Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0923731	12/19/2023
Name of Provider or Supplier	**Street Address, City, State**	
Angelina Pediatrics	1222 Ellis Avenue, Lufkin, 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 12/19/2023 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) records and attestation forms, personnel documents, and confirmed in interview, the laboratory failed to include the signatures of testing personnel performing test interpretation for six of six PT testing events in Microbiology in 2022 and 2023. The findings included: 1. Review of the API forms for the events 1st, 2nd, and 3rd events in 2022 and 2023 included the following microbiology PT challenges: Throat Culture Urine Colony Count A review of the API attestation forms had the following personnel listed for person(s) performing the test: 2022 Microbiology 1st Event: TP 15 (see TP crosswalk) TP 16 (see TP crosswalk) TP 1 2022 Microbiology 2nd Event: TP 15 TP 16 TP 21 (see TP crosswalk) TP 20 (see TP crosswalk) 2022 Microbiology 3rd Event: TP 15 TP 1 TP 20 2023 Microbiology 1st Event: TP 3 TP 4 TP 6 TP 33 (see TP crosswalk) TP 32 (see TP crosswalk) 2023 Microbiology 2nd Event: TP 3 TP 1 TP 31 (see TP crosswalk) TP 2 TP 4 2023 Microbiology 3rd Event: TP 3 TP 4 TP 6 TP 33 TP 32 2. The review of laboratory personnel documents, for the above, did not include training and competency evaluations for microbiology test interpretation for throat cultures and urine culture colony counts. In an interview on 12/19/2023 at 11: 35 hours, in the office, the technical consultant (TC) stated that the attestations signatures were for only those testing personnel (TP) preparing the sample for testing and that they did not perform test interpretation for the PT results. The TC stated that

	TP's 8 - 13 were the only ones trained and competent to perform test interpretation. The surveyor queried as to which TP provided the PT results for the 2022 and 2023 microbiology events and none was provided. 3. In an interview on 12/19/2023 at 11: 40 hours, in the office, the TC confirmed that the TP performing the test interpretation for the microbiology 2022 and 2023 PT results had not been documented or attested to.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on a review of quality controls, laboratory documentation, patient test records, and confirmed in interview, the laboratory failed to remediate eight of eight patients to the last acceptable quality control (QC) for QC that did not meet laboratory acceptability criteria in records reviewed in August and September 2023. The findings included: 1. A review of the laboratory document titled "Corrective Action Form Horiba Micros60" stated the following: "Any issue that arises with the Horiba Micros60 from changing reagents to controls being rerun to improper results must be documented and the controls rerun. Then patient remediation must be performed going back to the last QC. Even extended cleanings must be documented." 2. A review of the corrective action documentation for August and September 2023 had the following two QC failures that exceeded the laboratory's acceptability criteria and did not include patient remedial action: August 2023: Date - Issue - Action 8/5/2023 - Controls Not Passing - Concentrated cleaning & backflush The following five patients had CBC testing since the last acceptable QC on 8/4/2023: Patient 1 Patient 2 Patient 3 Patient 4 Patient 5 (see patient crosswalk) September 2023: Date - Issue - Action 9/8 /2023 - L Control won't pass, H - did not pass the first 2 times - Performed concentrated cleaning" The following three patients had CBC testing since the last acceptable QC on 9/7/2023: Patient 6 Patient 7 Patient 8 (see patient crosswalk) 3. In an interview on 12/19/2023 at 13:00, in the office, the technical consultant (TC) confirmed that remedial action had not been taken for the above patients.