

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0877934	(X3) Date Survey Completed 12/10/2025
Name of Provider or Supplier Childrens Clinic Of Lufkin Pa, The	Street Address, City, State 205 Gene Samford Ave, 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	The laboratory was found to be in compliance with 42 CFR Part 493, Requirements for Laboratories as a result of a recertification survey completed on December 10, 2025.
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory instructions for use, laboratory temperature records, and confirmed in interview, the laboratory failed to ensure corrective action was documented for 49 of 49 days where daily refrigerator temperatures were recorded out of range in records reviewed from January 2025 through November 2025. The findings included: 1. In a tour of the laboratory and supply areas on 12/10/2025 at 15:00, the surveyor noted the following microbiology media and laboratory hematology controls in the refrigerator: 2 boxes of "Horiba ABX Mintrol 16 Whole Blood Hematology Controls" 5 packs of "Hardy Diagnostics Strep Agar" 2. Review of the "Hardy Diagnostics Selective Strep Agar" manufacturer instructions for use, section "Storage and Shelf Life" included the following instructions: "Storage: Upon receipt store at 2-8(degrees) Celsius." Review of the "Horiba ABX Mintrol 16 Whole Blood Hematology Control" manufacturers IFU, section "Storage and Stability" included the</p>

following temperature storage requirements: "Storage and Stability: Do not freeze. ABX Mintrol tubes should be tightly capped and stored at 2 (degrees) C - 8 (degrees) C (35 to 48 (degrees) F) when not in use. 3. Review of the laboratory monthly temperature records for the refrigerator where the laboratory stored "Hardy Diagnostics Selective Strep Agar" and "Horiba ABX Mintrol 16 Whole Blood Hematology Control" did not include an acceptable range. Surveyor asked what the laboratory temperature acceptability was, and the technical consultant (TC) stated the temperature range was 35-45(degrees) F. 4. Review the laboratory refrigerator temperature records for January 2025 through November 2025 included the following 49 days where the temperature was recorded outside of the laboratory acceptability of 35 - 45 (degrees) F, with no corrective action documented for the temperature unacceptability: January 2025: 3 out of 25 days 01/02/2025 - AM temperature recorded at 34 F 01/10/2025 - AM temperature recorded at 34 F 01/25/2025 - AM temperature recorded at 32 F March 2025: 7 out of 27 days 03/05/2025 - PM temperature recorded at 34 F 03/07/2025 - PM temperature recorded at 33 F 03/10/2025 - PM temperature recorded at 34 F 03/14/2025 - AM temperature recorded at 34 F 03/20/2025 - AM temperature recorded at 34 F 03/21/2025 - PM temperature recorded at 30 F 03/24/2025 - PM temperature recorded at 34 F April 2025: 5 out of 23 days 04/01/2025 - AM temperature recorded at 32 F 04/09/2025 - AM temperature recorded at 33 F 04/14/2025 - AM temperature recorded at 33 F 04/28/2025 - AM temperature recorded at 32 F 04/29/2025 - AM temperature recorded at 30 F May 2025: 5 out of 23 days 05/06/2025 - AM temperature recorded at 34 F 05/06/2025 - PM temperature recorded at 34 F 05/08/2025 - AM temperature recorded at 32 F 05/10/2025 - AM temperature recorded at 33 F 05/23/2025 - PM temperature recorded at 32 F 05/28/2025 - PM temperature recorded at 32 F June 2025: 4 out of 20 days 06/05/2025 - AM temperature recorded at 33 F 06/05/2025 - PM temperature recorded at 34 F 06/09/2025 - AM temperature recorded at 34 F 06/12/2025 - PM temperature recorded at 34 F 06/20/2025 - AM temperature recorded at 33 F 06/20/2025 - PM temperature recorded at 34 F July 2025: 9 out of 23 days 07/02/2025 - AM temperature recorded at 32 F 07/03/2025 - AM temperature recorded at 30 F 07/03/2025 - PM temperature recorded at 34 F 07/11/2025 - AM temperature recorded at 34 F 07/16/2025 - PM temperature recorded at 32 F 07/17/2025 - PM temperature recorded at 32 F 07/18/2025 - AM temperature recorded at 34 F 07/24/2025 - PM temperature recorded at 34 F 07/25/2025 - PM temperature recorded at 34 F 07/31/2025 - PM temperature recorded at 32 F August 2025: 3 out of 23 days 08/26/2025 - AM temperature recorded at 32 F 08/27/2025 - PM temperature recorded at 34 F 08/28/2025 - PM temperature recorded at 34 F September 2025: 5 out of 22 days 09/02/2025 - AM temperature recorded at 34 F 09/03/2025 - AM temperature recorded at 32 F 09/23/2025 - PM temperature recorded at 34 F 09/05/2025 - AM temperature recorded at 34 F 09/30/2025 - AM temperature recorded at 55 F 09/30/2025 - PM temperature recorded at 32 F October 2025: 6 out of 26 days 10/01/2025 - AM temperature recorded at 33 F 10/01/2025 - PM temperature recorded at 33 F 10/14/2025 - PM temperature recorded at 33 F 10/26/2025 - AM temperature recorded at 34 F 10/27/2025 - AM temperature recorded at 34 F 10/28/2025 - PM temperature recorded at 34 F 10/30/2025 - PM temperature recorded at 34 F November 2025: 2 out of 22 days 11/03/2025 - AM temperature recorded at 34 F 11/13/2025 - PM temperature recorded at 34 F 5. In an interview on 12/10/2025 at 15:45 hours, in the conference room, the TC confirmed corrective action had not been documented by personnel for the refrigerator temperatures that were recorded outside of the laboratory acceptability temperature of 35 - 45 (degrees) F. Key C - Celsius F - Fahrenheit