Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2082858	09/05/2024
Name of Provider or Supplier	**Street Address, City, State**	
South Texas Er At Weslaco	330 W Expressway 83, Weslaco, TX	

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	Based on an announced validation inspection, the laboratory was found NOT to be in compliance with the CLIA regulations found at 42 CFR 493 CLIA requirements. The conditions not met were: D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; D6033 - 42 C.F.R. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant.
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 review of nursing and laboratory's policies and procedures, transfusion records, and interview, the facility failed to follow its policy and procedure for recording vital signs used to identify blood and blood product transfusion reactions for one out of four units reviewed. Findings follow. A. Review of the nursing policy and procedure titled "PC.3500 Administration of Blood and Blood Products," revised 06 /01/2021, under Procedure stated, "...11. Take baseline vitals before starting transfusion and record in Transfusion Record. After blood has started infusing, stay with the patient for at least 15 minutes to check for a transfusion reaction. Repeat vital signs at 15 minutes and at one hour after the start of transfusion, and then at the end of the transfusion. Document all vitals in the Transfusion Record...." The policy does not define what constitutes a vital sign. B. Review of the Emergency Blood Release Forms showed 4 units were transfused from March 2023 - June 2024. C. One transfusion was missing vital signs: 1. Medical Record Number (MR#) 5266288 Unit # W140923041288 packed red blood cells Started 12/09/2023 at 0431 Transferred 12

	/09/2023 at 0459 Vitals taken at: 0429 (prior), 0506 (35 minute) Per policy, missing 15-minute vital signs D. Interview with Technical Supervisor #1 (as listed on the CMS form 209) on September 4, 2024 at 1650 hours confirmed the findings.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: I. Based on review of manufacturer's instructions, quality control (QC) records, and interview, the laboratory failed to retain the Complete Blood Count (CBC) monthly QC reports from the Sysmex XS-1000i for two of two years reviewed. Findings follow. A. Review of the Sysmex XS-1000i Instructions for Use manual, 06/2013, under Chapter 6 Operation at 6.8 QC stated, "Quality control assures the reliability of the instrument and reagents system. Quality control allows log-term monitoring of the stability of analysis value. It can also identify problems at an earlier stage and prevent them... Quality control is analyzed using x-bar Control or the L-J Control program. The data is saved in the quality control file...." At Chapter 7 Quality Control under 15. QC Chart Screen stated, "The QC Chart screen shows the chart for the QC file selected on the QC File screen. One QC file can record and display up to 300 plots. If more are displayed, the excess points are automatically deleted, starting with the oldest.... Sysmex Insight Important! The Sysmex Insight screen is only intended for downloading QC data that will be sent to the Interlaboratory Quality Assurance Program. This program should not be used by the laboratory as a method to backup QC for their own records...." B. Review of the Sysmex XS-1000i quality control records showed the QC from the analyzer was not printed and retained. The laboratory retained the Insight reports, Insight reports did not show what analyte was out of range and the value, along with the QC ranges used to evaluate the QC runs. C. Surveyor requested QC records from the analyzer for March 2024 - June 2024 on September 3, 2024 at 1630 hours. No documentation was provided. D. Interview with Technical Consultant #1 (as listed on the CMS form 209), on September 3, 2024 at 1605 hours confirmed the findings, and confirmed they didn't retain the QC reports for the last two years. Continued interview at 1645 hours confirmed she was unable to access the QC files from March 2024 - June 2024 because the new QC files replaced the old files. II. Based on review of the laboratory's QC records, and interview, the laboratory failed to retain the control package inserts for the Radiometer Qualicheck 5+ lots in use for two of two years reviewed. Findings follow. A. The Radiometer Qualicheck 5+ control package inserts were requested on September 4, 2024 at 1520 hours but not provided. B. Interview with Technical Consultant #1 on September 4, 2024 at 1520 hours stated they did not keep prior package inserts, just for the current lot in use, for all platforms. III. Based on review of the laboratory's QC records, and interview, the laboratory failed to retain the control package inserts for the Immunoassay Plus Control lots in use for two of two years reviewed. Findings follow. A. The Immunoassay Plus Control package insert for Lot 85320 was requested on September 5, 2024 at 1215 hours but not provided. B. Interview with Technical Consultant #1 on September 5, 2024 at 1215 hours confirmed the package insert was not retained.
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 review of manufacturer instructions, quality control (QC) records, LIS report, interview, and pre-survey paperwork, the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems in Chemistry for two of two years. Findings follow. 1. The laboratory failed to have control procedures that detected immediate errors for Alanine Transaminase (ALT), Amylase (Amy), Aspartate Transaminase (AST), Chloride (Cl), Cholesterol (Chol), Creatine Kinase (CK), Iron (Fe), Phosphorus (Phos), Potassium (K), Sodium (Na), Blood Urea Nitrogen (BUN), and Uric Acid (UA) (refer to D5441). KEY: LIS = Laboratory Information System
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedure, quality control (QC) records, LIS report, presurvey paperwork, and interview, the laboratory failed to follow its own procedures for evaluating QC on the Siemens Sysmex CA 600 series for activated Partial Thromboplastin Time (APTT) for three out of three out of range values obtained from March 2024. Findings follow. A. Review of the laboratory's policy and procedure titled Lab.8545 Quality Control Program for Coagulation, revised 12/01 /2017, under Policy, stated, "4. At least 2 levels of control must be run on a daily basis. In Coagulation Section, ensure reliability and accuracy of testing process. 5. Document the results of the controls for each test and corrective action taken if the controls are out of tolerance. If patient results were from a test run that contained unacceptable QC results, the entire run must be repeated and be re-evaluated to determine if there is a clinical difference in the laboratory results. Document all the proceedings in either the collection comments or on the constituents' test report line..." Under Quality Control stated, "Procedural steps for Out of QC Range Results: Document all control values in the LIS even though the patient results have been rejected. Reconstitute new quality control material, repeat all constituents that are out of the control range (values exceed +/- 2 SD). If the repeated controls are within +/- 2 SD, patient results may be reported. If controls fail again, further investigation is necessary prior to releasing any patient results. Run assayed control; check instrument maintenance log for any trends or systemic problems. Call Technical Service for assistance and troubleshoot as necessary." B. Review of the laboratory's policy and procedure titled Lab.3028 Ci-Trol Coagulation Controls, Levels I and III, Performing

	QC and Troubleshooting, revised 06/01/2021, under Corrective Action stated, "If the control results are out 2 SD, the results will display on computer screen and will prompt the technologist to take action. Corrective action must be taken and documented as outlined below. All outliers can be categorized as systematic error is as random error. One random outlier is possible in 20 determinations since 2 SD is used in the acceptable tolerance limits. When this happens, the control specimen should be repeated 'alone'. If repeat is within range, the results may be accepted... After identifying the problem, correct it, rerun ALL the patients and controls. If the controls are back within tolerance limits, report the patient results..." C. Review of the quality control records titled Levey Jennings Chart from March 2024 revealed out of range QC values were accepted for Citrol 3 for APTT with the following comment: Test Date and Time/Result/Acceptable Range/ Comment 1. 03/02/2024 @ 15:01/56.10/56. 41 - 60.88/ within peer range 2. 03/11/2024 @ 22:34/55.90/56.41 - 60.88/ within peer range D. Review of a LIS report to identify patient testing titled Activity Report showed the following patients were reported: Date of service Accession # 1. 03/02 /2024 @2032 26-24-062-1783 2. 03/02/2024 @1602 26-24-062-1300 3. 03/02/2024 @1817 26-24-062-1531 4. 03/11/2024 @2252 26-24-071-2168 5. 03/11/2024 @0111 26-24-072-0197 E. Review of the presurvey paperwork titled Annual Test Volume & Proficiency Testing Programs Worksheet showed an annual test volume of 3,500 for PT and APTT. F. Interview with Technical Consultant #1 on September 4, 2024 at 1155 hours confirmed the laboratory did not follow procedure. KEY: LIS = Laboratory Information System
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and interview, the laboratory failed to identify signs and symptoms of a suspected transfusion reaction in a policy and procedure for two of two years reviewed. Findings follow. A. Review of the laboratory policy and procedure titled Lab.8721 Emergency Release Blood under III: Transfusion Reaction: stated "In the event of a suspected transfusion reaction, the Laboratory will call the pathologist immediately and give all symptoms and vitals information, and await any instructions as to further testing needed, or treatment of

	patient. Laboratory will obtain: 1. the blood unit bag, with all associated tubing in a biohazard bag 2. the labeled tube with the 2 segments pulled from unit 3. a post-transfusion specimen, properly labeled with patient information and 'POST' written on the label. 4. a post-transfusion urine specimen 5. all vitals and reactions observed during transfusion 6. pre-transfusion specimen (purple top used for CBC) and label as 'PRE' 7. a copy of the Emergency Release Form with all information completed Send all items STAT to the hospital where the patient is to be transferred. Call respective Blood Bank to let them know of incoming specimens". Review of the policy and procedure did not contain the signs and symptoms of a suspected transfusion reaction. B. Interview with Technical Supervisor #1 on September 4, 2024 at 1225 hours acknowledged the laboratory did not have a policy and procedure for suspected transfusion reactions.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory's policy and procedure, MNPT (Mean Normal Pro-Thrombin Time) study, presurvey paperwork, and interview, the laboratory failed to screen patients for the MNPT study for one of one study reviewed. Findings follow. A. Review of the Siemens Healthcare Diagnostics Sysmex CA-600 System Installation Package Rev 1.2 under Reference Interval, Verification of Reference Interval under Requirements stated, "Donors must be a healthy population (no known pathological condition, no pre-surgical or hospitalized patients) Donors should not take any medications, including aspirin. A minimum of 20 donors with a reasonably even distribution of males and females should be included. Donors should span the adult age range. (NOTE: A separate range should be established for pediatric populations) ..." B. Review of the laboratory's policy and procedure titled Lab.8548 Verification of Reference Ranges, revised 12/01/2017, under Policy stated, "Reference ranges should be established for each test that the laboratory will perform. It is important when establishing reference intervals that the donors are screened carefully utilizing the following guidelines: A minimum 20 normal samples, 10 males and 10 females should be used. A greater number may increase the reliability of the reference interval. The donors should be healthy and have no known pathological conditions. The donors should be on no medication. This includes oral contraceptive and estrogen therapy. The donors should span the adult age range. For pediatric patients, pediatric ranges should be established separately. The study should include a fairly even number of males and females..." C. Review of the Geometric Mean MNPT study of 03/06/2023 titled New Lot Innovin and Actin Verification of Reference Range did not indicate whether there was an equal number of males and females, that they were healthy and not taking medications, including aspirin, or their ages. D. Review of the presurvey paperwork titled Annual Test Volume & Proficiency Testing Programs Worksheet showed an annual test volume of 3,500 for PT and APTT. E. Interview with the Technical Consultant (as listed on the CMS form 209) on September 4, 2024 at 1030 hours confirmed they did not use a questionnaire or have any documentation that donors were screened for the establishment of the MNPT.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on review of manufacturer's instructions, humidity charts, LIS report, and interview, the laboratory failed to monitor the humidity within the Radiometer ABL80 FLEX manufacturer's specifications for performing Blood Gas testing for 59 of 61 days reviewed. Findings follow. A. Review of the Radiometer ABL80 FLEX Reference Manual on Chapter 6. Performance Characteristics at Experimental conditions stated, "Relative humidity 30 -50 %". B. Review of the laboratory's Room Temperature and Humidity Log Sheet had an acceptable humidity for the Core Lab of 30-80%. Review of logs from May 2024 - June 2024 showed the laboratory exceeded the manufacturer's range on 59 of 61 days reviewed. Date % Humidity 1. 05/03/2024 53 2. 05/04/2024 56 3. 05/05/2024 56 4. 05/06/2024 55 5. 05/07/2024 54 6. 05/08 /2024 56 7. 05/09/2024 52 8. 05/10/2024 56 9. 05/11/2024 59 10. 05/12/2024 54 11. 05/13/2024 55 12. 05/14/2024 55 13. 05/15/2024 56 14. 05/16/2024 55 15. 05/17 /2024 53 16. 05/18/2024 56 17. 05/19/2024 57 18. 05/20/2024 54 19. 05/21/2024 68 20. 05/22/2024 54 21. 05/23/2024 54 22. 05/24/2024 54 23. 05/25/2024 55 24. 05/26 /2024 57 25. 05/27/2024 58 26. 05/28/2024 56 27. 05/29/2024 53 28. 05/30/2024 53 29. 05/31/2024 52 30. 06/01/2024 53 31. 06/02/2024 54 32. 06/03/2024 54 33. 06/04 /2024 54 34. 06/05/2024 52 35. 06/06/2024 53 36. 06/07/2024 53 37. 06/08/2024 56 38. 06/09/2024 54 39. 06/10/2024 51 40. 06/11/2024 52 41. 06/12/2024 51 42. 06/13 /2024 54 43. 06/14/2024 54 44. 06/15/2024 53 45. 06/16/2024 53 46. 06/17/2024 52 47. 06/18/2024 53 48. 06/19/2024 52 49. 06/20/2024 53 50. 06/21/2024 56 51. 06/22 /2024 55 52. 06/23/2024 56 53. 06/24/2024 52 54. 06/25/2024 53 55. 06/26/2024 51 56. 06/27/2024 54 57. 06/28/2024 53 58. 06/29/2024 52 59. 06/30/2024 54 C. Review of a LIS report from 05/01/2024 - 06/30/2024 showed patient testing by date: Date of Service Accession # 1. 05/01/2024 26-24-122-2423 2. 05/01/2024 26-24-121-2771 3. 05/02/2024 26-24-123-1760 4. 05/02/2024 26-24-123-0263 5. 05/09/2024 26-24-130-0867 6. 05/14/2024 26-24-135-0828 7. 05/18/2024 26-24-139-1490 8. 05/19/2024 26-24-140-1114 9. 05/19/2024 26-24-140-1075 10. 05/19/2024 26-24-140-1131 11. 05/19 /2024 26-24-140-0819 12. 05/19/2024 26-24-140-1046 13. 05/20/2024 26-24-141-0936 14. 05/20/2024 26-24-141-1534 15. 05/21/2024 26-24-142-1983 16. 05/21/2024 26-24-142-1622 17. 05/21/2024 26-24-142-1892 18. 05/23/2024 26-24-144-1002 19. 05/23/2024 26-24-144-1969 20. 05/24/2024 26-24-145-0811 21. 05/25/2024 26-24-146-1776 22. 05/25/2024 26-24-146-1020 23. 05/26/2024 26-24-147-0957 24. 05/26 /2024 26-24-147-1704 25. 05/28/2024 26-24-149-1757 26. 05/29/2024 26-24-150-2038 27. 05/30/2024 26-24-151-1440 28. 05/31/2024 26-24-152-0209 29. 06/01/2024 26-24-153-1795 30. 06/03/2024 26-24-155-2360 31. 06/06/2024 26-24-157-2189 32. 06/07/2024 26-24-159-1838 33. 06/07/2024 26-24-159-1044 34.06/07/2024 26-24-159-1607 35. 06/10/2024 26-24-162-0800 36. 06/11/2024 26-24-163-2017 37. 06/15 /2024 26-24-167-1000 38. 06/15/2024 26-24-167-0245 39. 06/18/2024 26-24-170-1436 40. 06/19/2024 26-24-171-1639 41. 06/20/2024 26-24-172-0797 42. 06/20/2024 26-24-172-1381 43. 06/21/2024 26-24-173-1813 44. 06/21/2024 26-24-173-1801 45.

	06/21/2024 26-24-173-1976 46. 06/21/2024 26-24-173-1147 47. 06/21/2024 26-24-173-1980 48. 06/22/2024 26-24-174-1643 49. 06/25/2024 26-24-177-1397 50. 06/26/2024 26-24-178-2176 51. 06/27/2024 26-24-179-0692 52. 06/27/2024 26-24-179-1931 53. 06/28/2024 26-24-180-0809 54. 06/28/2024 26-24-180-0734 D. Interview with Technical Consultant #1 (as listed on the CMS form 209) on September 4, 2024 at 1540 hours confirmed the findings. KEY: LIS = Laboratory Information System
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: I. Based on review of manufacturer instructions, quality control (QC) records, LIS report, interview, and pre-survey paperwork, the laboratory failed to have control procedures that detected immediate errors for Alanine Transaminase (ALT), Amylase (Amy), Aspartate Transaminase (AST), Chloride (Cl), Cholesterol (Chol), Creatine Kinase (CK), Iron (Fe), Phosphorus (Phos), Potassium (K), Sodium (Na), Blood Urea Nitrogen (BUN), and Uric Acid (UA) when they used 3SD ranges from the package insert as 2SD ranges with the BioRad Liquid Assayed Multiqual controls tested on the Siemens Siemens Dimension EXL for two of two years. Findings follow. A. Review of the BioRad Liquid Assayed Multiqual package insert, 09/2023 5351-00, under Assignment of Values stated, "The mean values and corresponding +/- 3SD ranges in the Assignment of Values Data Charts (available separately) were derived from replicate analyses and are specific for this lot of product." The mean, 1 SD, and 2 SD ranges were calculated from the data chart, Lot 45980: 1. Alanine Transaminase (ALT) in U/L Level 1 29.6 2.7 24.3 - 34.9 Level 3 195 7 181 - 209 2. Amylase (Amy) in U/L Level 1 46.1 1.8 42.5 - 49.7 Level 3 326 8.7 309 - 343 3. Aspartate Transaminase (AST) in U/L Level 1 38.6 2.26 34.0 - 43.2 Level 3 261 7.3 246 - 276 4. Chloride (Cl) in mEq/L Level 1 75.2 1.33 72.5 - 77.9 Level 3 123 1.67 119.7 - 126.3 5. Cholesterol (Chol) in mg/dL Level 1 107 3.33 100.3 - 113.7 Level 3 267 6.67 260.3 - 280.3 6. Creatine Kinase (CK) in U/L Level 1 79.8 3.1 73.6 - 86 Level 3 613 14.3 584 - 642 7. Iron (Fe) in ug/dL Level 1 73.1 2.37 68.36 - 77.84 Level 3 232 5 222 - 242 8. Phosphorus (Phos) in mg/dL Level 1 2.09 0.09 1.91 - 2.27 Level 3 7.85 0.15 7.55 - 8.15 9. Potassium (K) in mEq/L Level 1 2.44 0.043 2.35 - 2.53 Level 3 7.45 0.12 7.21 - 7.69 10. Sodium (Na) in mEq/L Level 1 115 2.33 109.5 - 119.5 Level 3 157 2.67 151.7 - 162.3 11. Blood Urea Nitrogen (BUN) in mg/dL Level 1 15.4 0.83 13.7 - 17.06 Level 3 69.8 2.2 65.4 - 74.2 12. Uric Acid (UA) in mg/dL Level 1 3.37 0.11 3.15 - 3.59 Level 3 9.68 0.31 9.06 - 10.3 B. Review of the QC records from the Levy Jennings Chart from 03/23/2024 - 06/30/2024 showed the 3SD ranges from the package insert were used as 2SD: 1. Alanine Transaminase (ALT) in U/L Level 1 Low Limit 21.6 High Limit 37.6 Level 3 Low Limit 173 High Limit 216 2. Amylase (Amy) in U/L Level 1 Low Limit 40.7 High Limit 51.5 Level 3 Low Limit 300 High

Limit 352 3. Aspartate Transaminase (AST) in U/L Level 1 Low Limit 31.7 High Limit 45.5 Level 3 Low Limit 239 High Limit 283 4. Chloride (Cl) in mEq/L Level 1 Low Limit 71.2 High Limit 79.2 Level 3 Low Limit 118 High Limit 129 5. Cholesterol (Chol) in mg/dL Level 1 Low Limit 95.901 High Limit 117.149 Level 3 Low Limit 248 High Limit 287 6. Creatine Kinase (CK) in U/L Level 1 Low Limit 70.4 High Limit 89.1 Level 3 Low Limit 569 High Limit 656 7. Iron (Fe) in ug/dL Level 1 Low Limit 66.1 High Limit 80.2 Level 3 Low Limit 217 High Limit 247 8. Phosphorus (Phos) in mg/dL Level 1 Low Limit 1.816 High Limit 2.364 Level 3 Low Limit 7.414 High Limit 8.290 9. Potassium (K) in mEq/L Level 1 Low Limit 2.321 High Limit 2.569 Level 3 Low Limit 7.099 High Limit 7.811 10. Sodium (Na) in mEq /L Level 1 Low Limit 107.5 High Limit 122.5 Level 3 Low Limit 149 High Limit 165 11. Blood Urea Nitrogen (BUN) in mg/dL Level 1 Low Limit 12.5 High Limit 17.0 Level 3 Low Limit 64 High Limit 76.8 12. Uric Acid (UA) in mg/dL Level 1 Low Limit 3.04 High Limit 3.7 Level 3 Low Limit 8.791 High Limit 10.599 C. Review of QC records titled Levy Jennings Chart from 03/23/2024 - 04/30/2024 showed QC was outside the 2SD ranges on 33 out of 38 days reviewed for the following analytes on the following dates: Test Date Analyte Result QC Level 1. 03/23/2024@0841 Chol 259 Level 3 03/23/2024@0846 K 7.1 Level 3 03/23/2024@0846 Na 151 Level 3 2. 03 /25/2024@0414 Cl 72 Level 1 3. 03/26/2024@0421 CK 73 Level 1 4. 03/28 /2024@0441 CK 73 Level 1 03/28/2024@0441 Phos 2.3 Level 1 03/28/2024@0441 Iron 221 Level 3 5. 03/29/2024@0428 Cl 119 Level 3 03/29/2024@0428 CK 73 Level 1 03/29/2024@0428 Phos 2.3 Level 1 6. 03/31/2024@0457 CK 73 Level 1 7. 04 /01/2024@0419 CK 73 Level 1 8. 04/02/2024@0426 UA 3.7 Level 1 04/02 /2024@0426 Cl 127 Level 3 04/02/2024@0426 K 7.8 Level 3 9. 04/03/2024@0423 CK 72 Level 1 10. 04/04/2024@0420 CK 72 Level 1 11. 04/05/2024@0444 CK 72 Level 1 12. 04/07/2024@0418 CK 72 Level 1 04/07/2024@0418 ALT 180 Level 3 13. 04/08/2024@0419 CK 73 Level 1 04/08/2024@0419 ALT 180 Level 3 14. 04/09 /2024@0440 CK 73 Level 1 04/09/2024@0434 ALT 180 Level 3 15. 04/11 /2024@0427 ALT 179 Level 3 16. 04/12/2024@0422 CK 73 Level 1 17. 04/13 /2024@0431 CK 72 Level 1 04/13/2024@0434 ALT 179 Level 3 18. 04/15 /2024@0429 CK 73 Level 1 19. 04/16/2024@0423 ALT 176 Level 3 20. 04/17 /2024@0420 CK 73 Level 1 04/17/2024@0433 ALT 178 Level 3 04/17/2024@0433 Chol 281 Level 3 21. 04/18/2024@0447 CK 71 Level 1 04/18/2024@0447 ALT 177 Level 3 22. 04/19/2024@0432 CK 71 Level 1 04/19/2024@0433 ALT 179 Level 3 23. 04/20/2024@0552 Amy 42.0 Level 1 04/20/2024@0417 CK 73 Level 1 04/20 /2024@0552 ALT 174 Level 3 24. 04/21/2024@0420 CK 72 Level 1 04/21 /2024@0420 ALT 180 Level 3 25. 04/22/2024@0435 CK 72 Level 1 04/22 /2024@0435 ALT 178 Level 3 26. 04/23/2024@0419 CK 71 Level 1 04/23 /2024@0432 ALT 177 Level 3 27. 04/24/2024@0447 CK 71 Level 1 04/24 /2024@0438 ALT 177 Level 3 28. 04/25/2024@0435 CK 71 Level 1 04/25 /2024@0444 ALT 178 Level 3 29. 04/26/2024@0426 AST 33.0 Level 1 04/26 /2024@0422 CK 72 Level 1 04/26/2024@0422 ALT 179 Level 3 30. 04/27 /2024@0420 BUN 13.0 Level 1 31. 04/28/2024@0440 ALT 179 Level 3 32. 04/29 /2024@0433 Amy 42.0 Level 1 04/29/2024@0433 CK 72 Level 1 04/29/2024@0440 ALT 179 Level 3 33. 04/30/2024@0436 CK 73 Level 1 04/30/2024@0436 UA 3.7 Level 1 D. Review of a LIS report titled Activity Report showed a selection of random patients reported on the following random dates selected: Test Date & Time Accession # Test/Panel 1. 03/23/2024@1059 26-24-083-0858 BMP 2. 03/23 /2024@1057 26-24-083-0856 BMP 3. 03/23/2024@1131 26-24-083-0881 CMP 4. 03 /23/2024@0870 26-24-083-0870 CMP 5. 03/23/2024@1328 26-24-083-1127 CMP 6. 03/23/2024@1544 26-24-083-1303 CMP 7. 03/23/2024@1336 26-24-083-1129 CMP 8. 03/23/2024@1756 26-24-083-1642 BMP 9. 03/23/2024@1833 26-24-083-1680 CMP 10. 03/23/2024@2114 26-24-083-1965 CMP 11. 03/23/2024@2201 26-24-083-

	2028 CMP 12. 03/23/2024@2206 26-24-083-2028 Lipid Panel 13. 04/02/2024@2330 26-24-093-2530 CMP 14. 04/07/2024@1127 26-24-098-0972 CMP 15. 04/08 /2024@1501 26-24-099-1500 CMP 16. 04/08/2024@1629 26-24-099-1674 CMP 17. 04/12/2024@1725 26-24-103-1518 CK 18. 04/16/2024@0544 26-24-107-0492 CMP 19. 04/16/2024@1103 26-24-107-0955 CMP 20. 04/17/2024@1443 26-24-108-1443 CMP 21. 04/18/2024@1230 26-24-109-0908 CMP 22. 04/18/2024@1247 26-24-109-0849 CMP 23. 04/18/2024@1441 26-24-109-1371 CMP 24. 04/19/2024@1733 26-24-110-1923 CMP 25. 04/19/2024@2135 26-24-110-2359 CMP 26. 04/19/2024@2138 26-24-110-2359 BMP 27. 04/21/2024@1208 26-24-112-0822 CMP 28. 04/21 /2024@2019 26-24-112-1649 CMP 29. 04/22/2024@0057 26-24-113-0134 CMP 30. 04/22/2024@1337 26-24-113-1275 CMP 31. 04/23/2024@0652 26-24-114-0567 CMP 32. 04/23/2024@1849 26-24-114-1915 CMP 33. 04/23/2024@2010 26-24-114-2092 CMP 34. 04/23/2024@2228 26-24-114-2362 CMP 35. 04/24/2024@2257 26-24-115-2411 CMP 36. 04/25/2024@1832 26-24-116-1825 CMP 37. 04/26/2024@0055 26-24-117-0151 CMP 38. 04/26/2024@0213 26-24-117-0199 CMP 39. 04/26 /2024@0213 26-24-117-0199 CK 40. 04/26/2024@1152 26-24-117-1001 CMP 41. 04 /26/2024@1638 26-24-117-1515 CMP 42. 04/26/2024@0231 26-24-117-0229 CMP 43. 04/26/2024@1122 26-24-117-0928 CMP 44. 04/27/2024@1601 26-24-118-1448 CMP 45. 04/27/2024@1622 26-24-118-1421 CMP 46. 04/28/2024@0215 26-24-119-0216 BMP 47. 04/28/2024@1412 26-24-119-1203 CMP 48. 04/29/2024@0022 26-24-119-2223 CMP 49. 04/29/2024@1745 26-24-120-2075 CMP 50. 04/29/2024@1914 26-24-120-2265 CMP E. Interview with Technical Consultant #1 (as listed on the CMS Form 209) on September 5, 2024 at 1010 hours confirmed she used the ranges from the package insert and did not realize they represented 3SD (elapsed time 2 years). F. Review of the presurvey paperwork titled CMS Form 116 showed the laboratory had an estimated annual test volume of 108,000 chemistry tests. KEY: LIS = Laboratory Information System BMP = Basic Metabolic Panel, comprised of: Glucose (Gluc), Na, K, Cl, Carbon dioxide (CO2), BUN, Creatinine (Creat), Calcium (Ca) CMP = Comprehensive Metabolic Panel, comprised of: BMP, Albumin (Alb), TP, Total Bili (T Bili), Alkaline Phosphatase (ALP), AST, ALT Lipid Panel, comprised of: Chol, Triglycerides (Trig), Low Density Lipoprotein (LDL Direct), High Density Lipoprotein (HDL) II. Based on review of the quality control records, and interview, the laboratory failed to monitor accuracy and precision over time using the Radiometer ABL80 FLEX for Blood Gases with the Radiometer Qualicheck 5+ controls for two of two years. Findings follow. A. Review of the quality control records from June 2024 showed accuracy and precision were not monitored over time. Statistical calculations were requested on September 4, 2024 at 1505 hours but not provided. B. Interview with Technical Consultant #1 on September 4, 2024 at 1505 hours confirmed they do not do statistical calculations on their blood gas controls (elapsed time: 2 years) because the analyzer does not transmit to their Cerner system, nor do they enter the results manually into the Cerner system.
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 review of manufacturer instructions, textbook procedure, the laboratory's policy and procedure, quality control (QC) records, humidity charts, LIS report,

	interview, and pre-survey paperwork, the Laboratory Director failed to provide technical and scientific oversight of the laboratory for two of two years. Findings follow. 1. The laboratory director failed to monitor and evaluate the overall quality of the analytic systems; and correct problems in testing performed in Chemistry on the Siemens Dimension EXL for two of two years (see D6007). 2. The laboratory director failed to ensure a quality control program was maintained for Chemistry on the Siemens Dimension EXL for two of two years (see D6020). 3. The laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for Blood Gas testing performed (see D6023). KEY: LIS = Laboratory Information System
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on review of manufacturer instructions, quality control (QC) records, LIS report, interview, and pre-survey paperwork, the laboratory director failed to monitor and evaluate the overall quality of the analytic systems; and correct problems in testing performed in Chemistry on the Siemens Dimension EXL for two of two years. Findings follow. 1. The laboratory failed to have control procedures that detected immediate errors for Alanine Transaminase (ALT), Amylase (Amy), Aspartate Transaminase (AST), Chloride (Cl), Cholesterol (Chol), Creatine Kinase (CK), Iron (Fe), Phosphorus (Phos), Potassium (K), Sodium (Na), Blood Urea Nitrogen (BUN), and Uric Acid (UA) when they used 3SD ranges from the package insert as 2SD ranges with the BioRad Liquid Assayed Multiqual controls tested on the Siemens Dimension EXL for two of two years (refer to D5441).
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 review of manufacturer instructions, quality control (QC) records, LIS report, interview, and pre-survey paperwork, the laboratory director failed to ensure a quality control program was maintained for Chemistry on the Siemens Dimension EXL for two of two years. Findings follow. 1. The laboratory failed to ensure a

	quality control program was maintained for Alanine Transaminase (ALT), Amylase (Amy), Aspartate Transaminase (AST), Chloride (Cl), Cholesterol (Chol), Creatine Kinase (CK), Iron (Fe), Phosphorus (Phos), Potassium (K), Sodium (Na), Blood Urea Nitrogen (BUN), and Uric Acid (UA) when they used 3SD ranges from the package insert as 2SD ranges with the BioRad Liquid Assayed Multiqual controls tested on the Siemens Dimension EXL for two of two years (refer to D5441). KEY: LIS = Laboratory Information System
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, humidity charts, query, and interview, the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for Blood Gas testing performed. Findings follow. 1. The laboratory failed to monitor the humidity within the Radiometer ABL80 FLEX manufacturer's specifications for performing Blood Gas testing for 59 of 61 days reviewed (refer to D5413).
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 review of manufacturer instructions, laboratory policy and procedure, quality control (QC) records, LIS report, proficiency testing (PT) records, PT rotation schedule, competency evaluations, interview, and pre-survey paperwork, the Technical Consultant failed to provide the required technical oversight of the laboratory for two of two years reviewed. Findings follow. 1. The technical consultant failed to ensure a quality control program was maintained for Chemistry on the Siemens Dimension EXL for two of two years (refer to D6042). 2. The laboratory failed to follow its own procedures for evaluating QC on the Siemens Sysmex CA 600 series for activated Partial Thromboplastin Time (APTT) for three out of three out of range values obtained from March 2024 (refer to D6043). 3. The technical consultant failed to assess test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples for two out of five testing personnel competencies reviewed for the Complete Blood Counts (CBC) on the Sysmex XS-1000i, Prothrombin Time (PT), activated Partial Thromboplastin Time (APTT), and D-Dimer on the Siemens Sysmex 600 Series, Chemistries,

	Endocrinology, and Urine drug screens on the Siemens Dimension EXL, Wet Preps, microscopic Urinalysis, and Arterial Blood Gases (ABG) on the Radiometer ABL 80 (refer to D6051). KEY: LIS = Laboratory Information System
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on review of manufacturer instructions, quality control (QC) records, LIS report, interview, and pre-survey paperwork, the technical consultant failed to ensure a quality control program was maintained for Chemistry on the Siemens Dimension EXL for two of two years. Findings follow. 1. The laboratory failed to have control procedures that detected immediate errors for Alanine Transaminase (ALT), Amylase (Amy), Aspartate Transaminase (AST), Chloride (Cl), Cholesterol (Chol), Creatine Kinase (CK), Iron (Fe), Phosphorus (Phos), Potassium (K), Sodium (Na), Blood Urea Nitrogen (BUN), and Uric Acid (UA) when they used 3SD ranges from the package insert as 2SD ranges with the BioRad Liquid Assayed Multiqual controls tested on the Siemens Dimension EXL for two of two years (refer to D5441). KEY: LIS = Laboratory Information System
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedure, quality control (QC) records, query, presurvey paperwork, and interview, the laboratory failed to follow its own procedures for evaluating QC on the Siemens Sysmex CA 600 series for activated Partial Thromboplastin Time (APTT) for three out of three out of range values obtained from March 2024 (refer to D5401 II).
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, proficiency testing (PT) records, PT rotation schedule, competency evaluations, and interview, the technical

	consultant failed to assess test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples for two out of five testing personnel competencies reviewed for the Complete Blood Counts (CBC) on the Sysmex XS-1000i, Prothrombin Time (PT), activated Partial Thromboplastin Time (APTT), and D-Dimer on the Siemens Sysmex 600 Series, Chemistries, Endocrinology, and Urine drug screens on the Siemens Dimension EXL, Wet Preps, microscopic Urinalysis, and Arterial Blood Gases (ABG) on the Radiometer ABL 80. Findings follow. A. Review of the laboratory's policy and procedure titled Technical Staff Competency, revised 09/06/2022, under Scope /Application stated, "... All technical staff that perform testing on patient specimens are required to have competency assessment based on the following requirements: ... 5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples... Competency assessment including the six procedures must be performed for each test that the individual is approved to perform by the Laboratory Director..." B. Review of the College of American Pathologists (CAP) PT records attestation statements from the 1st and 2nd events of 2024 showed testing personnel #5 and 6 (as listed on the CMS form 209) did not participate in proficiency testing for the moderately complex testing. C. Review of the PT rotation schedule from 2023 (3 events) revealed six (C- Chemistry, CGL- Coagulation, CAR- Troponin, FH9- CBC, K- TSH, PSA, Serum B-HCG, and UDS- Urine Drug Screens) out of 10 moderately complex testing events was missing testing personnel #5, and 10 (AL2- Alcohol, AQ- Blood gases, C- Chemistry, CM- Clinical Microscopy, CGL- Coagulation, CAR- Troponin, FH9- CBC, K- TSH, PSA, Serum B-HCG, S- CRP, and UDS- Urine Drug Screens) out of 10 moderately complex testing events was missing testing personnel #6. D. Review of the annual competency evaluations from 2022, 2023, and 2024 revealed the form was completed for the criteria "Performs proficiency tests with no deficiencies" for all testing for testing personnel #5 (10/02/2022, 10/02/2023, 03/31/2024) and 6 (08/02 /2022, 08/02/2023, 03/31/2024). E. Interview with Technical Consultant #1 (as listed on the CMS Form 209) on September 3, 2024 at 1420 hours stated external proficiency testing was done with PRNs if they were here, and they did not test performance through previously analyzed specimens or internal blind testing samples for testing personnel #5 and 6 who were also PRNs. KEY: TSH = Thyroid Stimulating Hormone PSA = Prostate Specific Antigen B-HCG = Beta Human Chorionic Gonadotropin CRP = C- Reactive Protein PRN = pro re nata (as needed)
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, proficiency testing (PT) records, PT rotation schedule, competency evaluations, and interview, the technical supervisor failed to assess test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples for two out of five testing personnel competencies reviewed for the manual differential. Findings follow. A. Review of the laboratory's policy and procedure titled Technical Staff Competency, revised 09/06/2022, under Scope/Application stated, "... All technical staff that perform testing on patient specimens are required to have

	competency assessment based on the following requirements: ... 5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples... Competency assessment including the six procedures must be performed for each test that the individual is approved to perform by the Laboratory Director..." B. Review of the College of American Pathologists (CAP) PT records attestation statements from the 1st and 2nd events of 2024 showed testing personnel #5 and 6 (as listed on the CMS form 209) did not participate in proficiency testing for the highly complex testing. C. Review of the PT rotation schedule from 2023 (3 events) revealed one (BCP- manual differential) of one highly complex testing events was missing testing personnel #5 & 6. D. Review of the annual competency evaluations from 2022, 2023, and 2024 revealed the form was completed for the criteria "Performs proficiency tests with no deficiencies" for all testing for testing personnel #5 (10/02/2022, 10/02/2023, 03/31/2024) and 6 (08/02 /2022, 08/02/2023, 03/31/2024). E. Interview with Technical Supervisor #1 (as listed on the CMS Form 209) on September 3, 2024 at 1420 hours stated external proficiency testing was done with PRNs if they were here, and they did not test performance through previously analyzed specimens or internal blind testing samples for testing personnel #5 and 6 who were also PRNs. KEY: PRN = pro re nata (as needed)