

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0659180	(X3) Date Survey Completed 06/01/2023
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of the procedure manuals and interview with the laboratory's general supervisor #2, determined that the laboratory failed to follow their own written policy for reviewing procedures in 2022. The findings include: 1. Review of the laboratory's procedure manuals revealed, "The medical or laboratory director or the director's designee should review all copies of this procedure at least once a year. The director should keep a log of the copies being maintained." 2. Review of the procedure manuals' logs revealed no documented signatures for 2022. 3. Interview with the laboratory's general supervisor #2 at approximately 1:00 pm on June 1, 2023, confirmed there was no documented review of the laboratory's procedure manuals in 2022.</p>