Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0659180	10/01/2024
Name of Provider or Supplier	**Street Address, City, State**	
East Tennessee Reproductive Endocrine Lab	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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a random review of the laboratory's College of American Pathologists (CAP) proficiency testing (PT) attestation statements and staff interview, the laboratory director (or designee) and testing personnel failed to sign four of four proficiency testing attestation statements from 2023 and 2024. The findings include: 1. A random review of the laboratory's CAP PT records revealed the laboratory director (or designee) and testing personnel failed to sign the following attestation statements: 2023 FH9-B (Hematology-event two), 2023 C-A (General Chemistry-event one), 2024 FH9-A (Hematology-event one), and 2024 C-A (General Chemistry-event one). 2. An interview with the laboratory manager on 10.01.2024 at 1:45 p.m. confirmed the above survey findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the manufacturer's instruction manuals, environmental records, and staff interview, the laboratory failed to monitor ambient humidity in the areas where patient testing occurred in 2023 and 2024. The findings include: 1. Observation of the laboratory on 10.01.2024 at 9:45 a.m. revealed two testing areas with the following analyzers in use for patient testing: -area one: Siemens Atellica chemistry analyzer, serial number: FL400690569 -area two: Sysmex XN-10 hematology analyzer, serial number 82423, Fisher Scientific Excyte Erythrocyte sedimentation rate analysis analyzer, serial number 01637, and a Siemens Clinitek Advantus urinalysis analyzer, serial number KPS62222245. 2. A review of the manufacturer's instruction manuals revealed the following humidity requirements: Siemens Atellica: 20-80 percent (%) Sysmex XN-10: 20-85% Fisher Scientific Excyte: 10-98% Siemens Clinitek Advantus: 20-80% 3. A review of the laboratory maintenance logs revealed no humidity records were available for the two areas where the laboratory performed patient testing using the Siemens Atellica, Sysmex XN-10, Fisher Scientific Excyte, and Siemens Clinitek Advantus in 2023 or 2024. 4. An interview with the laboratory manager on 10.01.2024 at 1:45 p.m. confirmed the above survey findings.