Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0475431	06/22/2021
Name of Provider or Supplier	**Street Address, City, State**	
Coal County General Hospital Inc	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 recertification survey was performed on 06/21,22,23/2021. The laboratory was found out of compliance with the following CLIA regulation: 493.1489; D6168: Testing Personnel Qualifications The findings were reviewed with technical consultant /general supervisor #2 and general supervisor #1 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 policy, and interview with general supervisor #1, the laboratory failed to have a written technical consultant and general supervisor competency policy based on the position responsibilities as listed in Subpart M. Findings include: (1) On 06/21/2021 surveyor #2 reviewed the competency assessment policy. It did not include guidance for assessing the competency of the technical consultant and general supervisor; (2) Surveyor #2 then reviewed personnel records for competency assessments performed during 2020 and to date in 2021. There was no evidence of competencies performed for technical consultant #2, general supervisor #1, and general supervisor #2 based on their job responsibilities; (3) Surveyor #2 asked the laboratory manager if a written policy to evaluate the technical consultant, general supervisor #1, and general supervisor #2 based on job responsibilities was available. General supervisor #1 stated on 06/21/2021 at 09:50 am a policy had not been written and the above competencies had not been performed.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)

	Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a review of records and interview with general supervisor #1, the laboratory failed to ensure expired blood bank quality controls were not available for use for 1 of 6 days. Findings include: (1) On 06/21/2021 at 01:25 pm, general supervisor #1 stated to surveyor #1 Crossmatch testing was performed in the laboratory which included ABO Typing using the tube method; (2) On 06/22/2021, surveyor #2 reviewed quality control and patient testing records for testing performed from 04/07/2019 through 07 /11/2019 and identified an expired reagent had been used 1 of 6 days of testing reviewed as follows: (a) Immucor Anti-A,B lot #304020, expiration date 06/07/2019 had been used for patient testing on 06/11/2019. (3) Surveyor #2 reviewed the records with general supervisor #1 who stated on 06/22/2021 at 02:50 pm an expired reagent had been used as indicated above.
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 general supervisor #1, the laboratory failed to establish the performance specifications of analytical sensitivity and analytical specificity for 9 of 9 new analytes not cleared or approved by the FDA. Findings include: (1) On 06/23/2021 at 11:00 am, general supervisor #1 stated to surveyor #1 Estradiol, Ferritin, Folate, FSH (Follicle Stimulating Hormone), LH (Luteinizing Hormone), Progesterone, Pro-BNP (B-Type Natriuretic Peptide), Testosterone, and Troponin I testing were performed using the Ortho Vitros 7600XT analyzer 01/2020; (2) Surveyor #1 attempted to verify the classification of the analytes using the Ortho Vitros 7600XT analyzer on the FDA (Food and Drug Administration) test classification database, since classification of test systems are performed by the FDA. The database did not include a classification for the analytes /analyzer combination (if a test is not included on the FDA site, then it did not go through the FDA approval process, which defaults the classification of the test as high complexity); (3) Surveyor #1 explained this to general supervisor #1 who contacted the manufacturer and confirmed this information with the manufacturer's representative. Therefore, the analytes tested on the Ortho Vitros 7600 XT were classified as LDT (laboratory developed tests), which are high complexity, and requires the performance specifications of accuracy, precision, reportable range, analytical sensitivity, analytical specificity, and reference intervals (normal values) be

	established; (4) Surveyor #1 reviewed the implementation records for the analyzer. There was no evidence the analytical sensitivity and analytical specificity had been established for Estradiol, Ferritin, Folate, FSH, LH, Progesterone, Pro-BNP, Testosterone, and Troponin I; (5) Surveyor #1 reviewed the validation records with general supervisor #1 who stated on 06/23/2021 at 2:30 pm analytical sensitivity and analytical specificity had not been established because it was believed the entire test system had been FDA approved.
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 general supervisor #1, the laboratory failed to follow the manufacturer's instructions for performing annual maintenance procedures for the blood gas analyzer. Findings include: (1) On 06/21/2021 general supervisor #1 stated to surveyor #1 at 01:00 pm, Blood Gas (pH, pCO2, pO2) was performed on the Opti CCA analyzer; (2) On 06/22 /2021, surveyor #1 reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance log titled, "Appendix C Maintenance Log". The annual requirement was as follows: (a) Replace Peristaltic Pump (3) Surveyor #1 then reviewed maintenance records from January 2020 through May 2021. The annaul maintenance had not been documented as performed during the review period; (4) Surveyor #1 reviewed the findings with general supervisor #1 who stated on 06/22 /2021 at 01:40 pm the annual maintenance had not been documented as performed as identified above.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with general supervisor #1, the laboratory failed to perform control procedures each day of blood bank testing for 2 of 6 days of patient testing. Findings include: (1) On 06/21/2021 at 01:25 pm, general supervisor #1 stated to surveyor #1 the laboratory performed Crossmatch Testing, which consisted of ABO/Rh, Antibody Screen, and Compatibility testing (performed between the patient and red blood cell donor unit(s)) using the tube method; (2) On 06 /22/2021, surveyor #2 reviewed records for blood bank testing performed on 07/18 /2020, 07/20/2020, 10/08/2020, 12/06/2020, 12/28/2020, and 03/03/2021 and identified quality control had not been performed for 2 of 6 days when patient Type and Screen or Crossmatch testing had been performed as follows: (a) Patient #1 - A Type and Screen was performed on 10/08/2020; (b) Patient #2 - A Type and Screen

	and Crossmatch was performed on 03/03/2021. (3) Surveyor #2 reviewed the records with general supervisor #2. On 06/22/2021 at 04:05 pm, general supervisor stated quality control had not been performed as indicated above.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on a review of records and interview with general supervisor #1, the laboratory failed to have a system that twice a year evaluated and defined the relationship between test results using different analyzers. Findings include: (1) On 06/23/2021 at 09:20 am, general supervisor #1 stated the following to surveyor #1: (a) The laboratory began using the Sysmex XN 550 analyzer to perform CBC (Complete Blood Count) testing as the primary analyzer 02/2020; (b) The Beckman Coulter AcT Diff 2 analyzer was used as the back-up analyzer. (2) Surveyor #1 asked general supervisor #1 if the relationship between the test results using the two different analyzers had been evaluated at least twice annually in 2020 and to date in 2021. General supervisor #1 stated on 06/23/2021 at 09:45 am the test results between the two analyzers had been compared when the Sysmex XN 550 analyzer had been implemented 02/2020, but the relationship between the analyzers had not been evaluated since then.
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 general supervisor #1, the laboratory failed to have a policy for monitoring the effectiveness of their IQCP for 1 of 1 test systems. Findings include: (1) On 06/22/2021 at 04:00 pm, general supervisor #1 stated the following to surveyor #1: (a) Rhinovirus, Influenza A, AHI, AHI-2009, A1H3, Influenza B, Mycoplasma pneumoniae, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Respiratory Syncytial Virus, and SARS CoV-2, testing were performed using the Diagnostic Biomerieux BioFire analyzer; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) Surveyor #1 reviewed the IQCP (dated as approved on 07/29 /2020). The QA (Quality Assessment) portion of the IQCP did not include a schedule for evaluating the QCP (Quality Control Plan) to ensure it continued to provide accurate and reliable results; (3) Surveyor #1 reviewed the records with general supervisor #1, and asked if, in addition to the ongoing monitoring, the QA plan addressed how the laboratory will evaluate the QCP, including the frequency of the

	reviews. General supervisor #1 stated on 06/22/2021 at 04:40 pm, the QA plan did not include an evaluation of the QCP, and the frequency of the reviews.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on a review of records and interview with general supervisor #1, the laboratory failed to ensure testing personnel were qualified to perform high complexity testing. Findings include: (1) The laboratory failed to ensure that each person performing high complexity chemistry testing was qualified. Refer to D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and

storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with general supervisor #1, the laboratory failed to ensure that each person performing high complexity testing was qualified for 3 of 13 persons. Findings include: (1) On 06/23/2021 at 11:00 am, general supervisor #1 stated to surveyor #1 Estradiol, Ferritin, Folate, FSH (Follicle Stimulating Hormone), LH (Luteinizing Hormone), Progesterone, Pro-BNP (B-Type Natriuretic Peptide), Testosterone, and Troponin I testing were performed using the Ortho Vitros 7600XT analyzer 01/2020; (2) Surveyor #1 attempted to verify the classification of the analytes using the Ortho Vitros 7600XT analyzer on the FDA (Food and Drug Administration) test classification database, since classification of test systems are performed by the FDA. The database did not include a classification for the analytes /analyzer combination (if a test is not included on the FDA site, then it did not go through the FDA approval process, which defaults the classification of the test as high complexity); (3) Surveyor #1 explained this to general supervisor #1 who contacted the manufacturer and confirmed this information with the manufacturer's representative. Therefore, the analytes tested on the Ortho Vitros 7600 XT were classified as LDT (laboratory developed tests), which are high complexity; (4) On 06 /23/2021, surveyor #2 reviewed the Laboratory Personnel Report (Form CMS-209) that had been completed by the laboratory prior to the survey. General supervisor #1 stated 11:00 am to surveyor #2 that 9 of 13 testing persons were trained to perform chemistry testing on the Ortho Vitros 7600XT analyzer; (4) Surveyor #2 then reviewed personnel education and training records. There was no evidence that testing person #7, testing person #11, and testing person #13 had the qualifications to perform high complexity testing. The only education records contained in the files were a copy of a high school diploma for each person. The documentation in the training record verified that testing person #7, testing person #11, and testing person #13 had been trained to perform chemistry testing on the Ortho Vitros 7600XT analyzer; (5) Surveyor #2 reviewed the records with general supervisor #1 who stated on 06/23 /2021 at 3:30 pm, 3 of 13 testing persons did not meet the education requirement to perform high complexity testing as indicated above.