the survey day, 05.11.2026.