Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0672374	06/13/2019
Name of Provider or Supplier	**Street Address, City, State**	
Wichita Falls - Wichita County Public Health	1700 Third Street, Wichita Falls, 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
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on random review of patient test records for RPR from November 2018 to February 2019 revealed the laboratory failed to document the time 15 of 15 patient specimens were received. The findings were: 1. The following is a random sample of patient specimens in which the receipt time was not documented from November 2018 to February 2019: Date Specimen Received: 11-01-2018 Last three digits of Patient ID: 034 Date Specimen Received: 11-05-2018 Last three digits of Patient ID: 067 Date Specimen Received: 11-05-2018 Last three digits of Patient ID: 958 Date Specimen Received:11-06-2018 Last three digits of Patient ID: 814 Date Specimen Received: 11-06-2018 Last three digits of Patient ID: 263 Date Specimen Received: 11-06-2018 Last three digits of Patient ID: 523 Date Specimen Received: 11-08-2018 Last three digits of Patient ID: 766 Date Specimen Received: 12-03-2018 Last three digits of Patient ID: 868 Date Specimen Received: 12-06-2018 Last three digits of Patient ID: 432 Date Specimen Received: 01-14-2019 Last three digits of Patient ID: 738 Date Specimen Received: 02-07-2019 Last three digits of Patient ID: 226 Date Specimen Received: 02-11-2019 Last three digits of Patient ID: 791 Date Specimen Received: 02-13-2019 Last three digits of Patient ID: 606 Date Specimen Received: 02-21-2019 Last three digits of Patient ID: 180 Date Specimen Received: 02-26-2019 Last three digits of Patient ID: 704 2. The above findings were confirmed in interview of the technical consultant on June 13, 2019 at 15:00 hours in the office.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to

	the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on review of the patient test records and confirmed in interview, the laboratory failed to provide instructions for transportation of specimens to the laboratory from offsite locations. The findings included: 1. Review of patient test records revealed the laboratory received specimens from at least two (2) offsite locations. 2. n an interview at 15:30 hours on June 13, 2019 in the laboratory, the technical consultant confirmed that no client instructions had ever been distributed by the laboratory to offsite locations.
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 patient reports and staff interview, it was revealed the laboratory failed to provide reference intervals for RPR (rapid plasma regain) testing. The findings were: 1. A review of patient testing reports revealed 3 of 3 patient reports did not provide a reference range or the Expected Value for RPR. 2. The laboratory was asked to provide documentation providing reference intervals to aid providers in the assessment of patient results. No documentation was provided. 3. An interview with the technical consultant on June 13, 2019 at 14:33 hours in the office confirmed the findings.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the Form CMS-209 form, personnel records, and in interview with staff, the technical consultant failed to evaluate and document the performance of testing persons responsible for moderate complexity testing at least semiannually during the first year patient specimens were tested for 1 of 2 testing persons. The findings included: 1. Review of the Form CMS-209 form listed testing personnel two as performing moderate complexity testing for bacteriology, mycology, parasitology, and syphilis serology. 2. Review of the laboratory's personnel records for testing personnel two (as listed on Form CMS-209) he had a hire date of June 12, 2017. The personnel records included training for bacteriology, mycology, parasitology, and syphilis serology. However, the technical consultant failed to evaluate and document competency assessments at least semiannually for testing person two, as required the

	first year. 3. During an interview on 06/13/2019, at 13:15 hours, the technical consultant confirmed the above findings. Key: CMS - Centers for Medicare and Medicaid Services