

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2119424	(X3) Date Survey Completed 07/12/2023
Name of Provider or Supplier Falfurrias Family Clinic Pllc	Street Address, City, State 1204 S Saint Mary'S Street, Falfurrias, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Medonic M-series hematology analyzer maintenance records from January 2023 to June 2023, and staff interview, it was revealed the laboratory failed to have documentation of performing monthly maintenance for 2 of 6 months. The findings include: 1. A review of the laboratory's Medonic M-series hematology analyzer maintenance records from January 2023 to June 2023 revealed the laboratory failed to have documentation of performing monthly maintenance for 2 of 6 months. The months missing documentation were: January 2023 February 2023 2. The laboratory was asked to provide documentation of performing the required monthly maintenance. No documentation was provided. 3. An interview with the technical consultant on 07/12/2023 at 1050 hours in the employee lounge - after his review of the records- confirmed the findings.</p>
D5785	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.</p>

This STANDARD is not met as evidenced by:

Based on review of the laboratory's room temperature records from January 2022 to December 2022, and staff interview, it was revealed the laboratory failed to have documentation of performing corrective actions when room temperature were outside the laboratory's defined acceptable ranges. The findings include: 1. A review of the laboratory's room temperature records from January 2022 to December 2022 revealed the laboratory had a defined acceptable range for room temperature of 65 - 77F. 2. Further review of the laboratory's room temperature records from January 2022 to December 2022 identified 13 of 122 days where the documented room temperature was outside the laboratory's acceptable range. They were: a) January 2022 (2 of 21 days) 1/4 Temp: 63F 1/5 Temp: 64F b) February 2022 (5 of 20 days) 2/10 Temp: 63F 2/11 Temp: 63F 2/14 Temp: 61F 2/15 Temp: 64F 2/18 Temp: 64F c) March 2022 (4 of 21 days) 3/8 Temp: 64F 3/9 Temp: 64F 3/16 Temp: 64F 3/25 Temp: 64F d) April 2022 (1 of 19 days) 4/4 Temp: 64F e) December (1 of 22 days) 12/16 Temp: 63F 3. The laboratory was asked to provide documentation of performing corrective actions on the identified days. No documentation was provided. 4. An interview with the technical consultant on 07/12/2023 at 1030 hours in the employee lounge - after his review of the records- confirmed the findings. Key F - degrees Fahrenheit