Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0470030	08/22/2024
Name of Provider or Supplier	**Street Address, City, State**	
Purcell Municipal Hospital	2301 N 9th Ave, Purcell, 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 08/20,21,22/2024. The laboratory was found out of compliance with the following CLIA Conditions: 493.801; D2000: Enrollment and Testing of Samples 493.1250; D5400: Analytic Systems 493.1403; D6000: Laboratory Director The findings were reviewed with the laboratory director, chief executive officer, Operation/Finance Manager, lead technologist, and testing person #8 during an exit conference performed at the conclusion of the survey.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of records and interview with the laboratory director and lead technologist, the laboratory failed to enroll in a proficiency testing program for Mononucleosis, Qualitative Serum Pregnancy, and Rheumatoid Factor testing for five of five events reviewed. Findings include: (1) On 08/20/2024, a review of proficiency testing records for 2023 (first, second, and third events), and 2024 (first and second events) identified no evidence the laboratory was enrolled in proficiency testing for Mononucleosis, Qualitative Serum Pregnancy, and Rheumatoid Factor testing for five of five events; (2) The records were reviewed with the laboratory director and lead technologist who stated on 08/20/2024 at 12:40 pm, the laboratory had not enrolled in the proficiency testing as stated above; (3) A review of the test volume list completed

	for the survey identified the laboratory performed approximately 35 Mononucleosis, 204 Qualitative Serum Pregnancy, and 173 Rheumatoid Factor tests annually.
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. This STANDARD is not met as evidenced by: Based on a review of records, hospital policy, and interview with the laboratory director, lead technologist, and nursing director, the facility failed to ensure written policies were followed for preventing transfusion reactions for three of three units of packed red-blood cells transfused. Findings include: (1) On 08/20/2024 at 1:30 pm, the laboratory director stated that blood transfusions were performed by nursing staff; (2) On 08/21/2024, a review of the hospital policy titled, "Blood Products Administration" stated: (a) "Baseline vital signs should be recorded immediately prior to infusion, and every five (5) minutes for the first fifteen minutes, then every fifteen (15) minutes for the remainder of the hour, then every hour and again at the end of the transfusion." (3) A review of transfusion records for three units identified the vitals had not been documented as performed for the five and 15 minute increments as required by policy: (a) Unit #W091024200689 - The unit was started 05/07/2024 at 12:07 pm and vital signs had not been documented as performed as follows: (i) The five minute vitals had not been documented between 12:07 pm and 12:25 pm; (ii) The 15 minute vitals had not been documented between 12:25 pm and 01:25 pm. (b) Unit #W091024187172 - The unit was started 05/07/2024 at 02:45 pm and vital signs had not been documented as performed as follows: (i) The five minute vitals had not been documented between 02:45 pm and 03:00 pm; (ii) The 15 minute vitals had not been documented between 03:00 pm and 04:15 pm. (c) Unit #W091024267423 - The unit was started on 07/03/2024 at 09:55 am and vital signs had not been documented as performed as follows: (i) The five minute vitals had not been documented between 09:55 am and 10:10 am; (ii) One 15 minute vital had not been documented between 10:40 am and 11:40 am. (4) The records were reviewed with the nursing director who stated on 08/22/2024 at 01:30 pm, the vital signs had not been documented according to policy.
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 policies, and interview with the laboratory director, the laboratory failed to establish a written clinical consultant competency assessment policy, based on the position responsibilities as listed in the Subpart M. Findings include: (1) A review of written policies and interview with the laboratory director on 08/20/2024 at 04:15 pm identified no evidence of a policy for assessing

	the competency of the clinical consultant; (2) A review of Form CMS-209 (Laboratory Personnel Report) and personnel records for competency assessments performed during the review period of January 2023 through the current date identified no documentation competency assessments had been performed based on position responsibilities for one of one clinical consultant; (3) The findings were reviewed with the laboratory director on 08/20/2024 at 04:15 pm, who confirmed the laboratory failed to define and perform assessments based on the specific position responsibilities.
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 director, the laboratory failed to review and evaluate proficiency testing results for one of four Hematology Proficiency testing events reviewed from January 2023 through the current date. Findings include: (1) A review of Hematology Proficiency testing records for four events (first, second, and third 2023 and first 2024) identified the following failure with no evidence that corrective action had been documented as performed: (a) First 2024 Event - The laboratory attained a score of 80% for Blood Cell Identification (Sample BCI-03). (2) The records were reviewed with the laboratory director who stated on 08/20/2024 at 03:40 pm, corrective action had not been taken and documented for the failure.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director and lead technologist, the laboratory failed to verify the accuracy for five of five analytes at least twice annually during the review period of January 2023 through the current date. Findings include: (1) On 08/20/2024 at 12:40 pm, the laboratory director and lead technologist stated the laboratory performed the following: (a) Procalcitonin testing using the Abbott Alinity analyzer; (b) CRP (C-reactive protein) testing using the Abbott Alinity analyzer; (c) Ketone testing using the Germaine Laboratories Aimtab Ketone tablets and serum or plasma samples; (d) WP (wet preparation) on vaginal swabs; (e) Urine microscopic testing. (2) A review of 2023 and 2024 proficiency testing records identified the laboratory had not enrolled and participated in proficiency testing for the above analytes, therefore, it was determined the laboratory must verify the accuracy of the testing at least twice annually; (3) Interview with the laboratory director on 08/22/2024 at 09:59 am confirmed the laboratory did not have a method in place to verify the accuracy of Procalcitonin, CRP, Ketone, WP, and Urine Microscopic testing twice annually and the accuracy of the testing had not been verified for accuracy during 2023 and to date in 2024; (4) The following were examples of patient testing performed: (a) Procalcitonin (i) Patient # 45734 - testing

performed on 01/05/2023 (i) Patient # 219848 - testing performed on 01/13/2023 (ii) Patient # 42062 - testing performed on 01/27/2023 (iii) Patient # 224834 - testing performed on 05/02/2023 (iv) Patient # 240106 - testing performed on 05/12/2023 (v) Patient # 28919 - testing performed on 05/28/2023 (vi) Patient # 241741 - testing performed on 10/01/2023 (vii) Patient # 241822 - testing performed on 10/16/2023 (viii) Patient # 64015 - testing performed on 10/25/2023 (ix) Patient # 10008 - testing performed on 01/06/2024 (x) Patient # 29566 - testing performed on 01/15/2024 (xi) Patient # 243149 - testing performed on 01/30/2024 (xii) Patient # 245471 - testing performed on 07/19/2024 (xiii) Patient # 230015 - testing performed on 07/23/2024 (xiv) Patient # 58248 - testing performed on 08/12/2024 (b) CRP (i) Patient # 238126 - testing performed on 01/03/2023 (ii) Patient # 238927 - testing performed on 01/14 /2023 (iii) Patient # 40962 - testing performed on 01/30/2023 (iv) Patient # 239940 - testing performed on 05/01/2023 (v) Patient # 52675 - testing performed on 05/14 /2023 (vi) Patient # 207840 - testing performed on 05/30/2023 (vii) Patient # 241699 - testing performed on 10/01/2023 (viii) Patient # 208577 - testing performed on 10/16 /2023 (ix) Patient # 242903 - testing performed on 10/30/2023 (x) Patient # 73405 - testing performed on 01/10/2024 (xi) Patient # 242502 - testing performed on 01/15 /2024 (xii) Patient # 234956 - testing performed on 01/29/2024 (xiii) Patient # 51231 - testing performed on 07/01/2024 (xiv) Patient # 231225 - testing performed on 07/15 /2024 (xv) Patient # 37078 - testing performed on 07/24/2024 (xvi) Patient # 217037 - testing performed on 08/01/2024 (xvii) Patient # 209171 - testing performed on 08/15 /2024 (xviii) Patient # 237988 - testing performed on 08/20/2024 (xx) Patient # 245775 - testing performed on 08/20/2024 (c) Ketone (i) Patient # 670806263 - testing performed on 03/22/2023 (ii) Patient # 671987206 - testing performed on 04/18 /2023 (iii) Patient # 676349049 - testing performed on 07/31/2023 (iv) Patient # 677600756 - testing performed on 08/29/2023 (v) Patient # 679471059 - testing performed on 10/11/2023 (vi) Patient # 681976448 - testing performed on 12/08/2023 (vii) Patient # 682191172 - testing performed on 12/13/2023 (viii) Patient # 682536139 - testing performed on 12/21/2023 (ix) Patient # 685607358 - testing performed on 03/01/2024 (x) Patient # 686536976 - testing performed on 03/22/2024 (xi) Patient # 687995772 - testing performed on 04/25/2024 (xii) Patient # 688317594 - testing performed on 05/02/2024 (xiii) Patient # 691650664 - testing performed on 07 /21/2024 (xiv) Patient # 692096248 - testing performed on 07/31/2024 (xv) Patient # 692246323 - testing performed on 08/04/2024 (xvi) Patient # 692880987 - testing performed on 08/19/2024 (d) WP (i) Patient # 673137533 - testing performed on 05/15 /2023 (ii) Patient # 674061089 - testing performed on 06/06/2023 (iii) Patient # 674496324 - testing performed on 06/16/2023 (iv) Patient # 677971824 - testing performed on 09/07/2023 (v) Patient # 678793247 - testing performed on 09/26/2023 (vi) Patient # 679612754 - testing performed on 10/15/2023 (vii) Patient # 681593604 - testing performed on 11/30/2023 (viii) Patient # 681709081 - testing performed on 12 /03/2023 (ix) Patient # 682537221 - testing performed on 12/21/2023 (x) Patient # 684966058 - testing performed on 02/16/2024 (xi) Patient # 919578 - testing performed on 02/29/2024 (xii) Patient # 687477957 - testing performed on 04/13 /2024 (xiii) Patient # 688724408 - testing performed on 05/12/2024 (xiv) Patient # 689620551 - testing performed on 06/03/2024 (xv) Patient # 690925352 - testing performed on 07/03/2024 (xvi) Patient # 691457432 - testing performed on 07/16 /2024 (xvii) Patient # 691486017 - testing performed on 07/17/2024 (e) Urine Microscopic (i) Patient # 678093344 - testing performed on 09/10/2023 (ii) Patient # 678385028 - testing performed on 09/17/2023 (iii) Patient # 679065895 - testing performed on 10/02/2023 (iv) Patient # 679777352 - testing performed on 10/18/2023 (v) Patient # 680290713 - testing performed on 10/31/2023 (vi) Patient # 681761419 - testing performed on 12/04/2023 (vii) Patient # 682445374 - testing performed on 12 /19/2023 (viii) Patient # 682876503 - testing performed on 12/30/2023 (ix) Patient #

	684412197 - testing performed on 02/04/2024 (x) Patient # 684829774 - testing performed on 02/13/2024 (xi) Patient # 685328054 - testing performed on 02/24/2024 (xii) Patient # 687239144 - testing performed on 04/08/2024 (xiii) Patient # 687590160 - testing performed on 04/16/2024 (xiv) Patient # 688030748 - testing performed on 04/27/2024 (xv) Patient # 689598613 - testing performed on 06/02/2024 (xvi) Patient # 689941740 - testing performed on 06/10/2024 (xvii) Patient # 690584571 - testing performed on 06/25/2024 (xviii) Patient # 691159943 - testing performed on 07/09/2024 (xix) Patient # 691332055 - testing performed on 07/13 /2024 (xx) Patient # 691798955 - testing performed on 07/24/2024 (xxi) Patient # 692177726 - testing performed on 08/02/2024 (xxii) Patient # 692669682 - testing performed on 08/14/2024 (xxiii) Patient # 692918634 - testing performed on 08/20 /2024
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 a review of records, policies and procedures, manufacturer's instructions, observation, and interview with the laboratory director and lead technologist, the laboratory failed to monitor and evaluate the overall quality of analytic systems and correct identified problems for each specialty and subspecialty of testing performed during the review period of January 2023 through the current date. Findings include: (1) The laboratory failed to have step-by-step written procedures for one of four procedures reviewed. Refer to D5403; (2) The laboratory failed to follow the manufacturer's instructions for implementing two of four coagulation reagents; and ensure the mean of the normal reference interval was accurately entered into the analyzer for one of one PT reagent lot change. Refer to D5411; (3) The laboratory failed to ensure Alcor Seditrol control materials had not exceeded the room temperature expiration date. Refer to D5417; (4) The laboratory failed to utilize the demonstrated reportable range; and failed to ensure the performance specification data had been evaluated prior to implementing a new test system. Refer to D5421; (5) The laboratory failed to demonstrate the performance specifications for two of two new test methods. Refer to D5421; (6) The laboratory failed to perform calibration verification procedures at least once every 6 months for six of six analytes reviewed using the Abbott Alinity analyzer. Refer to D5439; (7) The laboratory failed to perform negative and positive control materials each day of patient Urine Drug Screen, Ketone, Mononucleosis, and Qualitative Serum Pregnancy testing. Refer to D5449; (8) The laboratory failed to use control materials of a similar matrix to that of patient specimens 14 of 14 days of patient Serum Ketone testing reviewed. Refer to D5465; (9) The laboratory failed to have an ongoing mechanism for performing quality assessment. Refer to D5791.
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 policies and procedures, and interview with the lead technologist and laboratory director, the laboratory failed to have step-by-step written procedures for one of four procedures reviewed. Findings include: (1) On 08/22/2024 at 09:45 am, the lead technologist stated Coagulation testing which included the analytes PT /INR (Prothrombin Time/International Normalized Ratio), PTT (Partial Thromboplastin Time), and D-dimer testing were performed using the Wefern ACL TOP 350 analyzer; (2) A review of laboratory procedure manuals identified no evidence of written procedures for Coagulation testing to include but not limited to: (a) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection; (b) Step-by-step performance of the procedure, including test calculations and interpretation of results to include reagent lot change procedures for PT/INR and PTT testing; (c) Control procedures to include: (i) Identity (e.g., normal, abnormal, level I,II, patient or a control); (ii) Number and frequency of testing controls; (iii) Control limits established (i.e., the laboratory's method for establishing quality control means and limits); (iv) Criteria to determine acceptable control results; (v) Corrective action to take when control results fail to meet the laboratory's criteria for acceptability. (d) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability; (e) Reference intervals (normal values); (f) Imminently life-threatening test results, or panic or alert values; (g) Pertinent literature references; (h) 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; (i) Description of the course of action to take if a test system becomes inoperable. (3) The findings were reviewed with the laboratory director and lead technologist. Both stated on 08/22/2024 at 12:40 pm, a written procedure manual for coagulation testing could not be located; (4) Refer to D5411 for examples of patient PT/INR and PTT testing performed.
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, manufacturer's instructions, observation, and interview with the laboratory director and lead technologist, the laboratory failed to follow the manufacturer's instructions for implementing two of four coagulation reagents; and ensure the mean of the normal reference interval was accurately entered into the analyzer for one of one PT reagent lot change. Findings include: REAGENT LOT CHANGES (1) On 08/22/2024 at 09:45 am, the lead technologist stated: (a) PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing were performed using the Werfen ACL TOP 350 analyzer (the INR was calculated using the PT normal reference interval mean); (b) The following reagent lot numbers were put into use as stated below: (i) PT - HemosIL Recombiplastin 2G, lot #N0925646 - In use on 08/28/2023 (ii) PTT - HemosIL SynthasIL, lot #N1237471 - In use on 07/31/2024 (2) A review of the manufacturer's instructions titled, "Changing Reagent or Lot Number of Reagent" stated "When changing to a new lot number of reagent or a new reagent, it is important to establish a new normal reference interval, establish new assay control ranges, and perform a comparison study for all tests" and provided procedures for each: (a) "Normal Reference Interval" Procedure (i) "Donors should be healthy and have no known pathological conditions. Donors should not be on medication affecting coagulation, including (but not limited to) oral contraceptives, estrogen therapy (HRT), anticoagulants, high-dose aspirin, etc"; (ii) "Donors should span the age range of the population being tested"; (iii) "Donors should be equally divided between male/female"; (b) "Changing Lot Number of Control" Procedure (i) "Establishing a control assay range is done under the following conditions": (aa) "With a change of the reagent lot number"; (bb) "With a change of the control lot number". (ii) "Perform at least 20 runs of each test for each level of control"; (iii) "Calculate the mean and +/-2 SD range as the target once the materials are put into routine use". (c) "Comparison Study" Procedure (i) "At least 50% of the samples should be outside of the laboratory normal reference interval, if possible"; (ii) "At least 40 specimens should be analyzed. More samples will improve the confidence in the data"; (ii) "Evaluate the new instrument or reagent over clinically meaningful range including data below and above the expected reference range"; (iii) "For a given specimen, analysis by the comparative and new methods or reagents should be accomplished within 1 hour of each other to avoid possible degradation of the samples"; (iv) "Analyze each patient sample using the new method (or reagents) and the comparative method". (3) A review of the implementation records for the PT and PTT reagents identified the following: (a) PT Reagent (i) Although the laboratory had used 20 donors, there was no evidence of the health status and medication history of the donors; (ii) The comparison study included 12 abnormal specimens instead of 20. (b) PTT Reagent (i) There was no documentation to prove the "Normal Reference Interval" procedure had been performed; (ii) There was no documentation to prove the "Changing Lot Number of Control" procedure had been performed; (iii) There was no documentation to proved the "Comparison Study" procedure had been performed. (4) The records were reviewed with the laboratory director and lead technologist. Both stated on 08/22/2024 at 12:45 pm, the manufacturer's instructions had not been followed for the reagent lot changes as specified above. MEAN OF THE NORMAL REFERENCE PROGRAMMED IN ANALYZER (1) During the review of the manufacturer's instructions, the following was reviewed for INR setup: (a) "If the INR system is utilized to report PT's, note the geometric mean value of the PT normal

	reference interval in seconds and use along with the lot-specific ISI value in the INR setup calculation page. (see INR Calculation Setup in this manual): (i) The "INR Calculation Setup" Section of the manual provided instructions for entering the geometric mean and lot-specific INR into the analyzer and stated, "If the INR calculation is not properly set up, then erroneous patient results may be reported. If the reagent lot number changes, then the new ISI value from the package insert and the new men of normal range for that lot number of PT reagent must be entered". (2) A review of the implementation records for the PT reagent lot change (lot #N0925646) identified the mean of the normal reference interval that had been calculated by the laboratory was 11.8; (3) Observation of the mean that had been programmed into the analyzer, with the assistance of the lead technologist on 08/22/2024 at 10:15 am, identified the value currently programmed in the analyzer was 11.6; (4) The findings were reviewed with the laboratory director and lead technologist. Both stated on 08/22/2024 at 12:45 pm, the mean of the normal reference interval of 11.6 that was programmed into the analyzer was not correct and should have been entered as 11.8. EXAMPLES OF PATIENT PT/INR AND PTT TESTING (1) The following were examples of PT/INR and PTT testing performed when the manufacturer's instructions had not been followed for the reagent lot changes; and when the mean of the normal reference interval for PT that had been calculated during the studies had not been programmed into the analyzer: (a) Patient #92417 - PT/INR testing performed on 10/04/2023 (b) Patient #235955 - PT/INR testing performed on 10/11/2023 (c) Patient #69981 - PT/INR testing performed on 10/13/2023 (d) Patient #28919 - PT/INR testing performed on 12/27/2023 (e) Patient #29446 - PT/INR testing performed on 01/04/2024 (f) Patient #233116 - PT/INR testing performed on 01/10/2024 (g) Patient #23122 - PT/INR testing performed on 01/11/2024 (h) Patient #234059 - PT/INR testing performed on 01/12/2024 (i) Patient #59566 - PT/INR testing performed on 01/15/2024 (j) Patient #686892934 - PT/INR testing performed on 04/01/2024 (k) Patient #687027642 - PT/INR testing performed on 04/03/2024 (l) Patient #687125500 - PT/INR testing performed on 04/05/2024 (m) Patient #687646908 - PT/INR testing performed on 04/17/2024 (n) Patient #687856347 - PT/INR testing performed on 04/22/2024 (o) Patient #688012787 - PT/INR testing performed on 04/25/2024 (p) Patient #688146532 - PT/INR testing performed on 04/29/2024 (q) Patient #688196591 - PT/INR testing performed on 04/30/2024 (r) Patient #692148000 - PT/INR testing performed on 08/01/2024 (s) Patient #692253666 - PT/INR testing performed on 08/04/2024 (t) Patient #692290980 - PT/INR and PTT testing performed on 08/05/2024 (u) Patient #692455127 - PT/INR and PTT testing performed on 08/08/2024 (v) Patient #692532783 - PT/INR and PTT testing performed on 08/10/2024 (w) Patient #692561781 - PT/INR and PTT testing performed on 08/12/2024 (x) Patient #692630138 - PT/INR and PTT testing performed on 08/13/2024 (y) Patient #692784648 - PT/INR testing performed on 08/16/2024 (z) Patient #692837824 - PT/INR and PTT testing performed on 08/18/2024 (aa) Patient #692861231 - PT/INR and PTT testing performed on 08/19/2024 (bb) Patient #692939323 - PT/INR and PTT testing performed on 08/20/2024
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 manufacturer's instructions, observation, and interview with the lead technologist, the laboratory failed to ensure Alcor Seditrol control materials had not exceeded the room temperature expiration date for one of two vials of QC (quality control) materials observed. Findings include: (1) On 08/21/2024 at 10:30 am, the lead technologist stated the following: (a) The laboratory began using the miniiSED Automated Erythrocyte Sedimentation Rate analyzer for patient testing on 09/28 /2023; (b) Alcor Seditrol Erythrocyte Sedimentation Rate QC materials (normal level 1 and abnormal level 2) were performed each day of patient testing. (2) Observation of the laboratory on 08/21/2024 at 11:20 am identified two vials of Seditrol QC materials in use, one of which had not been dated (Normal Level 1 lot #C142); (3) Review of the manufacturer's package insert for the QC materials under the heading "Storage & Stability" stated, "Once opened, product is stable for 60 days at room temperature (18 to 30 degrees C) when tightly capped and used with ALCOR ESR Analyzers only)"; (4) The findings were discussed with the lead technologist who stated on 08/21/2024 at 11:25 am, the QC vial had not been dated with the 60 day open vial expiration date.
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 the lead technologist, the laboratory failed to utilize the demonstrated reportable range; and failed to ensure the performance specification data had been evaluated prior to implementing the new test system for one of two new test methods introduced into the laboratory in September 2023. Findings include: (1) On 08/21/2024 at 10:30 am, the lead technologist stated the laboratory began using the miniiSED Automated ESR (Erythrocyte Sedimentation Rate) analyzer for patient testing on 09/28/2023; (2) A review of the performance specification records for the analyzer identified the following: (a) The laboratory had demonstrated a reportable range of 1-83 mm/hr; (b) No evidence the data had been signed and dated as approved by the laboratory prior to putting into use for patient testing. (3) Interview with the lead technologist on 08/21/2024 at 11:10 am confirmed the following: (a) The laboratory was using the manufacturer's reportable range of 1-130 mm/hr instead of the reportable range that had been demonstrated by the laboratory; (b) There was no documentation to prove the performance specification data had been reviewed and approved by the laboratory prior to putting into use. (4) Examples of patient ESR testing performed when the performance specification data had not been approved and examples of patient results reported beyond the reportable range that had been demonstrated by the laboratory were as follows: (a) Patient #679052569 - testing performed on 10/02/2023 (b) Patient #679692953 - testing performed on 10/17/2023 (c) Patient 680967788 - testing performed on 11/15/2023 (d) Patient #681297444 - 85 reported on 11/22/2023 (e) Patient #683433558 - 107 reported on 01/12/2024 (f) Patient #686923679 - testing performed on 04/01/2024 (g) Patient #68735859 - testing performed on 04/22/2024 (h) Patient #688763870 -

	testing performed on 05/13/2024 (i) Patient #688889520 - testing performed on 05/15 /2024 (j) Patient #689926603 - testing performed on 06/10/2024 (k) Patient #690521552 - testing performed on 06/24/2024 (l) Patient #691083262 - testing performed on 07/08/2024 (m) Patient #691383253 - testing performed on 07/15/2024 (n) Patient #691749229 - 96 reported on 07/22/2024 47979 Based on a review of records and interview with the laboratory director and lead technologist, the laboratory failed to demonstrate the performance specifications for two of two new test methods. Findings include: (1) On 08/20/2024 at 01:00 pm, the lead technologist stated the following test kits were put into use for patient testing in March 2023: (a) Cardinal Health hCG Combo Pregnancy Test Cassette using serum samples; (b) Sekisui Osom Mononucleosis test using serum or plasma samples. (2) A review of records for the test kits identified no evidence the performance specifications (accuracy, precision, etc, as applicable for the test systems) had been demonstrated; (3) Interview with the lead technologist on 08/21/2024 at 11:20 am confirmed the performance specifications, as applicable, had not been demonstrated prior to putting the test kits into use for patient testing.
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 a review of records and interview with the lead technologist, the laboratory failed to perform calibration verification procedures at least once every 6 months for six of six analytes reviewed using the Abbott Alinity analyzer during the review period of January 2023 through the current date in 2024. Findings include: (1) On 08 /21/2024 at 01:00 pm, the lead technologist stated the laboratory used the Abbott Alinity analyzer to perform patient Chemistry and Toxicology testing to include the analytes Alcohol, ALT (Alanine Aminotransferase), Ammonia, Chloride, Potassium, and Sodium; (2) A review of calibration records for 2024 identified the calibration procedures for the above analytes were performed with less than three levels of calibrators therefore, calibration verification procedures, using three or more levels of calibration materials that included a low, mid, and high value, were required every six

	months; (3) A review of records from January 2023 through the current date identified calibration verification had not been performed at least once every six months as follows: (a) Alcohol - Not performed prior to 08/08/2024 (b) ALT - Not performed prior to 08/06/2024 (c) Ammonia - Not performed prior to 08/08/2024 (d) Chloride - Not performed prior to 08/08/2024 (e) Potassium - Not performed prior to 08/08/2024 (f) Sodium - Not performed prior to 08/08/2024 (4) The records were reviewed with the lead technologist who stated on 08/21/2024 at 03:10 pm, calibration verification procedures had not been performed every six months; (5) The following were examples of patient testing performed when calibration verification procedures had not been performed (*CMP - Complete Metabolic Panel includes the analytes ALT, Chloride, Potassium and Sodium): (a) Patient #20666 - CMP testing performed on 01 /03/2023 (b) Patient #238836 - Alcohol testing performed on 01/04/2023 (c) Patient #238909 - Ammonia testing performed on 01/11/2023 (d) Patient #238932 - CMP testing performed on 01/15/2023 (e) Patient #228715 - CMP testing performed on 05 /01/2023 (f) Patient #240039 - Alcohol testing performed on 05/04/2023 (g) Patient #218972 - Ammonia testing performed on 05/08/2023 (h) Patient #219424 - CMP testing performed on 05/10/2023 (i) Patient #31395 - Alcohol and Ammonia testing performed on 05/11/2023 (j) Patient #57655 - CMP testing performed on 05/15/2023 (k) Patient #28919 - CMP testing performed on 10/02/2023 (l) Patient #241803 Ammonia testing performed on 10/06/2023 (m) Patient #67115 - CMP testing performed on 10/09/2023 (n) Patient #241838 - Alcohol testing performed on 10/10 /2023 (o) Patient #236156 - Ammonia testing performed on 10/10/2023 (p) Patient #227055 - Alcohol and CMP testing performed on 10/15/2023 (q) Patient #32760 - Alcohol and CMP testing performed on 12/31/2023 (r) Patient #52121 - Ammonia testing performed on 01/02/2024 (s) Patient #207918 - CMP testing performed on 01 /03/2024 (t) Patient #242853 - Alcohol testing performed on 01/05/2024 (u) Patient #242412 - CMP testing performed on 01/10/2024 (v) Patient #242728 - Alcohol, Ammonia, and CMP testing performed on 01/11/2024 (w) Patient #232205 - CMP testing performed on 01/15/2024 (x) Patient #21406 - Alcohol testing performed on 01 /15/2024 (y) Patient #907241230019 - CMP testing performed on 05/02/2024 (z) Patient #907241290027 - Ammonia testing performed on 05/08/2024 (aa) Patient #907241290092 - CMP testing performed on 05/08/2024 (bb) Patient #907241300060 - Ammonia testing performed on 05/09/2024 (cc) Patient #907241340079 - Alcohol and Ammonia testing performed on 05/13/2024 (dd) Patient #907241350075 - CMP testing performed on 05/14/2024 (ee) Patient #907241390008 - CMP testing performed on 05/18/2024 (ff) Patient #907241420016 - CMP testing performed on 05 /21/2024 (gg) Patient #907241430038 - CMP and Ammonia testing performed on 05 /22/2024 (hh) Patient #907241440080 - CMP and Alcohol testing performed on 05/23 /2024 (ii) Patient #907241850066 - CMP and Ammonia testing performed on 07/03 /2024 (jj) Patient #907241860032 - CMP and Ammonia testing performed on 07/05 /2024 (kk) Patient #907241920024 - CMP and Ammonia testing performed on 07/10 /2024 (ll) Patient #907242010045 - Alcohol, Ammonia, and CMP testing performed on 07/19/2024 (mm) Patient #907242040052 - CMP testing performed on 07/22/2024 (nn) Patient #907242070060 - CMP testing performed on 07/25/2024 (oo) Patient #907242110110 - CMP testing performed on 07/29/2024 (pp) Patient #907242130056 - CMP testing performed on 07/31/2024
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 the laboratory director and lead technologist, the laboratory failed to perform negative and positive control materials 67 of 75 days of patient Urine Drug Screen testing during the review period of August and October 2023, February and July 2024; failed to perform negative and positive control materials 5 of 22 days of patient Ketone testing during the review period of March 2023 through August 2024; failed to perform negative and positive control materials 15 of 22 days of patient Mononucleosis testing during the review period of February 2023 through August 2024; and failed to perform negative and positive control materials 20 of 81 days of patient Qualitative Serum Pregnancy testing during the period of September and November 2023, and January through July 2024.
Findings include: URINE DRUG SCREEN (1) On 08/20/2024 at 09:20 am, the laboratory director and lead technologist stated the laboratory performed Urine Drug Screen testing for the detection of Amphetamine, Barbiturates, Benzodiazepine, Buprenorphine, Cocaine, Ecstasy, Methadone, Methamphetamine using the Bio-Rad TOX/See urine drug screen test; (2) A review of QC (Quality Control) and patient testing records for testing performed from August and October 2023, February and July 2024 identified negative and positive QC materials had not been performed each day of patient testing for 67 of 75 days; (3) The records were reviewed with the lead technologist who stated on 08/21/2024 at 01:30 pm, QC materials had not been performed each day of patient testing; (4) The following were examples of patient testing performed: (a) Patient # 676897203 - testing performed on 08/13/2023 (b) Patient # 676925364 - testing performed on 08/14/2023 (c) Patient # 676971963 - testing performed on 08/15/2023 (d) Patient # 677283422 - testing performed on 08/22 /2023 (e) Patient # 677550613 - testing performed on 08/28/2023 (f) Patient # 679365655 - testing performed on 10/09/2023 (g) Patient # 679616358 - testing performed on 10/15/2023 (h) Patient # 679881034 - testing performed on 10/21/2023 (i) Patient # 680179543 - testing performed on 10/27/2023 (j) Patient # 684429260 - testing performed on 02/05/2024 (k) Patient # 684627536 - testing performed on 02/08 /2024 (l) Patient # 684970031 - testing performed on 02/16/2024 (m) Patient # 685455539 - testing performed on 02/27/2024 (n) Patient # 690869616 - testing performed on 07/02/2024 (o) Patient # 691054719 - testing performed on 07/07/2024 (p) Patient # 691400024 - testing performed on 07/16/2024 (q) Patient # 691608592 - testing performed on 07/19/2024 (r) Patient # 691835881 - testing performed on 07/25 /2024 KETONE (1) On 08/20/2024 at 09:20 am, the laboratory director and lead technologist stated the laboratory performed Ketone testing using the Germaine Laboratories Aimtab Ketone tablets and serum or plasma samples; (2) A review of QC and patient testing records for testing performed from March 2023 through August 2024 identified negative and positive QC materials had not been performed each day of patient testing for five of 22 days; (3) The records were reviewed with the lead technologist who stated on 08/21/2024 at 11:25 am, QC materials had not been performed each day of patient testing; (4) The following were examples of patient testing performed: (a) Patient # 681418739 - testing performed on 10/27/2023 (b) Patient # 681976448 - testing performed on 12/08/2023 (c) Patient # 682191172 - testing performed on 12/13/2023 (d) Patient # 686536976 - testing performed on 03/22 /2024 (e) Patient # 688317594 - testing performed on 05/02/2024 MONONUCLEOSIS (1) On 08/20/2024 at 09:20 am, the laboratory director and lead technologist stated the laboratory performed Mononucleosis on serum or plasma samples; (2) A review of QC and patient testing records for testing performed from

	February 2023 through August 2024 identified negative and positive QC materials had not been performed each day of patient testing for 15 of 22 days; (3) The records were reviewed with the lead technologist who stated on 08/21/2024 at 11:25 am, QC materials had not been performed each day of patient testing; (4) The following were examples of patient testing performed: (a) Patient # 669477939 - testing performed on 02/20/2023 (b) Patient # 672357906 - testing performed on 04/27/2023 (c) Patient # 676067613 - testing performed on 07/24/2023 (d) Patient # 676249407 - testing performed on 07/28/2023 (e) Patient # 676931118 - testing performed on 08/14/2023 (f) Patient # 684148233 - testing performed on 01/29/2024 (g) Patient # 684184973 - testing performed on 01/30/2024 (h) Patient # 685146015 - testing performed on 02/20 /2024 (i) Patient # 688306424 - testing performed on 05/02/2024 (j) Patient # 688960094 - testing performed on 05/17/2024 (k) Patient # 690699889- testing performed on 06/27/2024 (l) Patient # 692906413 - testing performed on 08/19/2024 QUALITATIVE SERUM PREGNANCY (1) On 08/20/2024 at 09:25 am, the laboratory director and lead technologist stated the laboratory performed Qualitative Serum Pregnancy testing using the Cardinal Health Combo Cassette on serum samples; (2) A review of QC and patient testing records for testing performed on September and November 2023, and January through July 2024 identified negative and positive QC materials had not been performed each day of patient testing for 20 of 81 days; (3) The records were reviewed with the lead technologist who stated on 08 /21/2024 at 01:30 pm, QC materials had not been performed each day of patient testing; (4) The following were examples of patient testing performed: (a) Patient # 678088669 - testing performed on 09/10/2023 (b) Patient # 680821109 - testing performed on 11/12/2023 (c) Patient # 680871813 - testing performed on 11/13/2023 (d) Patient # 681136490 - testing performed on 11/15/2023 (e) Patient # 681144597 - testing performed on 11/19/2023 (f) Patient # 684402580 - testing performed on 02/04 /2024 (g) Patient # 685336405 - testing performed on 02/25/2024 (h) Patient # 685781994 - testing performed on 03/06/2024 (i) Patient # 686592443 - testing performed on 03/25/2024 (j) Patient # 687814263 - testing performed on 04/21/2024 (k) Patient # 687969639 - testing performed on 04/24/2024 (l) Patient # 688119794 - testing performed on 04/28/2024 (m) Patient # 689146184 - testing performed on 05 /21/2024 (n) Patient # 689319562 - testing performed on 05/25/2024 (o) Patient # 689870223 - testing performed on 06/07/2024 (p) Patient # 689889035 - testing performed on 06/08/2024 (q) Patient # 689907374 - testing performed on 06/09/2024 (r) Patient # 690903274 - testing performed on 07/02/2024
D5465	CONTROL PROCEDURES CFR(s): 493.1256(d)(8)(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--Test control materials in the same manner as patient specimens. (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 director, the laboratory failed to use control materials of a similar matrix to that of patient specimens 14 of 14 days of patient Serum Ketone testing reviewed from March 2023 through the current date. Findings include: (1) On 08/20/2024 at 04:10 pm, the laboratory director stated the following: (a) Patient Ketone testing was performed using the Germaine Laboratories Aim Tab ketone tablets and Serum samples; (b) QC (Quality Control) testing was performed each day of patient testing using level 1 and level 2 MAS UA

	control Liquid Assayed Urinalysis controls. (2) A review of QC and patient Serum Ketone records from March 2023 through the current date identified that for 14 of 14 days of patient testing reviewed, positive and negative QC testing had been performed using urine control specimens; (3) The findings were reviewed with the laboratory director who stated on 08/20/2024 at 04:25 pm, the laboratory was using urine based controls instead of serum based control materials; (4) The following were patient testing performed: (a) Patient #670906263 - testing performed on 03/22/2023 (b) Patient #671987206 - testing performed on 04/18/2023 (c) Patient #676349049 - testing performed on 07/31/2023 (d) Patient #677600756 - testing performed on 08/29 /2023 (e) Patient #679471059 - testing performed on 10/11/2023 (f) Patient #682536139 - testing performed on 12/21/2023 (g) Patient #685460465 - testing performed on 02/27/2024 (h) Patient #685494480 - testing performed on 02/28/2024 (i) Patient #685854651 - testing performed on 03/07/2024 (j) Patient #686417035 - testing performed on 03/20/2024 (k) Patient #687995772 - testing performed on 04/25 /2024 (l) Patient #691650664 - testing performed on 07/21/2024 (m) Patient #692096248 - testing performed on 07/31/2024 (n) Patient #692880987 - testing performed on 08/19/2024
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, policies and procedures, manufacturer's instructions, observation and interview with the laboratory director and lead technologist, the laboratory failed to monitor and evaluate the overall quality of analytic systems and correct identified problems for each specialty and subspecialty of testing performed during the review period of January 2023 through the current date. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment because of the following issues identified during the survey: (a) The laboratory failed to have step-by-step written procedures for one of four procedures reviewed. Refer to D5403; (b) The laboratory failed to follow the manufacturer's instructions for implementing two of four coagulation reagents; and ensure the mean of the normal reference interval was accurately entered into the analyzer for one of one PT reagent lot change. Refer to D5411; (c) The laboratory failed to ensure Alcor Seditrol control materials had not exceeded the room temperature expiration date. Refer to D5417; (d) The laboratory failed to utilize the demonstrated reportable range; and failed to ensure the performance specification data had been evaluated prior to implementing a new test system. Refer to D5421; (e) The laboratory failed to demonstrate the performance specifications for two of two new test methods. Refer to D5421; (f) The laboratory failed to perform calibration verification procedures at least once every 6 months for six of six analytes reviewed using the Abbott Alinity analyzer. Refer to D5439; (g) The laboratory failed to perform negative and positive control materials each day of patient Urine Drug Screen, Ketone, Mononucleosis, and Qualitative Serum Pregnancy testing. Refer to D5449; (h) The laboratory failed to use control materials of a similar matrix to that of patient specimens 14 of 14 days of patient Serum Ketone testing reviewed. Refer to D5465.

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, policies and procedures, manufacturer's instructions, observation and interview with the laboratory director and lead technologist, the laboraory director failed to provide overall management and direction during the review period of January 2023 through the current date. Findings include: (1) The laboratory director failed to ensure verification procedures for new test systems were adequate to determine the performance characteristics. Refer to D6013; (2) The laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results. Refer to D6014; (3) The laboratory director failed to ensure enrollment and participation in a proficiency testing program. Refer to D6015; (4) The laboratory director failed to ensure proficiency testing reports were reviewed to evaluate the laboratory's performance and to identify any problems that require corrective action. Refer to D6018; (5) The laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services during the review period of January 2023 through the current date. Refer to D6020; (6) The laboratory director failed to ensure a quality assessment program had been established and maintained. Refer to D6021; (7) The laboratory director failed to ensure an approved procedure manual was available and followed by all personnel responsible for the testing process. Refer to D6031.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director and lead technologist, the laboratory director failed to ensure verification procedures for new test systems were adequate to determine the performance characteristics. Findings include: (1) The laboratory director failed to ensure the demonstrated reportable ranges had been utilized; and failed to ensure the performance specification data had been evaluated prior to implementing the new test system for one of two new test methods introduced into the laboratory in September 2023. Refer to D5421; (2) The laboratory director failed to ensure the performance specifications had been demonstrated for two of two new test methods. Refer to D5421.
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, observation, and interview with the laboratory director and lead technologist the laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results. Findings include: (1) The laboratory director failed to ensure the manufacturer's instructions were followed for implementing two of four coagulation reagents; and ensure the mean of the normal reference interval was accurately entered into the analyzer for one of one PT reagent lot change. Refer to D5411; (2) The laboratory director failed to ensure Alcor Seditrol control materials had not exceeded the room temperature expiration date for one of two vials of QC (quality control) materials observed. Refer to D5417.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director and lead technologist, the laboratory director failed to ensure enrollment and participation in a proficiency testing program. Findings include: (1) The laboratory director failed to ensure enrollment in a proficiency testing program for Qualitative Serum Pregnancy, Mononucleosis, and Rheumatoid Factor testing. Refer to D2000.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, the laboratory

	director failed to ensure proficiency testing reports were reviewed to evaluate the laboratory's performance and to identify any problems that require corrective action. Findings include: (1) The laboratory failed to review and evaluate proficiency testing results for one of four Hematology Proficiency testing events. Refer to D5211.
D6020	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 the quality control program is 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 and interview with the laboratory director and lead technologist, the laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services during the review period of January 2023 through the current date. Findings include: (1) The laboratory director failed to ensure the accuracy had been verified for five of five analytes at least twice annually. Refer to D5217; (2) The laboratory director failed to ensure calibration verification procedures had been performed at least once every 6 months for six of six analytes reviewed using the Abbott Alinity analyzer. Refer to D5439; (3) The laboratory director failed to ensure negative and positive contol materials had been performed each day of patient Urine Drug Screen, Ketone, Mononucleosis, and Qualitative Serum Pregnancy testing performed. Refer to D5449; (4) The laboratory director failed to ensure control materials of a similar matrix to that of patient specimens had been used 14 of 14 days of patient Serum Ketone testing reviewed. Refer to D5465.
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, policies and procedures, manufacturer's instructions, observation and interview with the laboratory director and lead technologist, the laboratory director failed to ensure a quality assessment program had been established and maintained during the review period of January 2023 through the current date. Findings include: (1) The laboratory director failed to ensure the laboratory had an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(13) 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)(13) 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 a review of records, written policies and procedures, and interview with the laboratory director and lead technologist, the laboratory director failed to ensure an approved procedure manual was available and followed by all personnel responsible for the testing process. Findings include: (1) The laboratory director failed to ensure the laboratory had a written clinical consultant competency assessment policy, based on the position responsibilities as listed in the Subpart M. Refer to D5209; (2) The laboratory director failed to ensure the laboratory had step-by-step written procedures for Coagulation testing. Refer to D5403.