

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0923731	<b>(X3) Date Survey Completed</b>  09/23/2020
<b>Name of Provider or Supplier</b>  Angelina Pediatrics	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by:  . Based on review of laboratory temperature logs and staff interview, the laboratory failed to maintain bacteriology incubator temperatures within the range specified in policy. Findings: 1. Laboratory quality assurance documentation was reviewed. The temperature chart for the Strep Incubator showed an acceptable range of 33-37 degrees Celsius (C). 2. Review of the temperature charts for 2019 and 2020 revealed the following readings outside the posted range: (Note: readings represent AM/PM temperatures read at beginning and end of shift) DATE TEMP (C) DATE TEMP (C)  04/03/2019 37/38 12/09/2019 37/38 04/25/2019 38/36 12/10/2019 37/38 05/02/2019 38/38 12/12/2019 38/37 05/07/2019 38/38 12/18/2019 39/38 05/29/2019 38/38 12/19/2019 37/39 05/31/2019 38/36 12/20/2019 37/38 06/19/2019 37/38 12/24/2019 37/38 07/15/2019 36/38 12/26/2019 38/38 07/16/2019 38/35 12/27/2019 38/38 07/17/2019 38/36 01/10/2020 38/37 07/18/2019 36/38 04/10/2020 38/38 08/28/2019 38/38 04/13/2020 38/38 08/29/2019 37/38 04/14/2020 36/38 08/30/2019 38/37 04/15/2020 38/38 09/04/2019 38/37 04/17/2020 36/38 09/05/2019 38/37 06/01/2020 38/37 09/12/2019 38/37 06/02/2020 37/38 09/26/2019 37/38 06/05/2020 37/38 09/27/2019 37/38 06/09/2020 38/36 10/02/2019 37/38 06/17/2020 38/38 10/03/2019 37/38 06/19/2020 38/38 10/28/2019 38/37 06/23/2020 38/38 10/29/2019 37/38 06/24/2020 36/38 10/30/2019 37/38 06/26/2020 38/36 10/31/2019 37/38 06/29/2020 37/38 11/05/2019 37/38 07/14</p>

/2020 37/38 11/26/2019 38/37 07/20/2020 37/38 12/02/2019 37/38 07/21/2020 38/39  
12/03/2019 36/38 3. No evidence of corrective action was found or could be offered at  
the time of the survey. 4. In an interview at the site at the time of the survey, the  
laboratory technical consultant (form CMS 209) verified the above readings outside  
the posted acceptable range. The laboratory performs an average of 3535 tests in the  
specialty of bacteriology per year.