Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0471996	03/12/2026
Name of Provider or Supplier	**Street Address, City, State**	
Family Health Center Of Southern Oklahoma, Inc	610 E 24th, Tishomingo, OK	

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	An onsite validation survey was conducted on 3/12/2026. Standard level deficiencies were cited.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of Form CMS-209, personnel records, proficiency testing, and the laboratory's procedure manual, the laboratory failed to ensure 3 of 3 hematology proficiency testing (PT) events in 2025 were analyzed by personnel who routinely perform testing on the Sysmex XN-330. Findings included: 1. Review of the Form CMS-209 laboratory Personnel Report (CLIA) included a total of 7 testing persons (TP) for Sysmex XN-330. According to personnel records, TP-1, TP-2, and TP-3 had been active testing persons for more than 2 years. 2. Review of American Proficiency Institute (API) hematology PT events 1, 2, and 3 in 2025 revealed TP-1 analyzed all three events. 3. Review of the laboratory's procedure "LAB-004" stated, "Proficiency testing is to be rotated and performed by ALL testing personnel on ALL testing systems, where applicable." The laboratory did not follow their own procedure for rotating and performing PT by personnel who routinely perform hematology testing on the Sysmex XN-330.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling,

	storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, final test reports, interview with staff, and review of verification studies, the laboratory failed to include Sysmex XN-330 complete blood count reference intervals (normal values) in their procedure manual (one of one test method). Findings included: 1. Review of the laboratory's procedure manual for Sysmex XN-330 complete blood count test procedure did not include reference intervals (normal values) for their patients. 2. A random review of 3 complete blood count (CBC) final test reports from 2/2025 included similar reference ranges for a 6-year old male, an adult male, and an adult female. 3. During an interview on 3/12/2026 at 1:22 pm, the surveyor asked technical consultants 1 and 2, and TP-1 whether the same reference ranges were verified for two different genders and adult versus pediatric population. They stated that reference ranges were selected by the laboratory director. 4. Review of Sysmex XN-330 analyzer verification studies from 4/25/2023 did not include data and data analysis of verifying the reference ranges. Refer to D5421.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on review of manufacturers' instructions, the laboratory's procedure manual, direct observation, and interview with TP-1, the laboratory failed to label 3 of 3 opened quality control (QC) vials for Sysmex XN-330 analyzer with the revised expiration date. Findings included: 1. Review of XN-L CHECK hematology control package insert (manufacturer's instructions) stated, "Storage and shelf like after first opening Open vials and vials which have been samples by cap piercing will retain stability for 15 days if stored at 2-8C after being re-capped." 2. Review of the laboratory's procedure manual stated, "XN-L CHECK, Storage Temp: 2 to 8c, Shelf

	life after open: 15 days." 3. During a tour of the laboratory on 3/12/2026 at 12:12 pm, there were 3 XN-L CHECK QC vials observed stored in the refrigerator with labeled opened dates of "3/11/26" but did not include a documented revised expiration date (of 3/26/2026): Level 1 Lot #60381401 Level 2 Lot #60381402 Level 3 Lot #60381403 4. During an interview on 3/12/2026 at 12:12 pm, the surveyor asked TP-1 for the stability of controls once opened, they stated "14 days." The laboratory failed to label the opened QC vials for Sysmex XN-330 analyzer with the revised expiration date.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of patient test reports, interview with staff, review of verification studies and the laboratory's procedure manual, the laboratory failed to verify Sysmex XN-330 hematology analyzer reference intervals (normal values) were appropriate for the patient population for one of one test method. Findings included: 1. A random review of 3 complete blood count (CBC) final test reports from 2/2025 included similar reference ranges for a 6-year old male, an adult male, and an adult female. 2. During an interview on 3/12/2026 at 1:22 pm, the surveyor asked technical consultants 1 and 2, and TP-1 whether the same reference ranges were verified for two different genders and adults versus pediatric population. They stated that reference ranges were selected by the laboratory director. 3. Review of Sysmex XN-330 analyzer verification studies from 4/25/2023 did not include data and data analysis of verifying the reference ranges. The binder of the verification studies had a document provided by Sysmex "Section 5 Additional Studies for Reference" and stated, "It is the customer's responsibility to perform any additional studies required by accrediting agencies." The document provided guidance on completing a reference range study, but the reference ranges "chosen by the laboratory director" were not included and normal patients' data was not included in the binder with an analysis for verification. 4. In addition, review of the laboratory procedure manual did not include the in-use reference ranges as required. Refer to D5403.