Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0450734	09/09/2024
Name of Provider or Supplier	**Street Address, City, State**	
Coffey County Hospital Laboratory	801 N 4th Street, Burlington, KS	

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	A recertification survey was completed on September 9, 2024. Coffey County Hospital laboratory was found not in compliance with the following CONDITIONAL LEVEL DEFICIENCIES: D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems D6033 - 42 C.F.R. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant D6033 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of the laboratory's 2023, and 2024 to date of survey American Proficiency Institute (API) proficiency testing (PT) documentation, CMS 209 personnel form, and interview with technical consultant (TC) #1, the laboratory failed to update the corrective action for four of five consecutive events of unacceptable results when the first corrective action did not correct the unacceptable results. Findings: 1. Review of the laboratory's 2023, and 2024 to date of survey API PT Performance Review and Corrective Action forms revealed five unacceptable sample results for five separate test events due to incorrect morphology for gram stain: a. Microbiology 2023 1st Event-GS-04 Gram stain-reported coccobacilli graded unacceptable. Corrective action statement was "will review with staff." b. Microbiology 2023 2nd Event -GS-9 Gram stain-reported coccobacilli graded unacceptable. Corrective action statement was "will review with staff." c. Microbiology 2023 3rd Event -GS-13 Gram stain-reported coccobacilli graded unacceptable. No documented evaluation. d. Microbiology 2024 1st Event -GS-5 Gram stain-reported coccobacilli graded unacceptable. Corrective action statement was "will review with staff." e. Microbiology 2024 2nd Event -GS-6 Gram stain-reported coccobacilli graded unacceptable. Corrective action statement was "will

	review with staff." 2. Review of the CMS 209 revealed all unacceptable gram stain results listed in 1 (a-e) were all performed by testing personnel (TP) #4. 3. Interview with TC #1 on 9/9/24 at 1:15 p.m. confirmed, the laboratory failed to update the corrective action for four of five consecutive events of unacceptable results when the first corrective action did not correct the unacceptable results.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the failure to have procedures that include specimen collection, labeling, specimen stability, specimen acceptance and rejection criteria, corrective action when controls fail, reportable ranges as determined by the laboratory, normal values, and course of action when test system becomes inoperable (refer to D5403), failure to follow manufacturer's instructions for prothrombin time and partial prothrombin time testing (refer to D5411), failure to determine that normal values are appropriate for laboratory's patient population (refer to D5421), failure to perform six month calibration and calibration verification as required (refer to D5439), failure to perform quality control (QC) as required (refer to D5445), and failure to include information as required on test records (refer to D5787), the laboratory failed to monitor and evaluate overall quality and correct identified problems in the analytic system.
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 upon a review of the laboratory procedures and interview with the technical consultant (TC) #1, the laboratory failed to define by written procedure: instructions for specimen collection, labeling, specimen stability, specimen acceptance and rejection criteria, corrective action when quality control (QC) fails acceptance criteria, reportable ranges as determined by the laboratory, normal values, and course of action when test system becomes inoperable for Amnisure Rupture of Membrane Test (ROM) test and ePOC Blood Analysis System for pH, pCO2 and pO2. Findings: 1. Review of the procedure "EPOC Blood Analysis System" revealed the instructions for specimen collection, labeling, corrective action when quality control (QC) fails acceptance criteria, reportable ranges as determined by the laboratory, normal values, and course of action when test system becomes inoperable were not included. 2. Review of the procedure " Amnisure Collection and Testing Procedure" revealed the instructions for specimen collection, labeling, criteria for specimen acceptability and rejection, normal values, and course of action when test system becomes inoperable were not included. 3. Interview with TC #1 on 9/9/24 at 3:40 p.m. confirmed, the laboratory failed to define by written procedure: instructions for specimen collection, labeling, specimen stability, specimen acceptance and rejection criteria, corrective action when QC fails acceptance criteria, reportable ranges as determined by the laboratory, normal values, and course of action when test system becomes inoperable for Amnisure ROM test and ePOC Blood Analysis System for pH, pCO2 and pO2.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of instrument type and test settings, lack of reagent lot evaluation data, manufacturer's instructions, patient testing volumes and interview with TC #1, the laboratory failed to follow manufacturer's instruction on reagent lot changes for both RecombiPlasTin 2G for prothrombin time (PT) and SynthASil reagent for partial thromboplastin time (PTT) prior to use for patient testing. Findings: 1. Prothrombin time (PT) and partial prothrombin time (PTT) testing are performed on the ACL Elite coagulation analyzer from Instrumentation Laboratory/Werfen. 2. ACL Elite coagulation analyzer instrument setting for PT testing showed RecombiPlasTin 2G reagent lot #N0138890, expiration 2/28/25. Mean normal patient (MNPT) was set at 11.82 seconds, and ISI value set at 1.08. 3. The surveyor requested documentation for the MNPT value used to calculate the international normalized ratio (INR) . No documentation was provided at the time of survey. 4. Manufacturer's instructions for RecombiPlasTin 2G contained under: a. Instrument/test procedures: "Enter the ISI value from the insert and establish the Mean of the PT Normal Range with each new lot. b. Expected values: "Due to many variables which may affect clotting time, each laboratory should verify its own normal range. 5. Lot #N0138890 was placed into use on 9/15/23 with 1,643 patient test results reported from 9/15/23 to 9/9/24. 6. ACL Elite instrument setting for PTT testing showed SynthASil reagent lot #N0148402, expiration 1/31/26. 7. Request was made to review the SynthASil reagent lot #N0148402 evaluation for normal values. No data was made available at the time of survey. 8. Manufacturer's instructions for SynthASil under expected values stated: "Due to many variables which may affect clotting times, each laboratory should

	establish its own normal range." 9. SynthASil reagent lot #N0148402 was placed into use on 11/15/23 with 538 patient results reported from 11/15/23 to 9/9/24. 10. Interview with TC #1 on 9/9/24 at 1:10 p.m. confirmed, the laboratory failed to follow manufacturer's instruction on reagent lot changes for both RecombiPlasTin 2G for prothrombin time (PT) and SynthASil reagent for partial thromboplastin time (PTT) prior to use for patient testing.
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 the review of verification performance specification on ePOC test system, and interview with TC #1, the laboratory failed to verify the normal ranges on the Siemens ePOC were appropriate for the patient population before use in patient testing for pH, pCO2 and pO2. Findings: 1. Review of the verification study for new ePOC analyzer, serial number 40953 revealed no documentation to determine if the normal ranges were appropriate for the laboratory's patient population. 2. Documentation revealed the Siemens ePOC serial number (S/N) 40953 was placed into use for patient testing on 11/1/22. 3. Results for 115 patients were reported from 11/1/22 to 9/9/24. 5. Interview with TC#1 on 9/9/24 at 3:40 p.m. confirmed, the laboratory failed to verify the normal ranges on the Siemens ePOC were appropriate for the patient population before use in patient testing for pH, pCO2 and pO2.
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 the review of the ACL Elite coagulation analyzer calibration records for the analyte D-dimer, and interview with TC#1, the laboratory failed to perform calibration at least once every six months for D-dimer. Findings: 1. Review of the ACL Elite calibration verification records for the analyte D-dimer revealed the laboratory last performed a calibration on 1/10/23. No documentation of D-dimer calibration from 1/11/23 to 9/9/24 were made available at the time of survey. 2. From 1/11/23 to 9/9/24, results for 227 patients were reported. 3. Interview with TC#1 on 9 /9/24 at 1:15 p.m. confirmed, the laboratory failed to perform calibration at least once every six months for D-dimer.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) documentation for AmniSure Rupture of Membrane (ROM) test, FilmArray GI panel, FilmArray Respiratory Panel 2.1, and ePOC test system, lack of individualized quality control plans (IQCP), patient test results and interview with TC #1, the laboratory failed to perform QC at least once day of patient testing for AmniSure ROM test, FilmArray GI panel, FilmArray Respiratory Panel 2.1, and failed to perform external QC every 8 hours of patient testing for the ePOC test system. Findings: 1. Review of the ROM QC documents for AmniSure test system revealed the laboratory failed to perform external QC each day of patient testing from 1/1/23 to 9/9/24. 2. No approved IQCP for the AmniSure ROM test system was provided at the time of survey. Patient results for 19 patients were reported without acceptable QC performed on the day of patient testing from 1/1/23 to 9/9/24. 3. Review of the FilmArray GI panel QC documents revealed the laboratory failed to perform external QC each day of patient testing from 1/1/23 to 9/9/24. 4. No approved IQCP for the FilmArray GI panel test system was provided at the time of survey. Patient results for 109 patients were reported without acceptable QC performed on the day of patient testing from 1/1/23 to 9/9/24. 5. Review of the FilmArray Respiratory Panel 2.1 QC documents revealed the laboratory failed to perform external QC each day of patient testing from 1/1/23 to 9/9/24. 6. No approved IQCP for the FilmArray Respiratory Panel 2.1 test system was provided at the time of survey. Patient results for 426 patients were reported without acceptable QC performed on the day of patient testing from 1/1/23 to 9/9/24. 7. Review of the ePOC test system QC documents revealed the laboratory failed to perform external QC every 8 hours of patient testing from 11/1/22 to 9/9/24. 8. No approved IQCP for the ePOC test system test system was provided at the time of survey. Patient results for 115 patients were reported without acceptable QC performed every 8 hours of patient

	testing from 11/1/22 to 9/9/24. 9. Interview with the TC#1 on 9/9/24 at 3:40 p.m. confirmed the laboratory failed to perform QC at least once day of patient testing for AmniSure ROM test, FilmArray GI panel, FilmArray Respiratory Panel 2.1, and failed to perform external QC every 8 hours of patient testing for the ePOC test system.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on the review of the "Amnisure TEST/QC LOG" and interview with the TC #3, the laboratory failed to ensure that the test records included documentation for analyte results, dates of testing and identity of the personnel who performed the test(s) for the Amnisure rupture of membrane (ROM) test. Findings: 1. Request was made for the test records for the Amnisure ROM test. Review of the documents for testing from 10 /25/22 to 9/7/24 revealed missing information for 11 of 30 entries. a. Date of testing for 6 results. b. Identity of testing personnel for 3 results. c. Patient test results for 2 results. 2. Interview with TC #3 on 9/9/24 at 5:05 p.m. confirmed, the laboratory failed to ensure that the test records included documentation for analyte results, dates of testing, and identity of the personnel who performed the test(s) for the Amnisure ROM test.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a lack of review documentation for both internal and external QC on the Amnisure ROM test (refer to D6042), and lack of testing personnel (TP) competencies that include the required elements for ROM TP (refer to D6046), the technical consultant failed to provide oversight for the Amnisure ROM test system.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

	This STANDARD is not met as evidenced by: Based upon review of Amnisure ROM QC from 10/25/22 to 9/7/24, lack of corrective action documentation for missing entries and interview with TC #3, the TC failed to ensure acceptable levels of analytic performance were maintained for the Amnisure ROM test system. Findings: 1. Review of the "Amnisure TEST/QC LOG" from 10/25 /22 to 9/7/24 revealed: a. No review documentation by TC #1 or TC #3. b. No corrective action documentation for failure to document internal control result for 7 of 30 entries. c. No documentation of patient remediation for patient results without internal control results for 7 of 30 entries. 2. Interview with TC #3 on 9/9/24 at 5:05 p. m. confirmed, the TC failed to ensure acceptable levels of analytic performance were maintained for the Amnisure ROM test system.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based upon a review of the laboratory's personnel competency assessment records and interview with TC #3, the TC failed to assess competency with the required elements for five of five moderate complexity TP for the Amnisure ROM test system. Findings: 1. Review of competency assessment of five of five moderate complexity TP revealed the assessment failed to include the required elements: a. Direct observation of routine patient test performance, including patient preparation, specimen handling, processing, and testing. b. Monitoring the recording and reporting of test results. c. Review of quality control records and proficiency testing results. d. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency test samples. 2. Interview with TC #3 on 9/9/24 at 5: 05 p.m. confirmed, the TC failed to assess competency with the required elements for five of five moderate complexity TP for the Amnisure ROM test system.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: The laboratory director (LD) failed to provide overall management and direction in accordance with 493.1445. Refer to D6092, D6094, and D6106.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's 2023, and 2024 to date of survey American Proficiency Institute (API) proficiency testing (PT) documentation, CMS 209 personnel form, and interview with technical consultant (TC) #1, the laboratory director (LD) failed to ensure that appropriate corrective action was taken for unacceptable PT reults for four of five consecutive events of unacceptable results when the first corrective action did not correct the unacceptable results. (Cross refer to D5221).
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on the review of the IQCPs for the Filmarray Respiratory Panel, Filmarray GI panel, and Amnisure ROM, Filmarray Respiratory Panel QC records, Filmarray GI panel QC records, Amnisure ROM test QC records, lack of monitoring documentation on the IQCPs for the Filmarray Respiratory Panel, Filmarray GI panel, and Amnisure ROM, review of ePOC Blood Analysis system procedure, lack of IQCP for ePOC Blood Analysis System, and interview with TC #1, the LD failed to assure the quality of laboratory services provided and identify failures in quality as they occur. Findings: 1. The surveyor requested the IQCP review records for the Filmarray Respiratory Panel, Filmarray GI panel, and Amnisure ROM. No IQCP review records for the Filmarray Respiratory Panel, Filmarray GI panel, and Amnisure ROM were provided at the time of survey. 2. Review of Filmarray Respiratory Panel QC records provided from 1/9/23 to 8/1/24 revealed no corresponding test records to support the "Respiratory QC Log" entries. 3. Review of Filmarray GI panel records provided from 9/15/22 to 8/12/24 revealed no corresponding test records to support the "GI Panel QC Log" entries. 4. Review of the Amnisure ROM test QC records revealed no review of QC results from 10/25/22 to 9/9/24. 5. Review of the "EPOC Blood Analysis System" procedure revealed QC to be performed wth in the first week of the month per IQCP. No IQCP was provided at the time of survey. Without an approved IQCP, QC for pH, pCO2 and pO2 are required every eight hours. 6. Interview with the TC #1 on 9/9/24 at 3:40 p.m. confirmed, the LD failed to assure the quality of laboratory services provided and identify failures in quality as they occur.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on the review of the procedures, lack of approval documentation by the LD and interview with TC #1, the LD failed to ensure that approved manuals or procedures were available to all laboratory personnel. Findings: 1. Review of laboratory procedures revealed the following procedures had no approval of the current LD. The

	current LD assumed this position 1/1/23. a. IQCP for Amnisure ROM test. b. IQCP for Filmarray Respiratory Panel c. IQCP for Filmarray GI panel d. IQCP for ePOC Blood Analysis System e. Introduction to the Laboratory Purpose & Responsibility f. Laboratory General Personnel Policies g. Reporting Procedures h. Reporting Critical Values 2. Interview with TC #1 9/9/24 at 3:40 p.m. confirmed, the LD failed to ensure that approved manuals or procedures were available to all laboratory personnel.