Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0475431	12/07/2018
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 12/03/18 through 12/07/18. The laboratory was found to be in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory supervisor, general supervisor #4, general supervisor #5, laboratory director, chief executive officer, and chief operating officer during an exit conference performed at the conclusion of the survey.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory failed to ensure proficiency testing attestation statements had been signed by the laboratory director or designee. Findings include: (1) On the first day of the survey, the surveyor reviewed 2017 and 2018 proficiency testing records. The following was identified for 2 of 20 testing events: (a) J-C 2017 Transfusion Medicine Event (i) The attestation was not signed by the laboratory director or designee; (b) Second 2018 Microbiology Event (i) The attestation was not signed by the laboratory director or designee. (2) The findings were reviewed with the laboratory supervisor who stated the attestations had not been signed as indicated above.

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 and interview with the laboratory supervisor the laboratory failed to perform a technical consultant competency based on the position responsibilities as listed in Subpart M. Findings include: (1) On the first day of the survey, the surveyor reviewed personnel records for competency assessments performed during 2017 and 2018. There was no evidence a technical consultant competency, based on their job responsibilities had been performed; (2) The surveyor asked the laboratory supervisor if a technical consultant competency based on job responsibilities had been performed. The laboratory supervisor stated a technical consultant competency based on job responsibilities had not been performed.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory failed to review and evaluate proficiency testing results. Findings include: BIASES (1) On the first day of the survey, the surveyor reviewed 2017 and 2018 proficiency testing records. The following biases were identified (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) Second 2017 Chemistry Core Event (i) Troponin I - 3 of 5 results exhibited a positive bias (aa) Sample CH-06- SDI of 2.6 (bb) Sample CH-08 - SDI of 2.3 (cc) Sample CH-09 - SDI of 3.3 (b) Third 2017 Chemistry Core Event (i) Gentamicin - 3 of 5 results exhibited a negative bias (aa) Sample CH-12- SDI of -2.4 (bb) Sample CH-13 - SDI of -2.8 (cc) Sample CH-14 - SDI of -3.3 (c) Second 2018 Chemistry Core Event (i) Lactic Acid - 3 of 5 results exhibited a negative bias (aa) Sample CH-06- SDI of -2.4 (bb) Sample CH-07 - SDI of -3.9 (cc) Sample CH-10 - SDI of -3.3 (d) Third 2018 Chemistry Core Event (i) Total Protein - 3 of 5 results exhibited a negative bias (aa) Sample CH-12- SDI of -2.3 (bb) Sample CH-14 - SDI of -2.3 (cc) Sample CH-15 - SDI of -2.1 (ii) Lactic Acid - 3 of 5 results exhibited a positive bias (aa) Sample CH-12 - SDI of 2.6 (bb) Sample CH-14 - SDI of 2.0 (cc) Sample CH-15 - SDI of 3.0 (iii) Alcohol - 3 of 5 results exhibited a negative bias (aa) Sample ALC-11 - SDI of -4.0 (bb) Sample ALC-12 - SDI of -2.3 (cc) Sample ALC-14 - SDI of -2.4 (dd) Sample ALC-15 - SDI of -2.6 (2) The surveyor could not locate evidence in the records proving the biases had been identified and addressed; (3) The records were reviewed with the laboratory supervisor who stated the biases had not been addressed. FAILURES (1) During the review of proficiency testing records, the surveyor identified the following failures in which there was no evidence of corrective action: (a) Third 2017 Chemistry Core Event (i) Total Bilirubin - The laboratory failed the results for 4 of 5 samples and attained a score of 20%. The results for samples CH-11, CH-12, CH-13 and CH-15 had failed. (2) The surveyor reviewed the

	records with the laboratory supervisor and asked if corrective action had been taken for the above failures. The laboratory supervisor stated there was no documentation to prove corrective action had been taken for the failures.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) 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). This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory failed to evaluate the accuracy of testing when a proficiency result had not been graded by the proficiency program. Findings include: (1) At the beginning of the survey, the surveyor reviewed 2017 and 2018 proficiency testing records and identified the following had not been evaluated by the proficiency testing program: (a) Hematology (i) 2017 third event (aa) Blood Cell Identification BCI-20 and BCI-21 (b) Chemistry Core (i) 2018 first event (aa) LDL (Low Density Lipoprotein) CH-02 and CH-03 (2) The surveyor further reviewed the records and could not locate documentation verifying the laboratory had performed a self-evaluation of the non-graded results; (3) The surveyor asked the laboratory supervisor if the results had been documented as evaluated. The laboratory supervisor reviewed the records and stated the non-graded results had not been documented as reviewed.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory failed to provide written instructions to clients collecting and referring hematology, chemistry, urinalysis, and toxicology specimens. Findings include: (1) On the first day of the survey, the laboratory supervisor stated the following to the surveyor: (a) The laboratory performed CBC (Complete Blood Count) testing using the Beckman Coulter AcT Diff2 analyzer; (i) Hematology specimens were transported to the laboratory from outside home health agencies, long-term care facilities and clinics. (b) The laboratory performed routine chemistry testing using the Ortho Vitros 4600 analyzer; (i) Routine chemistry specimens were transported to the laboratory from outside home health agencies, long-term care facilities and clinics. (c) The laboratory performed confirmatory toxicology testing using the AB Sciex Triple Quad 4500; (i) Confirmatory toxicology specimens were transported to the laboratory from outside home health agencies, long-term care facilities and clinics. (2) The surveyor asked the laboratory supervisor if instructions (e.g., client service manual) had been written and provided to the home health agencies, long-tem care facilities and clinics which would explain the laboratory's specimen handling policies (e.g., collection,

	preservation, storage, transport, testing schedule times, and how to obtain additional assistance for unusual circumstances). The laboratory supervisor stated specimen handling instructions had not been written and provided to the clients.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of the policy and procedure manual and interview with the technical supervisor and general supervisor #8, the laboratory failed to have a written procedure for the column change validation. Findings include: (1) On the second day of the survey, the surveyor reviewed the laboratory policy and procedure manual. The following could not be located: (a) Column change validation. (2) The surveyor reviewed the findings with the technical supervisor and general supervisor #8, and asked if the above policy and procedure was available. The technical supervisor and general supervisor #8 stated the policy and procedure had not been written.
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 general supervisor #8, the laboratory failed to verify the acceptable performance of the laboratory computer system. Findings include: (1) On the second day of the survey, general supervisor #8 stated to the surveyor the laboratory began patient urine drug testing on 09/28/18, which

	included installing the Lab Daq laboratory information system (LIS); (2) The surveyor asked general supervisor #8 for documentation to prove the laboratory ensured the LIS performed acceptably before it was put into use; (3) General supervisor #8 was not able to locate records and stated to the surveyor there was no documentation to substantiate the laboratory had determined the acceptable performance of the new LIS when it was installed.
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, procedure manual, and interview with general supervisor #8, the laboratory failed to establish the performance specification of reference range for urine drug testing. Findings include: (1) On the first day of the survey, the laboratory manager stated to the following to the surveyor: (a) The laboratory began performing drug testing using the AB Sciex Triple Quad 4500 LCMS (liquid chromatography-mass spectrometry) analyzer on 09/28/18 (see below for drugs tested); (2) The surveyor reviewed the performance specification records for the analyzer with the following identified: (a) There was no evidence the reference ranges (normal range) had been established. (3) The surveyor then reviewed the performance specification records with general supervisor #8. General supervisor #8 stated the reference ranges had not been established. LCMS testing includes the following drugs: 6MAM (Monoacetylmorphine), Aminoclonazepam, Alprazolam, Amphetamine, aOH-AlprazolamBenzyolecgonine, Buprenorphine, Carisoprodol, Codeine, EDDP (Methadone Metabolite), Fentanyl, Norfentanyl, Hydrocodone, Hydromorphone, Lorazepam, MDMA(methylenedioxymethamphetamine), Meperidine, Meprobamate, Methadone, Methamphetamine, Methylphenidate, Morphine, Norbuprenorphine, Oxazepam, Oxycodone, Oxymorphone, PCP (Phencyclidine), Propoxyphene, Tapentadol, Temazepam, THC-COOH (Tetrahydrocannabinol-9-carboxylic acid), Tramadol,
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 supervisor, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Findings include: (1) On the first day of the survey, the laboratory supervisor stated to the surveyor that Arterial Blood Gas (pH, pCO2 and pO2) testing was performed on the OPTI CCA analyzer; (2) On the third day of the survey, the surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs. The requirement for weekly maintenance was as follows: (a) Clean Sample Measurement Chamber (3) The surveyor then reviewed maintenance records for 9 months (April 2017 through December 2017). There was no evidence the weekly maintenance had been performed: (a) Between 07/11/17 and 07/31/17 (4) The surveyor reviewed the records with the laboratory supervisor, who stated the maintenance had not been documented as performed.
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, policy and procedure manual, and interview with general supervisor #8, the laboratory failed to define a function check protocol to ensure the centrifuge was functioning properly. Findings include: (1) On the second day of the survey, general supervisor #8 stated to the surveyor the ThermoScientific centrifuge was used to process urine specimens for urine drug testing at a speed of 3700 rpm (Revolutions Per Minute) and a time of 15 minutes (patient testing began on 09/28/18); (2) The surveyor reviewed the policy and procedure manual and could not locate a function check protocol that defined how often function checks (speed and timer checks) were to be performed on the centrifuge; (3) The surveyor then asked general supervisor #8 if the laboratory had a funcion check protocol for the centrifuge and if there was documentation that the speed and timer of the centrifuge had been checked since patient testing began on 09/28/18. General supervisor #8 stated to the surveyor the laboratory did not have a policy to check the speed and timer of the centrifuge and function checks had not been performed on the urine centrifuge.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system

	performance and environmental conditions, and variance in operator performance. (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 the laboratory supervisor, the laboratory failed to have control procedures that monitored the accuracy and precision of the analytic process. Findings include: (1) On the fourth day of the survey, the laboratory supervisor stated to the surveyor Ferritin, Folate, Insulin, Prolactin, Progesterone, and Vitamin D testing were performed using the Beckman Coulter DxI 600 analyzer. In addition, the laboratory supervisor stated the following: (a) Bio-Rad Liquichek Immunoassay Plus Control control materials (Level 1 and Level 3) were performed each day of patient Ferritin, Folate, Insulin, Prolactin, Progesterone, and Vitamin B12 testing; (b) Bio-Rad Liquichek Specialty Immunoassay Plus Control control materials (Level 1, Level 2) were performed each day of patient Vitamin D testing. (2) The surveyor reviewed quality control records for testing performed from 08/01/18 through 12/06/18 and identified the following: (a) Positive Bias (the control results were consistently above the established mean): (i) Ferritin (aa) Level 3 High Control 61 of 64 control results were above the mean. (ii) Prolactin (aa) Level 1 Low Control 115 of 121 control results were above the mean. (iii) Insulin (aa) Level 3 High Control 56 of 65 control results were above the mean (b) Negative Bias (the control results were consistently below the established mean): (i) Folate (aa) Level 1 High Control 65 of 65 control results were below the mean; (bb) Level 3 High Control 65 of 65 control results were below the mean. (ii) Progesterone (aa) Level 3 High Control 18 of 43 control results were below the mean. (iv) Vitamin D (aa) Level 2 High Control 90 of 100 control results were below the mean. (3) There was no evidence in the records the above control biases had been identified and addressed; (4) The surveyor reviewed the records with laboratory supervisor, who stated the control biases had not been addressed.
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, observation, and interview with the laboratory supervisor and general supervisor #5, the laboratory failed to ensure units of blood were stored under appropriate conditions that included an adequate temperature alarm system that is regularly inspected. Findings include: ALARM CHECKS (1) At the beginning of the survey, the laboratory supervisor stated to the surveyor that units of packed red blood cells were stored in the blood bank refrigerator. The units were to be used for patient transfusions; (2) On the third day of the survey, the laboratory supervisor stated to the surveyor Blood Bank alarms were checked quarterly for high /low activation; (3) The surveyor reviewed the refrigerator alarm check records for 2017 through the third day of the survey (12/05/18). The records indicated the alarm checks had not been performed quarterly. They had not been performed between 12/27

	/17 and 08/23/18; (4) The surveyor reviewed the records with the laboratory supervisor and general supervisor #5 who both stated the alarm checks had not been performed quarterly as required. THERMOGRAPH TEMPERATURE CHARTS (1) On the third day of the survey, the surveyor observed the thermograph temperature recorder for the blood bank refrigerator. The refrigerator had a recorder connected to it for continuously recording the temperature on thermograph charts (Note: units of packed cells must be stored at 1-6 degrees Centigrade). Each chart monitored the temperature for a 7 day period; (2) The surveyor 12 refrigerator charts dated from March 2018 through May 2018. The review indicated that 1 of 12 charts had not been changed by the 7th day of usage as follows: (a) Chart #3 - The chart was put into use on 03/15/18 and removed on 03/26/18 (12 days). (3) The surveyor reviewed the charts with the laboratory supervisor and general supervisor #5, who both stated the charts had not been changed by the 7th day of usage as indicated above.
D6151	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(b)(3)(4) (3) The director or technical supervisor may delegate to the general supervisor the responsiblity for providing orientation to all testing personnel; and (4) Annually evaluating and documenting the performance of all testing personnel. This STANDARD is not met as evidenced by: Based on a review of records and interview with general supervisor #8, the general supervisor failed to ensure that persons performing high complexity testing had the appropriate training. Findings include: (1) On the first day of the survey, the surveyor reviewed personnel records. The following was identified: (a) Testing person #1 - This person was hired on 08/2018. There was no evidence that this person had been trained to perform high complexity testing. (2) The surveyor reviewed the records with the general supervisor #8, who stated there were no records to prove this person had been initially trained to perform high complexity testing.