Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0659711	07/28/2022
Name of Provider or Supplier	**Street Address, City, State**	
Northeast Texas Phd Regional Laboratory	815 North Broadway, Tyler, 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
D0000	An onsite survey conducted 07/27/2022 to 07/28/2022 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: A. Based on a review of laboratory policy, instructions for use, patient requisitions, and confirmed in an interview, the laboratory failed to ensure acceptable conditions for specimen transportation for five of five patients received for RPR/TP-PA testing on 7/28/2022. The findings include: 1. Review of the laboratory policy titled "Syphilis Serology Procedure Manual" section III "Specimen Processing" stated: "7. Each Specimen must be received within 5 days of collection at 2-8 C (Celsius) or be received frozen." 2. Review of patent requisitions for RPR and TP-PA serology testing has the following check-boxed question: "Serum received: __Cold __ Frozen" Surveyor queried 7/27/2022 at 11:25 hours, in the laboratory manager's office, for documentation of the temperature in which the specimens were received. The laboratory manager stated there were no temperature logs, and that the specimens were sent in coolers with ice packs, and that the specimens were acceptable as long as they were cold to the touch upon receipt. 3. On 7/28/2022 at 10:10 hours the surveyor observed the following five patients received for RPR testing without ensuring acceptable conditions for specimen transport: Lab No 666 Lab No 667 Lab No 668 Lab No 669 Lab No 670 4. In an interview on 7/27/2022 at 11:30 hours, in the

	laboratory manager's office, the laboratory manager confirmed that the laboratory did not ensure specimen storage acceptability during transport for RPR, TP-PA. B. Based on a review of laboratory policy, instructions for use, patient requisitions, and confirmed in an interview, the laboratory failed to ensure acceptable conditions, as specified by the manufacturer, for specimen transportation for five of five patients received for Chlamydia/Gonorrhea screening on 7/28/2022. The findings include: 1. Review of the "Aptima Urine Specimen Collection Kit for male and Female Urine Specimens" instructions for use, section "Specimen Transport and Storage" had the following statement: "After collection, transport the processed urine specimens in the Aptima urine specimen transport tube at 2 C to 30 C and store at 2 C to 30 C until tested." 2. Review of patient requisition for Chlamydia/Gonorrhea screening did not include a way to indicate the specimen transport temperature. Surveyor queried, as above, and the laboratory manager stated that if the specimens were received cold to the touch, they were acceptable. 3. On 7/28/2022 at 10:10 hours the surveyor observed the following five patients received for Chlamydia/Gonorrhea screening in the Aptima Urine Specimen collection kit without ensuring acceptable conditions for specimen transport: Number 1 Number 2 Number 3 Number 4 Number 5 See the patient alias list for specific patient identifiers. 4. In an interview on 7/27/2022 at 11:30 hours, in the laboratory manager's office, the laboratory manager confirmed that the laboratory did not ensure specimen storage acceptability, as defined by the manufacturer, for Chlamydia/Gonorrhea screening on the Aptima 2 Combo.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a review of the laboratory test menu, the Centers for Medicare and Medicaid (CMS) personnel form 209, competency assessments, and confirmed in interview, the technical consultant failed to perform annual competency assessments for two of two testing personnel performing moderate complexity testing reviewed from 2021 to 2022. The findings include: 1. Review of the laboratory test menu for moderate complexity testing has the following two tests being performed: RPR - rapid plasma reagin TP-PA - treponema pallidium particle agglutination 2. Review of the laboratory annual competency evaluations for moderate complexity testing for the RPR serology testing had two TP-PA signatures, qualified under 493.1423(b)(2), at the bottom of each sheet with the TC signature at a later date. Surveyor queried why there were two testing persons' signatures, and it was stated that they observed and signed off on each other's competency assessments and that the technical consultant would come behind later and sign it. 2022 TP2 annual competency for RPR serology testing was evaluated by TP1 on 1/4/2022 with the technical consultant's signature on 1/24/2022 2022 TP1 annual competency for RPR serology testing was evaluated by TP2 on 1/20/2022, with the technical consultant's signature on 1/24/2022. 3. In an interview on 7/27/2022 at 09:43 hours, in the laboratory manager's office, the laboratory manager confirmed that the testing personnel, not the technical consultant, had signed off on each other's annual competency assessments for RPR serology testing.