Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0472805	03/29/2019
Name of Provider or Supplier	**Street Address, City, State**	
Cimarron Memorial Hospital	100 South Ellis, Boise City, 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 03/27/19 - 03/29/19. The laboratory was found out of compliance with the following CLIA regulations: 1. D5024: 493.1215: Condition: Hematology 2. D6000: 493.1403: Condition: Laboratory Director, Moderate Complexity 3. D6033: 493.1409: Condition: Technical Consultant, Moderate Complexity The findings were reviewed with the laboratory manager at the conclusion of the survey.
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to retain records of the demonstration of performance specifications for new test sytems. Findings include: DIAGNOSTICA STAGO START 4 (1) On the first day of the survey, the laboratory manager stated to the surveyor the laboratory began using the Dianostica Stago STart 4 coagulation analyzer on 06/01/18 to perform patient PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing; (2) On the second day of the survey, the surveyor reviewed the laboratory's demonstration of performance specifications (i.e., accuracy and precision) and establishment, or verification of reference intervals for the new test system. The surveyor could not locate the raw data (i.e. analyzer printouts) from the accuracy and precision studies; (3) The surveyor asked the laboratory manager for the raw data obtained during the implementation studies. The laboratory manager stated to the surveyor, the raw data had not been retained but the results were reviewed and summaries of the testing were available that verified the results were acceptable; (4) The surveyor explained to the

	laboratory manager, all documentation from the demonstration of performance specifications for a new test system was to be retained for at least 2 years after the laboratory no longer used the analyzer. SIEMENS VIVA E (1) The laboratory manager stated to the surveyor the laboratory performed patient urine drug screen testing from 06/16/17 through 06/08/18 using the Siemens Viva E analyzer. The testing screened for the following: (a) 6-Acetylmorphine (b) Amphetamine (c) Benzodiazepine (d) Cocaine Metabolites (e) Opiates (f) THC (Cannabinoid) (g) Buprenorphine (h) Oxycodone (i) Ecstasy (j) Ethyl Alcohol (2) The surveyor reviewed the manufacturer's "Validation Binder," which included instructions for the demonstration of the performance specifications of accuracy. The instructions stated, "Run 10 specimens on your analyzer for all tests. Name patients One through Ten. Send same to reference laboratory for comparison. Run qualitative testing (positive and negative) on the patients. Compare results to make sure they match. Place in Section 2 of the Validation Binder"; (3) The surveyor then reviewed the laboratory's implementation records dated 05/31/17. The surveyor could not locate the raw data (i. e., analyzer printouts) from the accuracy studies. The surveyor asked the laboratory manager for the raw data obtained in the accuracy studies. The laboratory manager stated to the surveyor, the analyzer printouts had not been retained from the accuracy study, but the results had been reviewed and a summary was available that verified the accuracy was acceptable; (4) The surveyor explained to the laboratory manager, all documentation from the demonstration of performance specifications for a new test system was to be retained for at least 2 years after the laboratory no longer used the analyzer.
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a review of records, written policies and procedures, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to ensure the requirements were met for the specialty of Hematology. Findings include: (1) The laboratory failed to ensure a written procedure no longer in use had been discontinued. Refer to D5409; (2) The laboratory failed to follow the manufacturer's instructions for the testing performed in the laboratory. Refer to D5411; (3) The laboratory failed to follow the manufacturer's specifications for quality control materials. Refer to D5479; (4) The laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.
D5409	PROCEDURE MANUAL 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 review of written policies and procedures, and interview with the laboratory manager, the laboratory failed to indicate procedures no longer in use as discontinued,

	with the date of discontinuance. Findings include: (1) On the first day of the survey, the laboratory manager stated the following to the surveyor: (a) The laboratory began urine drug screen testing on 06/16/17 using the Siemens Viva E analyzer. The testing was discontinued on 06/08/18; (b) The laboratory performed coagulation testing (i.e. PT/INR-Prothrombin Time/International Normalized Ratio and PTT-Partial Thromboplastin Time) using the Hemochron Jr. Signature + test system until 05/31/18 when it was replaced with the Diagnostica Stago STart 4 on 06/01/18; (c) The laboratory began using the GenMark ePlex test system for the detection of bacterial and viral stool and respiratory pathogens on 10/24/17. The testing was discontinued on 07/30/18; (d) The laboratory performed chemistry testing (i.e. Albumin, Glucose, Potassium, etc.) using the Dimension Xpand Plus analyzer. The testing was discontinued on 10/20/18. (2) The surveyor reviewed the laboratory policy and procedure manual, which included detailed procedures for testing performed on the Siemens Viva E, Hemochron Jr. Signature +, GenMark ePlex, and the Dimension Xpand Plus analyzers. There was no evidence the procedures had been discontinued; (3) The surveyor reviewed the procedures with the laboratory manager. The laboratory manager stated to the surveyor the test procedures listed above, should have been indicated as discontinued, with the dates of discontinuance. NOTE: Discontinued procedures must be maintained for two years as required at 493.1105(a)(2).
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 a review of records, manufacturers' instructions, and interview with the laboratory manager, the laboratory failed to follow the manufacturers' instructions for the testing performed in the laboratory. Findings include: ACCURACY (1) On the first day of the survey, the laboratory manager stated to the surveyor the laboratory began using the Diagnostica Stago STart 4 coagulation analyzer on 06/01/18 to perform patient PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing; (2) On the second day of the survey, the surveyor asked the laboratory manager for the manufacturer's implementation instructions. The laboratory manager stated to the surveyor there were no instructions included with the analyzer when it was purchased. The surveyor then reviewed the surveyor's copy of the manufacturer's "Method Validation Procedure, Acceptance Criteria, and Implementation" guidelines. The manufacturer required the following for the demonstration of the performance specification of accuracy: (a) "Collect 40 specimens in the anticoagulant currently in use."; (b) "The number of samples utilized follows the minimum numbers recommended by CLSI. Any deviation from these numbers will be the responsibility of the customer."; (c) "Using the existing system (old instrument, old anticoagulant and old reagents) Perform testing on 40 samples for the routine tests." (3) The surveyor then reviewed the laboratory's implementation records and identified the laboratory failed to use the manufacturer's minimum number of 40 samples: (a) PT: 17 samples were used (b) PTT: 19 samples were used (4) The surveyor reviewed the findings with the laboratory manager and explained when a new test system is implemented, the laboratory must follow the manufacturer's

instructions to demonstrate the laboratory can obtain performance specifications comparable to the manufacturer's, prior to using the test system for patient testing; (5) The laboratory manager stated to the surveyor, the laboratory did not follow the manufacturer's instructions as listed above; (6) Examples of patients tested when the laboratory failed to follow the manufacturer's instructions for the implementation of the coagulation analyzer, included the following: (a) PT/INR: (i) Patient #5: Testing performed 06/02/18 (ii) Patient #6: Testing performed 06/15/18 (iii) Patient #7: Testing performed 06/17/18 (iv) Patient #8: Testing performed 06/27/18 (v) Patient #9: Testing performed 06/30/18 (vi) Patient #10: Testing performed 07/02/18 (vii) Patient #11: Testing performed 07/10/18 (viii) Patient #12: Testing performed 07/24 /18 (ix) Patient #13: Testing performed 08/08/18 (x) Patient #14: Testing performed 08 /17/18 (xi) Patient #15: Testing performed 08/23/18 (xii) Patient #16: Testing performed 09/18/18 (xiii) Patient #17: Testing performed 09/11/18 (xiv) Patient #18: Testing performed 09/17/18 (xv) Patient #19: Testing performed 10/10/18 (xvi) Patient #20: Testing performed 10/22/18 (xvii) Patient #21: Testing performed 10/25 /18 (xviii) Patient #22: Testing performed 10/20/18 (xix) Patient #23: Testing performed 11/05/18 (xx) Patient #24: Testing performed 11/19/18 (xxi) Patient #25: Testing performed 11/21/18 (xxii) Patient #26: Testing performed 12/10/18 (xxiii) Patient #27: Testing performed 12/15/18 (xxiv) Patient #28: Testing performed 12/18 /18 (xxv) Patient #29: Testing performed 01/09/19 (xxvi) Patient #30: Testing performed 01/11/19 (xxvii) Patient #31: Testing performed 01/31/19 (xxviii) Patient #32: Testing performed 02/13/19 (xxix) Patient #33: Testing performed 02/22/19 (xxx) Patient #34: Testing performed 02/28/19 (b) PTT: (i) Patient #35: Testing performed 10/20/18 (ii) Patient #36: Testing performed 10/23/18 (iii) Patient #37: Testing performed 11/21/18 REFERENCE INTERVAL (1) On the second day of the survey, the surveyor asked the laboratory manager for the manufacturer's implementation instructions. The laboratory manager stated to the surveyor there were no instructions included with the analyzer when it was purchased. The surveyor then reviewed the surveyor's copy of the manufacturer's "Method Validation Procedure, Acceptance Criteria, and Implementation" guidelines. The manufacturer required the following for the establishment of the reference intervals (i.e. normal ranges) when a new test system is implemented: (a) "Reference range data will be collected during method validations." (b) "For routine tests (PT, PTT), the number of reference samples as suggested by CLSI is 120 donors for non-parametric analysis": (i) "50% of the routine reference samples should be processed and assayed "fresh"; (ii) "Any deviation from this minimum 120 sample requirement will be noted on the final signoff sheet"; (iii) "Collect 'normal donors' in 3.2% sodium citrate according to CLSI guidelines (H21-A5)"; (iv) "Criteria for reference range 'normal' donors:" (aa) "Age": (i) "Include ages that span the population, reflecting your patient diversity. (Be careful not to use all young lab employees.)" (bb) "Sex": (i) "Equal numbers of males and females" (cc) "Drug History": (i) "Patients excluded if taking the following drugs: (aaa) "Birth control or estrogen containing products" (bbb) "Coumadin" (ccc) "Heparin (UFH, LMWH or heparinoid)" (ddd) "Direct Thrombin Inhibitors" (eee) "Antibiotics" (dd) "Conditions": (i) "Patients excluded if they are pregnant or have any known immunologic diseases" (ii) "Note: Possible source for normal samples is ambulatory out-patient surgery, i.e. eye surgery." (2) The surveyor reviewed the laboratory's implementation records and identified the laboratory failed to follow the manufacturer's instructions for establishing the reference intervals, as follows: (a) PT: (i) 17 samples were utilized instead of 120 normal patient samples; (ii) There was no documentation of the donor: (aa) Age (bb) Sex (cc) Medication history (dd) Health conditions (b) PTT: (i) 19 samples were utilized instead of 120 normal patient samples; (ii) There was no documentation of the donor: (aa) Age (bb) Sex (cc) Medication history (dd) Patient health conditions (3) The surveyor reviewed the

	findings with the laboratory manager and explained the manufacturer required that a full reference interval study (i.e. 120 screened normal patient samples) be performed if one had not been performed for the new test system, prior to use; (4) The laboratory manager stated to the surveyor, the laboratory did not follow the manufacturer's instructions as indicated above; (5) For examples of patients tested when the laboratory failed to follow the manufacturer's instructions, see above. TRANSIT TEMPERATURE (1) On the first day of the survey, the laboratory manager stated to the surveyor the laboratory used the i-STAT 1 analyzer and performed ABG's (Arterial Blood Gases-pH, pO2, pCO2) testing. In addition, the laboratory manager stated the laboratory used the G3+ cartridge to perform ABG testing until 03/07/18, when it was replaced with the CG4+ test cartridge (pH, pO2, pCO2, and Lactic Acid); (2) The surveyor reviewed the manufacturer's instructions (operator's manual) for the test system. The instructions stated, "Read and Record Temperature Strip with Each New Shipment of Cartridges. Record the information on the temperature strip card on the 'Receipt of New Cartridges' log. Retain logs for two years in a file for quality control"; (3) The surveyor reviewed the findings with the laboratory manager and asked if the information from the temperature strip included in new shipments of test cartridges was documented and maintained. The laboratory manager stated to the surveyor the condition of the temperature strip was noticed but was not documented and maintained; (4) Therefore, the surveyor could not determine that the temperature of each shipment of test cartridges received between 01/01/18 and 03/27/19 had been acceptable upon receipt.
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 manager, 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 manager stated to the surveyor the laboratory performed patient urine drug screen testing from 06/16/17 through 06/08/18 using the Siemens Viva E analyzer. The testing screened for the following: (a) 6-Acetylmorphine (b) Amphetamine (c) Benzodiazepine (d) Cocaine Metabolites (e) Opiates (f) THC (Cannabinoid) (g) Buprenorphine (h) Oxycodone (i) Ecstasy (j) Ethyl Alcohol (2) On the second day of the survey, the surveyor reviewed the manufacturer's daily maintenance procedures for the analyzer, which included the following: (a) Fill water container with 10 liters of DI water and 25mL of System Solution; (b) Empty waste containers (follow safety instructions for working with potentially infectious material); (c) Check rotor blank results for SD errors. Change cuvette rotor if necessary; (d) Set onboard reagent expiration dates to four weeks. Discard reagent bottles and their contents at the expiration date or when a new lot of reagent will be used; (e) Fill HCl bottle on the reagent rotor with 0.1 N HCl; (f) Fill tube in W position on sample rotor with Needle rinse; (g) Remove measurement disk cover and inspect wash arm, mixer belt and measurement rotor; (h) Check that the reagent rotor compartment is being cooled; (i) Perform an instrument Fill System. (3) The surveyor then reviewed the laboratory's maintenance records and identified the daily maintenance procedures had not been performed as required on the following days of

	patient testing: (a) 11/17/17: Patient #3 (b) 03/30/18: Patient #4 (4) The surveyor reviewed the records with the laboratory manager. The laboratory manager stated to the surveyor, the maintenance had not been performed as indicated above.
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, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to have control procedures that would detect immediate errors that would occur due to test system failure, adverse environmental conditions, and operator performance for a chemistry analyte. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor: (a) The laboratory performed chemistry testing (i.e., AST (Aspartate Aminotransferase), etc.) using the Dimension Xpand Plus analyzer until 10/20/18 when the testing was discontinued; (b) Two levels (Level I and Level II) of BioRad Lyphochek Assayed Chemistry QC (Quality Control) materials were tested each day of patient testing; (c) The laboratory established its own means and SD (Standard Deviation) for the limits of acceptability. (2) On the third day of the survey, the surveyor reviewed QC records (i.e. Levey Jennings (LJ) graphs) from 6 months (November 2017; January, March, July, and September 2018; and February 2019) for 6 analytes (Albumin, AST, CK (Creatinine Kinase), Potassium, TSH (Thyroid Stimulating Hormone), and Total Protein). The laboratory utilized 2 QC lot numbers during the review period-Level 1, Lot #26431 and Level 2, Lot #26432; (3) The surveyor identified from the review of the LJ graphs, that Level 1, Lot #26431, had no control outliers during 5 of the 6 months reviewed for the analyte AST.(Approximately 1 out of every 20 control results should be defined as unacceptable and there were no results that were beyond the laboratory's established range). In addition, the following was identified for the review period: (a) The laboratory established: (i) A mean of 43.0 with an SD +/- 2.0 (ii) The 2SD acceptable range was 41.0 - 46.0 (b) The LJ graphs included the following: (i) The mean of 43.0 with an SD +/- 10.7 was used (ii) The 2SD acceptable range in use was 21.6 - 64.4 (4) The surveyor then reviewed the manufacturer's assay value sheets, specific for the lot number of the Level 1 QC material. It stated, "The mean values and corresponding +/- 3SD ranges in the Assignment of Values Data Charts were derived from replicate analyses and are specific for this lot of product." The assay value sheet included the following information for AST and QC Level 1: (i) The mean was 40.9 with an SD +/- 3.78 (ii) The 3SD acceptable range was 33.3 - 48.4 (iii) The laboratory used an SD of +/- 10.7, which was wider than the manufacturer's SD of 3.78. (5) The surveyor reviewed the findings with the laboratory manager, who stated to the surveyor the laboratory thought the absence of outliers indicated QC was acceptable; (6) Patients with testing performed during the period the laboratory failed

	to monitor AST testing for immediate errors, included the following: (a) Patient #1: Testing performed 06/19/18 (b) Patient #2: Testing performed 08/31/18 NOTE: D5441 was cited at the previous recertification survey performed 05/15/2017 to 05/17 /17.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to follow the manufacturer's specifications for quality control materials. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor the laboratory began using the Diagnostica Stago STart 4 coagulation analyzer on 06/01/18 to perform patient PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing; (2) The laboratory manager also verified with the surveyor, two levels of QC (Quality Control) materials were performed each 8 hours of patient testing: (a) Pacific Hemostasis Level I (Normal) (b) Pacific Hemostasis Level II (Abnormal) (3) The surveyor reviewed the manufacturer's instructions for the QC materials, which stated, "Ranges must be determined in each laboratory with each change of lot number, reagent, or instrument." In addition, the "Certificate of Analysis" specific for each level and lot number stated, "Actual values recovered in the user laboratory will depend on reagent lot number, instrument and technique in use. Each laboratory should establish ranges using instrument, reagent and technique in place;" (4) The surveyor then reviewed the QC records from 05/14/18 (implementation of the analyzer) to 03/27/19. From the records of the establishment of the QC ranges, the surveyor identified 4 lot numbers had been utilized during the review period: (a) Level I, Lot #246830 - Used from 05/14/18 to 03/27/19 (b) Level II: (i) Lot #912298 - Used from 05/14/18 to 06/1/18 (ii) Lot #301824 - Used from 06/01/18 to 02/08/19 and from 02/20/19 to 03/27/19 (iii) Lot #290517 - Used from 02/10/19 to 02/19/19 (5) From the review, the surveyor determined for 1 of the 4 lot numbers utilized (Level II, Lot #301824), the laboratory failed to establish QC ranges (i.e. mean and 2SD (Standard Deviation) from at least 30 replicates) before it was returned to use on 02/20 /19. In addition, the laboratory continued to use the QC ranges established for Lot #290517 after Lot #301824 was returned to use; (6) The surveyor reviewed the findings with the laboratory manager and asked if additional documentation was available to show the ranges had been established for Level II, Lot #301824 before it was put into use on 02/20/19. The laboratory manager stated to the surveyor there was no documentation located which showed the laboratory established the QC ranges before the lot number was returned to use on 02/20/19; (7) Patients tested when the laboratory failed to follow the manufacturer's instructions to establish ranges for QC materials, included the following: (a) Patient #32: PT Testing performed 02/13/19 (b) Patient #33: PT Testing performed 02/22/19
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, manufacturers' instructions, written policies and procedures, and interview with the laboratory manager, the laboratory failed to monitor and evaluate the overall quality of analytic systems. Findings include: (1) The laboratory failed to ensure written procedures no longer in use had been discontinued. Refer to D5409; (2) The laboratory failed to follow the manufacturers' instructions for the testing performed in the laboratory. Refer to D5411; (3) The laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Refer to D5429; (4) The laboratory failed to have control procedures that would detect immediate errors that would occur due to test system failure, adverse environmental conditions, and operator performance for a chemistry analyte. Refer to D5441; (5) The laboratory failed to follow the manufacturer's specifications for quality control materials. Refer to D5479.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to follow the manufacturer's instructions for urine drug screen testing. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor the laboratory performed patient urine drug screen testing from 06/16/17 through 06/08/18 using the Siemens Viva E analyzer. The testing screened for the following: (a) 6-Acetylmorphine (b) Amphetamine (c) Benzodiazepine (d) Cocaine Metabolites (e) Opiates (f) THC (Cannabinoid) (g) Buprenorphine (h) Oxycodone (i) Ecstasy (2) On the second day of the survey, the surveyor reviewed the manufacturer's instructions (package insert) for the testing performed, which stated, "The Emitt II Plus Assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC /MS) is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgement should be applied to any drug-of-abuse test result, particularly when preliminary positive results are used."; (3) The surveyor reviewed 2 patient urine drug screening test reports. For 2 of the 2 test reports, the laboratory failed to follow the manufacturer's requirement that urine drug screen results are preliminary and must be confirmed with another method (i.e., GC /MS); (4) The surveyor reviewed the findings with the laboratory manager who stated

	to the surveyor the laboratory failed to follow the manufacturer's requirement that screening results must be confirmed by another method for final results; (5) Examples of testing performed when the laboratory failed to follow the manufacturer's requirement for urine drug screen testing included the following: (a) Patient #3: Testing performed 11/17/17 (b) Patient #4: Testing performed 03/30/18
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, manufacturers' instructions, written policies and procedures, and interview with the laboratory manager, the laboratory director failed to provide overall management and direction in accordance with 493.1407 of this subpart. Findings include: (1) The laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results were reported. Refer to D6014; (2) The laboratory director failed to ensure a quality assessment program had been established and maintained. Refer to D6021.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager, the laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results were reported. Findings include: (1) The laboratory director failed to ensure the laboratory followed the manufacturer's instructions. Refer to D5411; (2) The laboratory director failed to ensure the laboratory followed the manufacturer's specifications for quality control materials. Refer to D5479.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

	This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, written policies and procedures, and interview with the laboratory manager, the laboratory director failed to ensure a quality assessment program had been established and maintained. Findings include: (1) The laboratory director failed to ensure an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.
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 review of records, manufacturer's instructions, and interview with the laboratory manager, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure the establishment and maintenance of acceptable levels of analytic performance. Refer to D6042.
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 on a review of records, manufacturer's instructions, policies and procedures, and interview with the laboratory manager, the technical consultant failed to ensure the establishment and maintenance of acceptable levels of analytic performance. Findings include: (1) The technical consultant failed to ensure policies and procedures were current. Refer to D5409; (2) The technical consultant failed to ensure the manufacturer's instructions were followed. Refer to D5411; (3) The technical consultant failed to ensure the manufacturer's instructions for quality control materials were followed. Refer to D5479.