Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0660780	03/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Abilene-Taylor County Public Health	850 North 6th, Abilene, TX	

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
D3029	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(2) Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance. This STANDARD is not met as evidenced by: Based on a review of laboratory policies and procedures and interview with facility personnel, the laboratory failed to retain a copy of the previous revision of the rapid plasma reagin (RPR) procedure. The findings included: 1. Based on review of the procedure "Rapid Plasma Reagin (RPR)", effective December 18th, 2017, the procedure states "Check and record room temperature (23 - 29 degrees Celsius)". 2. Based on review of the ASI RPR Card Test for Syphilis, the assay instructions for use states the following: "Preparation for the Assay: 1. Allow all reagents and samples to warm to room temperature (20 - 30 degrees Celsius) before use." 3. In an interview at 12:39 hours on 3/20/2018 in the laboratory office, when the surveyor asked to see the previous revision of the laboratory procedure to compare the room temperature requirements, the Laboratory Director stated that a testing person (who was no longer employed) had taken or destroyed the previous revisions of many procedures.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities

	specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on surveyor observation, review of the laboratory's policies and procedures, and interview with facility personnel, the laboratory failed to establish and follow a maintenance protocol to ensure the performance of 2 of 2 LW Scientific Centrifuges. The findings included: 1. Based on surveyor observation at 11:28 hours on 03/20 /2018 in the laboratory, the laboratory had two (2) LW Scientific Centrifuges: Serial Number: 09628 Serial Number: 09343 2. Based on a review of the laboratory's procedures, the laboratory had not established a maintenance and function check protocol to verify the timer and speed settings of 2 of 2 LW Scientific Centrifuges. Review of equipment documentation indicated the following: Serial Number: 09628 LW Scientific Centrifuges had been evaluated at 3460.76 RPM on December 15, 2016, approximately 15 months prior to the date of the survey. Serial Number: 09343 LW Scientific Centrifuges had been evaluated at 3506.12 RPM on December 15, 2016, approximately 15 months prior to the date of the survey. 3. In an interview at 11: 28 hours on 03/20/2018, the Laboratory Director stated that the laboratory recently recognized that a maintenance protocol had not been established for evaluating time and speed of the 2 LW Scientific centrifuges. Key RPM - Revolutions per minute
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of the verification study for the Abbott Emerald hematology analyzer, the Abbott Emerald operator's manual, patient records, and interview with the Laboratory Director, the laboratory failed to provide pertinent reference intervals or normal values for 1 of 1 patient complete blood count performed between January 1, 2018 and the day of the survey, March 20th, 2018. The finding included: 1. The laboratory failed to verify the manufacturer reference values as part of the verification study for the Abbott Emerald hematology analyzer in March 2013. For the red blood count (RBC), the laboratory calculated a range based on 20 patient specimens of 3.97 - 5.41 m/uL. The laboratory wrote down the previous reference range as follows: Males: 4.69 -6.13 Females: 4.04 - 5.48 The laboratory documentation included the following statement: "Health Department Normal Range Verified" Based on the verification study documentation, the source of the "previous normal ranges" or the "Health Department Normal Range" could not be determined. Based on the verification study documentation, the methodology for choosing "normal" patient specimens to verify the reference range is not clear, including inclusion and exclusion criteria for the study. 2. On page 4-16 of the Abbott Emerald operator's manual (9140848F -April 2012), the manufacturer reference ranges are provided as follows: White blood cell count (WBC) -4.70 - 10.3 Red blood cell count (RBC) -4.03 - 5.46 Hemoglobin (HGB) - 12.40 - 16.90 Platelet count (PLT) - 165 - 385 Mean corpuscular hemoglobin (MCH) - 27.50 - 33.10 3. Review of a random patient final report (Order ID: 14571, collected 1/29/2018) indicates that the laboratory's current reference values displayed on the final patient report were as follows: White blood cell count (WBC) -4.6 -10.2 Red blood cell count (RBC) -4.69 -6.13 Hemoglobin

	(HGB) - 14.10 -18.10 Platelet count (PLT) - 142 -424 Mean corpuscular hemoglobin (MCH) - 26 - 32 On this patient's report, the patient had a Mean corpuscular hemoglobin (MCH) value of 32.2, which was flagged as high. Based on the manufacturer's reference ranges, this value would be within normal limits. On this patient's report, the patient had a Platelet count (PLT) value of 157, which was considered normal. Based on the manufacturer's reference ranges, this value would be lower than the reference interval. 4. In an interview at 10:22 hours on March 20, 2018 in the laboratory office, the Laboratory Director confirmed the laboratory's reference ranges currently in use on final patient reports did not match the Abbott Emerald hematology analyzer methodology and the source of the reference ranges could not be determined. Key: White blood cell count (WBC) Red blood cell count (RBC) Hemoglobin (HGB) Platelet count (PLT) Mean corpuscular hemoglobin (MCH) Picograms (pg) g/dL -grams per deciliter k/uL -Thousand per microliter m/uL - Million per microliter