

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0475431	(X3) Date Survey Completed 03/22/2023
Name of Provider or Supplier Coal County General Hospital Inc	Street Address, City, State 6 N Covington, Coalgate, 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 certification survey was performed on 03/20,21,22/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the chief executive officer, technical consultant, laboratory supervisor, and testing person #9 at the conclusion of the survey.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, written policies and procedures, and interview with the technical consultant and testing person #9, the laboratory failed to follow their written policy to assess the competency of the technical consultant and technical supervisor, based on the position responsibilities as listed in Subpart M, for one of one person serving as technical consultant and technical supervisor during the review period of June 2021 through the current date. Findings include: (1) On 03/21/2023 a review of the competency assessment policy identified competencies for the technical consultant and technical supervisor, based on the position responsibilities were to be performed annually; (2) A review of the Form CMS-209 and personnel records for competency assessments performed during the review period of June 2021 through the current identified competencies, based on job responsibilities, had not been performed as follows: (a) Technical Consultant - Not performed between 06/29/2021 and 03/21/2023; (b) Technical Supervisor - Not performed between 06/29/2021 and 03/21/2023. (3) The findings were reviewed with the technical consultant and testing person #9. Both stated on 03/21/2023 at 02:41 pm, the competencies had not been performed for the positions as shown above.</p>

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 supervisor, the laboratory failed to ensure materials were stored as required for seven of seven months reviewed. Findings include: FREEZER #1 (1) On 03/22/2023 at at 01:30 pm, observation of the contents of the freezer identified the following materials: (a) One box containing one vial and one box containing five vials of Quidel Triage Total 5 Control 2, lot #C3901AN - the storage requirement as stated on the box was -20 degrees C (Centigrade) and colder; (b) One box containing five vials of Quidel Triage Total 5 Control 1, lot #C3896AN - the storage requirement as stated on the box was -20 degrees C (Centigrade) and colder. (2) A review of temperature records for seven months (August 2022 through February 2023) identified the documented temperatures were warmer than -20 degrees C for two of seven months as follows: (a) October 2022 - One of 31 temperatures were documented as warmer than -20 degrees C; (b) January 2023 - four of 31 temperatures were documented as warmer than -20 degrees C. (3) The records were reviewed with the laboratory supervisor who stated on 03/22/2023 at 01:40 pm, the materials were not being stored as required by the manufacturer. FREEZER #2 (1) On 03/22/2023 at at 01:30 pm, observation of the contents of the freezer identified the following materials: (a) Six boxes containing six vials each of Bio-Rad Liquichek Cardiac Markers Plus Ct controls, lot #87831 - the storage requirement as stated on the box was -20 to -70 degrees C; (b) Eight boxes containing six vials each of Bio-Rad Liquichek Cardiac Markers Plus Ct controls, lot #87833 - the storage requirement as stated on the box was -20 to -70 degrees C; (c) Four boxes containing six vials each of Bio-Rad Liquichek Cardiac Markers Plus Ct controls, lot #87841 - the storage requirement as stated on the box was -20 to -70 degrees C; (d) Four boxes containing six vials each of Bio-Rad Liquichek Cardiac Markers Plus Ct controls, lot #87843 - the storage requirement as stated on the box was -20 to -70 degrees C. (2) A review of temperature records for seven months (August 2022 through February 2023) identified the documented temperatures were warmer than -20 degrees C for six of seven months as follows: (a) August 2022 - 17 of 31 temperatures were documented as warmer than -20 degrees C; (b) September 2022 - Five of 30 temperatures were documented as warmer than -20 degrees C; (c) October 2022 - One of 31 temperatures were documented as warmer than -20 degrees C; (d) November 2022 - Two of 30 temperatures were documented as warmer than -20 degrees C; (e) December 2022 - Five of 31 temperatures were documented as warmer than -20 degrees C; (f) January 2023 - Five of 31 temperatures were documented as warmer than -20 degrees C. (3) The records were reviewed with the laboratory supervisor who stated on 03/22/2023 at 01:40 pm, the materials were not being stored as required by the manufacturer. FREEZER #3 (1) On 03/22/2023 at at 01:30 pm, observation of the contents of the freezer identified the following materials: (a) 12 boxes containing three bottles each of level one, level two, and level three control materials, lot #0150 - the storage requirement as stated on the box was -20 degrees C

and colder; (b) Two boxes of Vitros CKMB Calibrator, lot #3360 - the storage requirement as stated on the box was -20 degrees C and colder; (c) Two boxes containing six vials each of Bio-Rad Liquichek Specialty Immunoassay control level two, lot #64922 - the storage requirement as stated on the box was -20 to -70 degrees C; (d) Five boxes containing 12 vials each of Bio-Rad Immunoassay Plus control level one, lot #85301 - the storage requirement as stated on the box was -20 to -70 degrees C. (2) A review of temperature records for seven months (August 2022 through February 2023) identified the documented temperatures were warmer than -20 degrees C for seven of seven months as follows: (a) August 2022 - Nine of 31 temperatures were documented as warmer than -20 degrees C; (b) September 2022 - Two of 30 temperatures were documented as warmer than -20 degrees C; (c) October 2022 - 12 of 31 temperatures were documented as warmer than -20 degrees C; (d) November 2022 - Nine of 30 temperatures were documented as warmer than -20 degrees C; (e) December 2022 - Nine of 31 temperatures were documented as warmer than -20 degrees C; (f) January 2023 - Two of 31 temperatures were documented as warmer than -20 degrees C; (g) February 2023 - Five of 28 temperatures were documented as warmer than -20 degrees C. (3) The records were reviewed with the laboratory supervisor who stated on 03/22/2023 at 01:40 pm, the materials were not being stored as required by the manufacturer.

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on a review of records, FDA database, and interview with the technical consultant, laboratory supervisor, and testing person #9, the laboratory failed to establish the performance specifications of analytical sensitivity and analytical specificity for eight of eight analytes not cleared or approved by the FDA. Findings include: (1) On 03/22/2023 at 01:00 pm, the technical consultant and laboratory supervisor stated Estradiol, Ferritin, Folate, FSH (Follicle Stimulating Hormone), LH (Luteinizing Hormone), Progesterone, Testosterone, and Troponin I testing were performed using the Ortho Vitros 7600XT analyzer; (2) A review of the classification of the analytes using the OrthoVitros 7600XT analyzer on the FDA (Food and Drug Administration) test classification database identified the database did not include a classification for the analytes/analyzer combination. This confirmed that the tests had not been approved/classified by the FDA; (3) Interview with the technical consultant, laboratory supervisor, and testing person #9 on 03/22/2023 at 02:30 pm, confirmed the following: (a) The laboratory originally began testing the above analytes in January 2020; (b) The performance specifications performed at that time did not include the establishment of analytical sensitivity and analytical specificity; (c) There was no documentation to prove the analytical sensitivity and analytical specificity had

been established to date. NOTE: D5423 was cited on the previous recertification survey performed on 06/22/2021.

D5555

IMMUNOHEMATOLOGY

CFR(s): 493.1271(c)(f)

(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the technical consultant, the laboratory failed to ensure units of blood were stored under appropriate conditions for six of 48 blood bank refrigerator temperature charts reviewed from 02/25/2022 through 01/18/2023. Findings include: (1) On 03/20/2023 at 10:40 am, the technical consultant stated units of packed red blood cells were stored in the blood bank refrigerator, with a recorder connected to it to continuously record the temperature on thermograph charts and monitored the temperature for a seven day period: (2) A review of 48 refrigerator charts dated from 02/25/2022 through 01/18/2023 identified six of 48 charts had not been changed by the seventh day as follows: (a) Chart #1 - The chart had been put into use on 03/25/2022 and removed on 04/02/2022 (eight days); (b) Chart #2 - The chart had been put into use on 04/15/2022 and removed on 04/23/2022 (eight days); (c) Chart #3 - The chart had been put into use on 04/23/2022 and removed on 05/02/2022 (nine days); (d) Chart #4 - The chart had been put into use on 09/09/2022 and removed on 09/21/2022 (13 days); (e) Chart #5 - The chart had been put into use on 09/21/2022 and removed on 09/29/2022 (eight days); (f) Chart #6 - The chart had been put into use on 01/18/2023 and removed on 01/26/2023 (eight days) (3) The charts were reviewed with the technical consultant who stated on 03/20/2023 at 01:50 pm, the above charts had not been changed by the 7th day.