Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0445440	01/23/2024
Name of Provider or Supplier	**Street Address, City, State**	
Osceola Family Medical Center	855 Arduser Drive, Osceola, MO	

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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of refrigerator/humidity/room temperature logs, and interview with the technical consultant (TC), the laboratory failed to document refrigerator/humidity /room temperature for 7 of 22 days in January 2024. Findings: 1. Review of January 2024 refrigerator temperature log showed no documentation of refrigerator temperature for January 16, 17, 18, 19, 20, 21 and 22. 2. Review of January 2024 humidity log showed no documentation of humidity for January 16, 17, 18, 19, 20, 21 and 22. 3. Review of January 2024 room temperature log showed no documentation of room temperature for January 16, 17, 18, 19, 20, 21 and 22. 3. Interview with the TC on January 23, 2024 at 1:00 PM confirmed the laboratory failed to document refrigerator/humidity/room temperature for 7 days in January 2024.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper

	use. This STANDARD is not met as evidenced by: Based on review of Beckman Coulter hematology DxH520 quality control (QC) package insert, observation of hematology DxH520 QC and interview with the technical consultant (TC), the laboratory failed to document expiration date on hematology QC. Findings: 1. Review of Beckman Coulter hematology DxH520 QC package insert states "Assumes that the instructions for Use section of the Consumable IFU/Setting Sheet is performed a maximum of 16 times within 16 days, provided they are handled properly". 2. Observation of hematology DxH520 QC lot # 352415611, 362415612 and 372415613 included no expiration date on QC vials. 3. Interview with the TC on January 23, 2024 at 1:00 PM confirmed the laboratory failed to document expiration date on hematology QC.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of temperature logs, observation of testing personnel (TP) # 1 and interview with the technical consultant (TC), the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified. Findings: 1. Review of refrigerator/humidity /room temperature logs showed no documentation on January 16, 17, 18, 19, 20, 21 and 22. 2. Observation of TP #1 showed that while onsite in front of the CLIA inspector TP #1 filled in documentation for all dates that were missing for temperatures. 3. Interview with TP #1 and the TC, TP #1 stated she "had a great memory and could remember all temperatures". 4. Interview with TC on January 23, 2024 at 1:00 PM confirmed the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified.