Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0472664	01/18/2023
Name of Provider or Supplier	**Street Address, City, State**	
Fairview Regional Medical Center	523 E State Road, Fairview, 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	The recertification survey was performed on 01/17,18/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the chief executive officer and laboratory manager during an exit conference performed at the conclusion of the survey.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of records, written policies and procedures, and interview with the laboratory manager, the laboratory failed to have a written policy to assess the competency of the general supervisor and technical supervisor, based on the position responsibilities as listed in Subpart M, for three of three persons serving as general supervisor and two of two persons serving as technical supervisor. Findings include: (1) On 01/17/2023, a review of the competency assessment policy identified no guidance, including the frequency, for assessing the competency of the general supervisors and technical supervisors; (2) A review of the Form CMS-209 and personnel records for competency assessments performed during the review period of 2021 through the current date in 2023 identified competencies, based on job responsibilities, had not been performed as follows: (a) General Supervisor - Not performed during the review period for three of three persons listed on Form CMS-209; (c) Technical Supervisor - Not performed during the review period for two of two persons listed on Form CMS-209. (3) The findings were reviewed with the laboratory manager who stated on 01/17/2023 at 01:45 pm a policy had not been written and competencies had not been performed for the positions as shown above.

D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to verify the accuracy of Qualitative Semen Analysis (presence or absence of sperm) at least twice annually for one of two years reviewed. Findings include: (1) On 01/17/2023 at 10:50 am, the laboratory manager stated the laboratory performed Qualitative Semen Analysis to detect presence or absence of sperm; (2) A review of records for testing performed during 2021 and 2022 identified the testing had not been verified for accuracy since 09/14/2021; (3) The records were reviewed with the laboratory manager who stated on 01/18/2023 at 09:04 am, Qualitative Semen Analysis had not been verified for accuracy at least twice annually in 2022.
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 a review of records, observation, and interview with the laboratory manager, the laboratory failed to ensure materials were stored as required for 12 of 12 months reviewed. Findings include: (1) On 01/18/2023 at 01:30 pm, observation of the contents of the American BioTech Supply freezer identified the following materials: (a) One box of LGC Maine Standards GC1 test set materials for calibration verification of Direct Bilirubin and Total Bilirubin, lot #10613613 - the storage requirement as stated on the box was -25 to -10 degrees C (Centigrade); (b) One box of LGC Maine Standards GC4 test set materials for calibration verification of HDL (High Density Lipoprotein), lot #10640560 - the storage requirement as stated on the box was -25 to -10 degrees C (2) A review of temperature records for 12 months (January 2022 through December 2022) identified the documented temperatures were colder than -25 degrees C (the coldest temperature allowed for the materials) during 12 of 12 months as follows: (a) January 2022 - 31 of 31 temperatures were documented as colder than -25 degrees C (b) February 2022 - 28 of 28 temperatures were documented as colder than -25 degrees C (c) March 2022 - 30 of 31 temperatures were documented as colder than -25 degrees C (d) April 2022 - 30 of 30 temperatures were documented as colder than -25 degrees C (e) May 2022 - 30 of 31 temperatures were documented as colder than -25 degrees C (f) June 2022 - 28 of 30 temperatures were documented as colder than -25 degrees C (g) July 2022 - 28 of 31 temperatures were documented as colder than -25 degrees C (h) August 202 - 29 of 31 temperatures were documented as colder than -25 degrees C (i) September 2022 - 26 of 30 temperatures were documented as colder than -25 degrees C (j) October 2022 -

	25 of 31 temperatures were documented as colder than -25 degrees C (k) November 2022 - 17 of 30 temperatures were documented as colder than -25 degrees C (l) December 2022 - 23 of 31 temperatures were documented as colder than -25 degrees C (3) The records were reviewed with the laboratory manager who stated on 01/18 /2023 at 02:10 pm, the materials were not being stored as required by the manufacturer.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) 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. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures for the Sysmex XS 1000i analyzer during two of 12 months reviewed from January 2022 through December 2022. Findings include: (1) On 01/17/2023 at 10:40 am, the laboratory manager stated CBC (Complete Blood Count) testing was performed using the Sysmex XS 1000i analyzer; (2) On 01/18 /2023 a review of the manufacturer's maintenance log showed the following required weekly maintenance procedure: (a) "Power Down IPU" (3) A review of maintenance logs from January 2022 through December 2022 identified weekly maintenance had not been documented as performed between: (a) 07/22/2022 and 08/05/2022 (b) 09/02 /2022 and 09/16/2022 (c) 09/16/2022 and 09/30/2022 (4) The records were reviewed with the laboratory manager who stated on 01/18/2023 at 11:45 am, the weekly maintenance had not been documented as performed as shown above.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to ensure the urine centrifuge was functioning properly for two of two years. Findings include: (1) On 01/17/2023 at 10:50 am, the laboratory manager stated the following: (a) Urine sediment examinations were performed in the laboratory; (b) The specimens were processed in the Horizon Model 642 VES centrifuge at a speed of 1500 rpm (revolutions per minute) for five minutes; (c) The laboratory checked the speed and timer annually. (2) On 01/18/2023 a review of the centrifuge records from 2021 through the current date identified the following: (a) Check performed on 05/21/2021 - The documentation stated "pass" and the actual

	speed and time that had been obtained had not been recorded; (b) Check performed on 11/22/2021 - The documentation stated "pass" and the actual speed and time that had been obtained had not been recorded; (c) There was no documentation to prove the centrifuge speed and timer had been checked during 2022. (3) The records were reviewed with the laboratory manager who stated on 01/18/2023 at 09:06 am, the laboratory had not ensured the centrifuge was functioning properly as stated above.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to perform calibration verification procedures at least once every six months for one of four test systems reviewed from January 2021 through December 2022. Findings include: (1) On 01/17/2023 at at 10:50 am, the laboratory manager stated the laboratory performed D-dimer testing using the Biosite Triage Meter Pro analyzer; (2) On 01/18/2023 a review of records for the test system from January 2021 through December 2022 identified calibration verification had not been performed between 06/11/2021 and 06/29/2022; (3) The records were reviewed with the laboratory manager who stated on 01/18/2023 at 11:41 am, calibration verification had not been performed every six months for D-dimer testing.
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 a review of records and interview with the laboratory manager, the laboratory failed to follow their policy for monitoring the effectiveness of their QCP (quality control plan) for two of four test systems. Findings include: (1) On 01/17 /2023 at 10:45 am, the laboratory manager stated the following: (a) PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing were performed using the Hemochron Signature Elite analyzer; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) A review of the IQCP identified that QA (Quality Assessment) reviews of the QCP were to be performed on an annual basis; (3) A review of records for the test system from November 2020 through the current date identified no documentation QA reviews had been performed between 11/23/20 and 12/30/22; (4) The records were reviewed with the laboratory manager who stated on 01/17/2023 at 05:34 pm, the annual QA review for 2021 had not been documented as performed.