Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2119424	12/13/2021
Name of Provider or Supplier	**Street Address, City, State**	
Falfurrias Family Clinic Pllc	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 representatives at the entrance and exit conferences. The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of 6 random patient test reports from July 2020 to December 2021, and staff interview, the laboratory failed to ensure final test reports included the address of the laboratory where patient testing was performed on 6 of 6 reports. The findings included: 1. A review of 8 random patient test reports from July 2020

	through December 2021 found 6 of 6 test reports failed to include the address of the testing laboratory. The patient identification numbers and test dates reviewed were: Date Order Number 12-02-2020 287708 12-02-2020 287863 09-08-2021 356058 09-08-2021 355832 01-20-2021 299806 12-08-2021 378158 2. The laboratory was asked to provide documentation of the address on patient reports. No documentation was provided. 3. An interview with the technical consultant on 12/13/2021 at 15:00 hours in the laboratory confirmed the findings. He said the laboratory moved to the location in March or April of 2020.
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, random review of patient records from December 2020, January 2021, and September 2021, and staff interview, the laboratory failed to provide documentation of notification to an authorized person for 8 of 8 panic values. The findings included: 1. Review of the laboratory's hematology testing policy titled, "Reporting Panic Values" approved by the laboratory director on 10/01/2016, it stated, "It is the policy of this laboratory to document the reporting of critical values." Document: - Who was notified - When was the person notified - By whom was the person notified" 2. Review of the laboratory's policy titled, "Panic Values" approved by the laboratory director on 10/01/2016, it stated: Parameter: HGB (hemoglobin) Panic Values: less than 7.5 mg/dL and greater than 18 mg/dL Parameter: HCT (hematocrit) Panic Values: less than 25 and greater than 55 % 3. Random review of patient records from December 2020 and September 2021 found the following 8 patient results which met the laboratory's criteria as a critical value: Date: 12/01/2020 Analyzer Sequence Number: 7513 Panic Value: Hemoglobin = 18.4 Date: 12/02/2020 Analyzer Sequence Number: 7518 Panic Value: Hemoglobin = 18.4 Date: 12/21/2020 Analyzer Sequence Number: 7603 Panic Value: Hemoglobin = 6.8 Date: 01/20/2021 Analyzer Sequence Number: 7736 Panic Value: Hemoglobin = 18.8 Date: 09/08/2021 Analyzer Sequence Number: 8727 Panic Value: Hematocrit = 68.6, Hemoglobin = 22.0 Date: 09/08/2021 Analyzer Sequence Number: 8739 Panic Value: Hematocrit = 64.9, Hemoglobin = 20.8 4. The laboratory was asked to provide documentation of reporting the critical value according to their policy. No documentation was provided. 5. During an interview with the technical consultant on 12/13/2021 at 15:00 hours in the laboratory after his review of the records confirmed the findings. Key: mg/dL - milligrams per deciliter
D6061	CLINICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1419(c) The clinical consultant must ensure that reports of test results include pertinent information required for specific patient interpretation. This STANDARD is not met as evidenced by: Based on review of the laboratory's established normal patient reference ranges for males and females, review of patient final reports, and confirmed in interview of

	facility personnel, the clinical consultant failed to ensure patient final reports included pertinent information for patient interpretation for 3 of 5 patients results reviewed from August 2020 to December 2021. The findings included: 1. Review of the laboratory's established patient normal ranges for males and females approved by the laboratory director on July 10, 2018 found the following ranges: Males Females WBC 4.3 - 11.0 4.3 - 11.0 LYM% 20.0 - 45.0 20.0 - 45.0 MID% 2.0 - 15.0 2.0 - 15.0 GRA% 35.0 - 80.0 35.0 - 80.0 LYM 1.2 - 3.4 1.2 - 3.4 MID 0.1 - 0.6 0.1 - 0.6 GRAN 1.2 - 8.0 1.2 - 8.0 RBC 4.60 - 6.20 4.20 - 5.40 HGB 14 - 18 12.0 - 16.0 HCT 42 - 52 36.0 - 47.0 MCV 82 - 100 80.0 - 94.0 MCH 26.0 - 33.0 26.0 - 33.0 MCHC 31.0 - 36.0 31.0 -36.0. RDW% 11.5 - 14.5 11.5 - 14.5 PLT 150 - 375 150 - 375 MPV 7.4 - 10.4 7.4 - 10.4 2.. Random review of 5 of 5 patient final reports found the laboratory utilized two different final patient reports for patient interpretation of results. The final report from the analyzer was distributed to the patient and one final report is retained in the patient's electronic health record. 3. Review of 3 of 5 patient final reports found the refence range for males did not match the laboratory's established refence ranges on the report found in the patient's electronic health record: Date: 12/02/2020 Order Number: 287863 (male) RBC Reference Range: 4.20 - 5.40 HGB Reference Range: 12.0 - 16.0 HCT Reference Range: 36.0 - 47.0 MCV Reference Range: 80.0 - 94.0 Date: 01/20/2021 Order Number: 355832 (male) RBC Reference Range: 4.20 - 5.40 HGB Reference Range: 12.0 - 16.0 HCT Reference Range: 36.0 - 47.0 MCV Reference Range: 80.0 - 94.0 Date: 01/20/2021 Order Number: 299806 (male) RBC Reference Range: 4.20 - 5.40 HGB Reference Range: 12.0 - 16.0 HCT Reference Range: 36.0 - 47.0 MCV Reference Range: 80.0 - 94.0 4. An interview with the technical consultant on December 13, 2021 at 15:00 hours in the laboratory confirmed the findings. Key: WBC - white blood cell LYM% - percent lymphocytes MID% - percent mids GRA% - percent granulocytes LYM - lymphocytes MID - monocytes, eosinophils, basophils, blasts or other precursor white blood cells GRAN - granulocytes RBC - red blood cell HGB - hemoglobin HCT - hematocrit MCV - mean cell volume MCH - mean corpuscular hemoglobin MCHC - mean corpuscular hemoglobin concentration RDW% - percent red cell distribution width PLT - platelets MPV - mean platelet volume