

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 37D0472664	<b>(X3) Date Survey Completed</b> 05/14/2021
<b>Name of Provider or Supplier</b> Fairview Regional Medical Center	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The recertification survey was performed on 05/12,13,14/2021. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory manager and technical consultant #3 at the conclusion of the survey.
<b>D5215</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager and technical consultant #3, the laboratory failed to evaluate the accuracy of testing when proficiency results had not been graded by the proficiency program for 1 of 3 Immunohematology events. Findings include: (1) On 05/12/2021, the surveyor reviewed the first, second, and third Immunohematology proficiency testing events for 2020. The review showed the laboratory did not address results that were not graded by the proficiency testing program for 1 of 3 events as follows: (a) Third Event 2020 (i) Antibody Screen - 1 of 5 results (sample SER-11) had not been evaluated by the proficiency testing program. Under "Expected Result" it stated, "See Data Summary." There was no evidence the laboratory reviewed the data summary to evaluate their result. (2) The surveyor reviewed the records with the laboratory manager and technical consultant #3. Both stated on 05/12/2021 at 04:40 pm, the laboratory had not evaluated the result that was not graded by the proficiency testing program.</p>
<b>D5409</b>	<b>PROCEDURE MANUAL</b>

CFR(s): 493.1251(e)

The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).

This STANDARD is not met as evidenced by:

Based on a review of the procedure manual and interview with the laboratory manager and technical consultant #3, the laboratory failed to ensure that written procedures no longer in use had been discontinued. Findings include: (1) On 05/14/2021, the surveyor reviewed the manual titled, "Policies & Procedures" and identified a procedure titled, "CLIA Waived iSTAT Chem 8+"; (2) The surveyor reviewed the procedure with the laboratory manager and technical consultant #3. Both stated on 05/14/2021 at 12:40 pm, the procedure should have been indicated as discontinued when the when the Chem 8+ cartridge had been discontinued in February 2020. NOTE: 493.1105(a)(2) requires that discontinued procedures be maintained for at least 2 years.

**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, manufacturer's instructions, observation, and interview with the laboratory manager, the laboratory failed to ensure materials were stored as required for 5 of 5 months. Findings include: (1) On 05/12/2021 at 10:00 am, the laboratory manager stated to the surveyor Lipase testing was performed using the Vital Diagnostics Envoy 500 analyzer; (2) On 05/13/2021 at 01:40 pm, the surveyor observed the following stored in the white ABS freezer: (a) ELI Tech Group ELICAL 2, lot #06-6080-01, which had been reconstituted and aliquoted into 5 vials. (3) The laboratory manager stated to the surveyor on 05/13/2021 at 01:43 pm, the material was used to perform calibration procedures for Lipase testing; (4) The surveyor reviewed the manufacturer's package insert for the calibrator. Under "After Reconstitution", it stated, "Stability of the components: Between -25 and -15 C; 4 weeks (when frozen once)"; (5) The surveyor then reviewed the temperature records from January 2021 through the current date for the ABS freezer, and identified the materials were being stored at temperatures colder than -25 degrees C (Centigrade) for 132 of 132 days reviewed as follows: (a) January - 31 of 31 documented temperatures were colder than -26 degrees C (b) February - 28 of 28 documented temperatures were colder than -26 degrees C (c) March - 31 of 31 documented temperatures were colder than -26 degrees C (d) April - 30 of 30 documented temperatures were colder than -26 degrees C (e) May 12 of 12 documented temperatures were colder than -26 degrees C (6) The surveyor reviewed the records with the laboratory manager who stated on 05/13/2021 at 03:00 pm, the freezer temperatures were unacceptable for the materials as shown above.

**D5421**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**

CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 a review of records, and interview with the laboratory manager and technical consultant #3, the laboratory failed to ensure the demonstrated reportable range was utilized for a new test method. Findings include: (1) On 05/12/2021 at 10:00 am, the laboratory manager stated to the surveyor, the laboratory began using the TOSOH AIA-900 analyzer to perform PSA (Prostate Specific Antigen) testing June 2020; (2) On 05/13/2021, the surveyor reviewed the performance specification records and identified the laboratory had demonstrated a reportable range of 0.05-91.7 ng/ml; (3) The surveyor requested the reportable range that was being utilized by the laboratory. The laboratory manager and technical consultant provided the surveyor with the manufacturer's reportable range of 0.05-96.5 ng/dl; (4) The surveyor reviewed the findings with the laboratory manager and technical consultant #3. Both stated on 05/13/2021 at 04:35 pm, the laboratory was not using the reportable range that had been demonstrated by the laboratory.