Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1048585	04/03/2018
Name of Provider or Supplier	**Street Address, City, State**	
East Wood Clinic Pllc	1323 East Wood Street, Paris, 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	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory's procedure titled "Calibration Verification Linearity Testing Reportable Range", 12.27.17 calibration records for Sodium (Na+), Potassium (K+), Chloride (CL-), 2016 and 2017 calibration verification records, and interview with the technical consultant, the laboratory failed to follow procedure for calibration verification in 2016, 2017, and 2018. The findings include: 1. Observation of the laboratory on 04.03.18 revealed the Ortho Vitros 350 instrument in use for patient testing for chemistry analytes. 2. Review of the laboratory procedure titled "Calibration Verification Linearity Testing Reportable Range" revealed the following statements under the subsection Calibration Verification: "For analyzer and analytes that are not calibrated with a minimum of three calibrators verifying the low, midpoint and high end of the reportable range, a calibration verification must be performed to substantiate the continued accuracy of the monitors throughout the reportable range, after the initial validation studies are performed with the setup of the analyzer. Calibration verification is performed every six months as stated in the current CLIA regulations." "To perform the calibration verification, low, midpoint, and high level standards are tested in the same manner as patient samples." 3. Review of the 12.27.17 calibration records for the Na+, K+, and Cl- analytes revealed calibration performed using two levels of calibrator. 4. Review of the 2016 and 2017 calibration verification records for the Na+, K+, and Cl- analytes revealed calibration verification performed without using three levels to include a low, mid and high point. 5. Interview with the technical consultant on

	04.03.18 at 11:45 am confirmed that calibration for the Na+, K+, and Cl- analytes does not include three calibrators to include a low, mid, and high point; the calibration verification was not performed using three levels every six months; and the laboratory failed to follow procedure for calibration verification for Na+, K+, and Cl- analytes in 2016, 2017, and 2018.