Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2119424	11/08/2019
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	The laboratory was found out of compliance with the CLIA regulations. The condition not met was: 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. 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.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by:

	Based on review of laboratory policy, review of quality control records, and confirmed in interview of facility personnel, the laboratory failed to have documentation of verifying new lot numbers of quality control reagent before placing them into use. The findings included: 1. Review of the laboratory's policy titled, "Quantitative Control Policy" approved by the laboratory director on October 1, 2016 it stated, "Controls will be run concurrently with patients for at least 5 days. If the mean of all results is within the stated range, then the stated range will be used as the expected range for this lab." 2. Review of quality control records from July 2018 to September 2019 revealed no records of the laboratory performing lot to lot quality verification studies. 3. The findings were confirmed in interview with Testing Personnel #2 (as listed on Form CMS-209) on November 8, 2019 in the laboratory. When asked if she performs lot roll over studies prior to putting a new lot number into use, she stated, "No." She confirmed that when an old lot is through, the new lot is started. She went on to say that sometimes the QC material is late to be ordered, so no correlation can be done.
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 review of laboratory policy, quality control records, and confirmed in interview of facility personnel, the laboratory failed to ensure corrective action was performed when a quality control run failed. The findings were: 1. Review of the laboratory's policy titled, "Control Policy" approved by the laboratory director on October 1, 2016 stated, "Patient testing must not be performed or reported when control test results are outside the expected range." 2. Review of the laboratory's quality assurance plan approved by the laboratory director on October 1, 2016 stated, "2. Identify problems in our laboratory and apply corrective actions." 3. Review of the laboratory's policy titled, "CBC Quality Control Policy" approved by the laboratory director on October 1, 2016 stated, "Our lab has a policy of running 3 levels of controls on every day of patient testing and for every 8 hours of operation. All testing personnel should be aware of the need to have at least two controls within 2 standard deviations (SD) and the third control within 3 SD before patient testing is reported. Patient testing may not be performed if an analyte is beyond 2SD consequitively [sic]". 4. Random review of quality control records from February 2018 to August 2019 revealed the following documented quality control failures: February 20, 2019 Abnormal Low: HGB = 5.3 (pass) Normal: HGB = 10.7 (fail) Abnormal High: HGB = 14.2 (fail) 2 out of 3 QC failed February 26, 2019 Abnormal Low: PLT = 69 (failure) Normal: PLT = 272 (failure) Abnormal High: PLT = 448 (pass) 2 out of 3 QC failed April 2, 2019 QC expired: all analytes failed April 3, 2019 QC expired: all analytes failed April 5, 2019 QC expired: all analytes failed 5. Review of patient final reports found the following patients were tested and reported when quality control failed. February 20, 2019 CBC Order # 165892 CBC Order # 165776 CBC Order # 165854 CBC Order # 165879 CBC Order # 165793 CBC Order # 165924 CBC Order

	# 165939 CBC Order # 165865 February 26, 2019 CBC Order # 167153 April 2, 2019 Instrument Sequence #5425 Date of Birth: 07-25-2000 April 3, 2019 Order # 173509 Order # 173550 Order # 173589 Order # 173559 Order # 173615 Order # 173503 Order # 173625 Order # 173676 Order # 173648 Order # 173772 April 5, 2019 Instrument Sequence # 5270 Date of Birth: 09-09-1921 6. Review of laboratory records revealed no record of corrective action was documented when patients were tested when quality control had failed. The laboratory must perform corrective action since the last acceptable quality control run. 7. Interview with Testing Personnel #2 (as listed on Form CMS-209) on November 8, 2019 at 10:30 hours confirmed the findings. Key: HGB - hemoglobin PLT - platelet CBC - complete blood count CMS - Centers for Medicare and Medicaid Services
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on a review of laboratory policy, review of the laboratory's personnel records, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of education records to ensure 1 of 3 testing persons were qualified to perform moderate complexity testing (refer to D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on a review of laboratory policy, review of the laboratory's personnel records, and confirmed in interview of facility personnel, the laboratory failed to have documentation of the education for 1 of 3 testing personnel in order to qualify them to perform moderate complexity testing. The findings included: 1. A review of the Form CMS-209 (signed by the laboratory director on 11-08-2019) revealed the laboratory designated 3 testing personnel to perform moderate complexity testing. 2. Review of the laboratory's policy titled, "Personnel Policy" approved by the laboratory director on October 1, 2016 stated, "All Testing Personnel must qualify as follows: Be a High School graduate or equivalent," and, "This laboratory will maintain personnel records on all laboratory staff to show: proof of education; Education and experience of staff;

	Continuing Education (E.G. Seminar attendance)." 3. Review of the laboratory's personnel records revealed the laboratory failed to have documentation of education for Testing Personnel #3 (as listed on Form CMS-209) whose termination date was two weeks prior to the survey. 4. Interview with the technical consultant on November 8, 2019 at 10:00 hours in the laboratory confirmed the findings.