Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2189668	01/20/2023
Name of Provider or Supplier	**Street Address, City, State**	
Lillie's Lab Solutions	3901 East Stan Schlueter Loop Suite 103, Killeen, 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	The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D2000 - 42 C.F.R. 493.801 Condition: Enrollment and testing of [proficiency testing] samples; D5016 - 42 C.F.R. 493.1210 Condition: Routine chemistry; D6033 - 42 C.F.R. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant; D6056 - 42 C.F.R. 493.1415 Condition: Laboratories performing moderate complexity testing; clinical consultant; Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference.
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 review of patient testing records, proficiency testing (PT) records, interview, and email, the laboratory failed to enroll in proficiency testing for Sodium, Potassium, Chloride, Carbon Dioxide, Glucose, BUN (Blood Urea Nitrogen), Total Bilirubin, Calcium, Protein, Albumin, ALP, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), Cholesterol, HDL (High-Density Lipoprotein), Triglycerides, Uric Acid, and Magnesium performed on the Alera Alfa-Wasserman for two of two months reviewed. Findings follow. A. Testing records showed the laboratory started

	reporting patient testing on the Alera Alfa-Wasserman on November 1, 2022. B. Proficiency testing records were requested on January 3, 2023, at 11:20 but not provided. C. Interview with testing personnel #1 on January 3, 2023, at 1120 was confused as to what PT was and confirmed they were not enrolled. Phone interview with the Laboratory Director on January 3, 2023, at 1125 acknowledged they should have enrolled in PT, and had discussed this with testing personnel #1 in September. D. Email from testing personnel #1 on January 10, 2023, at 0940 showed 2027 tests had been run from 11/01/22 - 01/03/23.
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: Based on review of quality control (QC) records and interview the laboratory failed to retain all QC activities performed for Sodium, Potassium, Chloride, Carbon Dioxide, Glucose, BUN (Blood Urea Nitrogen), Total Bilirubin, Calcium, Protein, Albumin, ALP, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), Cholesterol, HDL (High-Density Lipoprotein), Triglycerides, Uric Acid, and Magnesium performed on the Alera Alfa-Wasserman for 3 out of 30 days reviewed. Findings follow. A. Review of the QC Requisition Reports from 11/01/22 - 11/18/22 and 12/01/22 - 12/14/22 showed missing QC runs on: Testing Date QC Analytes 1. 11 /07/22 Level 1 Sodium, Potassium, Chloride, Carbon Dioxide, Glucose, BUN, Total Bilirubin, Calcium, Protein, Albumin, ALP, ALT, AST, and Uric Acid 2. 11/11/22 Level 1 Sodium, Potassium, Chloride, Carbon Dioxide, Glucose, BUN, Total Bilirubin, Calcium, Protein, Albumin, and Uric Acid 3. 11/12/22 Level 2 Sodium, Potassium, Chloride, Carbon Dioxide, Glucose, BUN, Total Bilirubin, Calcium, Protein, Albumin, and Uric Acid B. Interview with testing personnel #2, as listed on CMS-209, on January 4, 2023, at 1555 hours confirmed the findings.
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on observation, review of the patient testing records, temperature charts, manufacturer's instructions, verification of performance specification records, QC (Quality Control) records, interview and email, the laboratory failed to meet the applicable requirements in the specialty of Chemistry for two of two months reviewed. 1. The laboratory failed to monitor the refrigerator used to store patient specimens located in the lab with the Alera Alfa-Wasserman for two of two months reviewed from 11/01/2022 - 01/04/2023 (refer to D5413 I). 2. The laboratory failed to monitor the room temperature in the lab for two of two months reviewed from 11/01 /2022 - 01/04/2023 (refer to D5413 II). 3. The laboratory failed to perform accuracy and precision for Sodium, Potassium, Chloride, ALP (Alkaline Phosphatase), Uric

	Acid, and Magnesium on the Alera Alfa-Wasserman for six of 18 chemistry analytes reported in the lab from 11/01/2022 - 01/03/2023 (refer to D5421 I). 4. The laboratory failed to verify the precision obtained for Cholesterol on the Alera Alfa-Wasserman during the verification of performance specifications for 1 of 2 levels measured (refer to D5421 II). 5. The laboratory failed to perform a reportable range study for Sodium, Potassium, Chloride, Carbon Dioxide, Glucose, BUN (Blood Urea Nitrogen), Total Bilirubin, Calcium, Protein, Albumin, ALP, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), Cholesterol, HDL (High-Density Lipoprotein), Triglycerides, Uric Acid, and Magnesium on the Alera Alfa-Wasserman for 18 of 18 chemistry analytes reported in the lab from 11/01/2022 - 01/03/2023 (refer to D5421 III). 6. The laboratory failed to verify the normal reference range for Sodium, Potassium, Chloride, Carbon Dioxide, Glucose, BUN, Total Bilirubin, Calcium, Protein, Albumin, ALP, ALT, AST, Cholesterol, HDL, Triglycerides, Uric Acid, and Magnesium on the Alera Alfa-Wasserman for 18 of 18 chemistry analytes reported in the lab from 11/01/2022 - 01/03/2023 (refer to D5421 IV). 7. The laboratory failed to ensure two levels of QC were performed before reporting out patient results for Cholesterol, Triglycerides, and HDL using the Alera Alfa-Wasserman on 2 out of 4 days of testing (refer to D5447). 8. The laboratory failed to ensure two levels of QC were acceptable before reporting out patient results for chemistries using the Alera Alfa-Wasserman on 11 out of 30 days of testing (refer to D5481). 9. The laboratory failed to document corrective action taken when it repeated QC for chemistries using the Alera Alfa-Wasserman on 40 out of 76 occurrences over a period of 30 days reviewed (refer to D5783 I).
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: I. Based on review of patient testing records, observation, review of temperature charts, and interview, the laboratory failed to monitor the refrigerator used to store patient specimens located in the lab with the Alera Alfa-Wasserman for two of two months reviewed from 11/01/2022 - 01/04/2023. Findings follow. A. Review of Patient Requisition Reports showed testing began November 1, 2022. B. Surveyor observed on January 4, 2023, at 1145 hours five patient specimens in SST tubes in the Igloo refrigerator located in the lab with the Alera Alfa-Wasserman. Patient ID 1&2. 4389834, 2 SST tubes 3. 4389644, 1 SST tube 4. 4389679, 1 SST tube 5. 4389732, 1 SST tube. C. Temperature charts for the Igloo refrigerator were requested on January 4, 2023, at 1150 hours but not provided. D. Interview with testing personnel #1, as listed on the CMS form 209, on January 4, 2023, at 1150 hours confirmed they do not monitor the refrigerator used to store patient specimens. II. Based on observation, review of manufacturer's instructions, temperature charts, patient testing records, and interview, the laboratory failed to monitor the room temperature in the lab for two of two months reviewed from 11/01/2022 - 01/04/2023. Findings follow. A. Surveyor observed on January 4, 2023, at 1135 hours in the lab with the Alera Alfa-Wasserman,

	the following boxes of reagents on the counter: 1. ACE Total Bilirubin, 2 boxes, Lot F4609 2. ACE Creatinine, 2 boxes, Lot F4634 3. ACE Total Protein, 4 boxes, Lot 4617 4. ACE Albumin, 4 boxes, Lot F4626 5. ACE Calcium- Arsenazo, 1 box, Lot F4613 6. ACE ISE Wash, 1 box, Lot F4555 7. ACE Direct Bilirubin, 1 box, Lot F4593. B. Review of the manufacturer's instructions printed on the boxes showed "18-26 degrees Celsius". C. Review of the Alfa-Wasserman Operator's Manual, P/N 7C1298 rev 5 07/15, starting on page 31 at 2.8 Specifications stated, "Ambient Room Temperature" 15 - 27 degrees Celsius (59 - 80 degrees Fahrenheit). D. Room temperature charts for the lab with the Alera Alfa-Wasserman were requested on January 4, 2023, at 1135 hours but not provided. E. Review of Patient Requisition Reports showed testing began November 1, 2022. F. Interview with testing personnel #2 on January 4, 2023, at 1135 hours confirmed they did not monitor the room temperatures and was not aware they needed to do that.
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: I. Based on review of patient testing records, verification of performance specification records, interview, and email, the laboratory failed to perform accuracy and precision for Sodium, Potassium, Chloride, ALP (Alkaline Phosphatase), Uric Acid, and Magnesium on the Alera Alfa-Wasserman for six of 18 chemistry analytes reported in the lab from 11/01/2022 - 01/03/2023. Findings follow. A. Review of Patient Requisition Reports showed testing began November 1, 2022. B. Review of the verification of performance specifications for 1) Sodium, 2) Potassium, 3) Chloride, 4) ALP, 5) Uric Acid, and 6) Magnesium showed no data for precision and accuracy. Precision and accuracy from the validation were requested on January 3, 2023, at 1425 hours but not provided. C. Interview with testing personnel #1, as listed on the CMS form 209, on January 3, 2023, at 1445 acknowledged the rep had performed the validation, and was not aware of any missing documentation except for Uric Acid because they had no reagents at the time of the validation. D. Email from testing personnel #1 on 01/10/23 at 09:40 showed the following number of patients had been reported from 11/01/22 - 01/03/23: Sodium = 289 Potassium = 289 Chloride = 289 ALP = 170 Uric Acid = 1 Magnesium = 21 II. Based on review of verification of performance specification records, manufacturer's instructions, interview, and email, the laboratory failed to verify the precision obtained for Cholesterol on the Alera Alfa-Wasserman during the verification of performance specifications for 1 of 2 levels measured. Findings follow. A. Review of precision in the validation for Cholesterol showed the precision results were 37.44% CV (coefficient of variation) for Level 2. B. Review of the package insert for the ACE Cholesterol Reagent, PN 909060-9 D 6/19, under Performance Characteristics at Precision showed the CV for Level 2 using the Alera (n=20 days) was 2.4%. C. Interview with testing personnel #1, as listed on the CMS form 209, on January 3, 2023, at 1455 confirmed the findings. D. Email from testing personnel #1 on 01/10/23 at 09:40 showed 17 patients had been reported from

	11/01/22 - 01/03/23 for Cholesterol. III. Based on review of patient testing records, verification of performance specification records, interview, and email, the laboratory failed to perform a reportable range study for Sodium, Potassium, Chloride, Carbon Dioxide, Glucose, BUN (Blood Urea Nitrogen), Total Bilirubin, Calcium, Protein, Albumin, ALP, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), Cholesterol, HDL (High-Density Lipoprotein), Triglycerides, Uric Acid, and Magnesium on the Alera Alfa-Wasserman for 18 of 18 chemistry analytes reported in the lab from 11/01/2022 - 01/03/2023. Findings follow. A. Review of Patient Requisition Reports showed testing began November 1, 2022. B. Review of the verification of performance specifications for 1) Sodium, 2) Potassium, 3) Chloride, 4) Carbon Dioxide, 5) Glucose, 6) BUN, 7) Total Bilirubin, 8) Calcium, 9) Protein, 10) Albumin, 11) ALP, 12) ALT, 13) AST, 14) Cholesterol, 15) HDL, 16) Triglycerides, 17) Uric Acid, and 18) Magnesium showed no data for the reportable range study. The reportable range study from the verification of performance specifications was requested on January 3, 2023, at 1455 hours but not provided. C. Interview with testing personnel #1, as listed on the CMS form 209, on January 3, 2023, at 1445 hours acknowledged the rep had performed the validation, but was not aware of any missing documentation. D. Emails from testing personnel #1 on 01/10 /23, at 09:40 and 01/19/23 at 10:08 showed the following number of patients had been reported from 11/01/22 - 01/03/23: Sodium = 289, Potassium, = 289 Chloride = 289, Carbon Dioxide = 289, Glucose = 289, BUN = 289, Total Bilirubin = 289, Calcium = 289, Total Protein = 170, Albumin = 170, ALP = 170, ALT = 170, AST = 170 Cholesterol = 17, HDL = 17, Triglycerides = 17 Uric Acid = 1, and Magnesium = 21. IV. Based on review of patient testing records, verification of performance specification records, interview, and email, the laboratory failed to verify the normal reference range for Sodium, Potassium, Chloride, Carbon Dioxide, Glucose, BUN, Total Bilirubin, Calcium, Protein, Albumin, ALP, ALT, AST, Cholesterol, HDL, Triglycerides, Uric Acid, and Magnesium on the Alera Alfa-Wasserman for 18 of 18 chemistry analytes reported in the lab from 11/01/2022 - 01/03/2023. Findings follow. A. Review of Patient Requisition Reports showed testing began November 1, 2022. B. Review of the verification of performance specifications for 1) Sodium, 2) Potassium, 3) Chloride, 4) Carbon Dioxide, 5) Glucose, 6) BUN, 7) Total Bilirubin, 8) Calcium, 9) Protein, 10) Albumin, 11) ALP, 12) ALT, 13) AST, 14) Cholesterol, 15) HDL, 16) Triglycerides, 17) Uric Acid, and 18) Magnesium showed no data for the verification of the normal reference range. The verification of the normal reference range from the validation was requested on January 3, 2023, at 1215 hours but not provided. C. Interview with testing personnel #1, as listed on the CMS form 209, on January 3, 2023, at 1240 confirmed the verification of the normal range was not performed and was told the reference ranges were in the analyzer. D. Emails from testing personnel #1 on 01/10/23, at 09:40 and 01/19/23 at 10:08 showed the following number of patients had been reported from 11/01/22 - 01/03/23: Sodium = 289, Potassium, = 289 Chloride = 289, Carbon Dioxide = 289, Glucose = 289, BUN = 289, Total Bilirubin = 289, Calcium = 289, Total Protein = 170, Albumin = 170, ALP = 170, ALT = 170, AST = 170 Cholesterol = 17, HDL = 17, Triglycerides = 17 Uric Acid = 1, and Magnesium = 21.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different

	concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of QC (quality control) records, testing records, and interview, the laboratory failed to ensure two levels of QC were performed before reporting out patient results for Cholesterol, Triglycerides, and HDL (High-Density Lipoprotein) using the Alera Alfa-Wasserman on 2 out of 4 days of testing. Findings follow. A. Review of the QC Requisition Reports from 11/01/22 - 11/18/22 and 12/01/22 - 12/14 /22 showed QC was not performed on 2 out of 4 days of testing: 1. 12/08/22: No QC run for Cholesterol, Triglycerides, or HDL 2. 12/09/22: No QC run for Cholesterol, Triglycerides, or HDL B. Review of patient instrument printouts (by testing date and patient ID) showed when testing was performed, and the Laboratory Requisition (by accession #) showed three patients were reported when QC was not performed: Testing date Patient ID Accession # 12/08/22: 1. 4389314 2301120036 2. 4389316 2301040016 12/09/22: 3. 4389277 2301090022 C. Interview with testing personnel #2, as listed on CMS-209, on January 4, 2023, at 1555 hours confirmed the findings.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of an email concerning tech support help, quality control (QC) records, testing records, and interview, the laboratory failed to ensure two levels of QC were acceptable before reporting out patient results for chemistries using the Alera Alfa-Wasserman on 11 out of 30 days of testing. Findings follow. A. In an email from the facility on 01/20/23 at 09:35, tech support was contacted by the facility and said the code RNG was listed on QC reports when the control results were out of range, and the code was not in the Alfa Wasserman Operator's Manual. B. Review of the QC Requisition Reports from 11/01/22 - 11/18/22 and 12/01/22 - 12/14/22 against the QC package insert (Level 1 = Lot 1501 UNCM, Level 2 = 1166UECM) showed QC was unacceptable on 11 out of 30 days of testing, and included the code RNG: Test date Analyte QC Results Acceptable range 1. 11/01/22 ALT Level l 43, 43, 44, 43 (46-60 U/L). 2. 11/02/22 ALT Level 1 45, 45, 45 (46-60 U/L); ALP Level 1 76, 77, 77 (57.2 - 74.8 U/L). 3. 11/11/22 @ 09:48 ALP Level 2 345 (346.6 - 453.4 U/L). 4. 11/15/22 ALT Level 1 41, 40 (46-60 U/L); ALT Level 2 116, 111 (120.6 - 157.4 U /L); ALP Level 1 83, 83 (57.2 - 74.8 U/L); AST Level 1 40, 41 (42.4 - 55.6 U/L). 5. 11 /18/22 Na Level 1 149.9, 151.7, 150.0, 148.9 (128.52 - 146.88 mmol/L); Na Level 2 132.6 (114.62 - 130.98 mmol/L). 6. 11/18/22 K Level 1 4.43, 4.49, 4.44, 4.42 (3.716 - 4.384 mmol/L); Cl Level 1 115.3, 116.7, 115.5, 114.6 (99.68 - 113.92 mmol/L); Cl Level 2 87.9 (75.32 - 86.08 mmol/L). 7. 12/01/22 Glu Level 1 99, 101, 99, 102, 100, 100, 102 (86 - 98 mg/dL, per QC test report) 8. 12/03/22 Na Level 2 131.8, 131.8 (114.62 - 130.98 mmol/L); K Level 2 8.09, 8.16 (7.396 - 8.064 mmol/L); Cl Level 2 87.5, 87.3 (75.32 - 86.08 mmol/L). 9. 12/10/22 ALT Level 1 45, 44, 44, 44 (46-60 U /L) 10. 12/11/22 Mg Level 1 2.1, 2.2 (2.16 - 2.64 mg/dL). 11. 12/14/22 ALP Level 1 75 (57.2 - 74.8 U/L); Mg Level 1 2.2 (2.16 - 2.64 mg/dL). C. Review of patient instrument printouts (by testing date and patient ID) showed when testing was performed, and the Laboratory Requisition (by accession #) showed 38 patients were

	reported when QC failed: Testing date Patient ID Accession # 11/01/22: 1. 4388802 2301120010 2. 4388810 2301120009 3. 4388816 2301120008 4. 4388814 2301120007 5. 4388806 2301120006 11/02/22: 6. 4388833 2301120016 7. 2211010001 2301120015 8. 2211020004 2301120014 9. 2211020005 2301120013 11 /11/22: 10. 4388972 2301120019 11. 4388968 2301120026 12. 4388964 2301120025 13. 4388934 2301120024 14. 4388975 2301120021 11/15/22: 15. 4388814 2301120031 16. 4389043 2301120030 17. 4389944 2301120029 18. 4388882 2301120028 19. 4388934 2301120027 11/18/22: 20. 4388968 2301120034 21. 4388975 2301120033 22. 4389037 2301120032 12/01/22: 23. 4389112 2301090014 24. 4389080 2301090033 12/03/22: 25. 4389166 2301090011 26. 4389228 2301090012 27. 4389233 2301090013 28. 4392312 2301090015 12/10/22: 29. 4389354 2301090020 30. 4389347 2301090021 12/11/22: 31. 4389347 2301090025 12/14/22: 32. 4389241 2301090032 33. 4389403 2301090026 34. 4389425 2301090027 35. 4389370 2301090028 36. 4389347 2301090029 37. 4389263 2301090030 38. 2214220001 2301090031 D. Interview with testing personnel #2, as listed on CMS-209, on January 4, 2023, at 1515 hours confirmed the findings.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: I. Based on review of an email concerning tech support help, quality control (QC) records, and interview, the laboratory failed to document corrective action taken when it repeated QC for chemistries using the Alera Alfa-Wasserman on 40 out of 76 occurrences over a period of 30 days reviewed. Findings follow. A. In an email from the facility on 01/20/23 at 09:35, tech support was contacted by the facility and said the code RNG was listed on QC reports when the control results were out of range, and the code was not in the Alfa Wasserman Operator's Manual. B. Review of the QC Requisition Reports from 11/01/22 - 11/18/22 and 12/01/22 - 12/14/22 against the QC package insert (Level 1 = Lot 1501 UNCM, Level 2 = 1166UECM; acceptable range) showed no documentation of corrective action for 40 out of 76 occurrences for the following out of range results with the code RNG: Time & Date QC Analyte Result Acceptable range 1. 11/02/22 @ 07:53: Level 1 ALT 45 (46-60 U/L); ALP 77 (57.2 - 74.8 U/L). 2. 11/02/22 @ 08:01: Level 1 ALT 45 (46-60 U/L); ALP 77 (57.2 - 74.8 U /L). 3. 11/08/22 @ 06:56: Level 1 Mg 2.2 (2.16 - 2.64 mg/dL) 4. 11/15/22 @ 09:11: Level 1 ALT 40 (46-60 U/L); AST 41 (42.4 - 55.6 U/L); ALP 83 (57.2 - 74.8 U/L). 5. 11/16/22 @ 09:02: Level 1 Na 153.6 (128.52 - 146.88 mmol/L); K 4.64 (3.716 - 4.384 mmol/L); Cl 118.3 (99.68 - 113.92 mmol/L); Glu 107 (86 - 98 mg/dL, per QC test report); BUN 14 (10.4 - 13.6 mg/dL); TP 5.2 (4.2 - 4.8 g/dL). 6. 11/16/22 @ 10:00: Level 1 Na 160.0 (128.52 - 146.88 mmol/L); K 4.71 (3.716 - 4.384 mmol/L); Cl 123.0 (99.68 - 113.92 mmol/L); Glu 110 (86 - 98 mg/dL, per QC test report) BUN 15 (10.4 - 13.6 mg/dL); TP 5.3 (4.2 - 4.8 g/dL). 7. 11/16/22 @ 10:00: Level 2 Na 135.2 (114.62 - 130.98 mmol/L); K 8.14 (7.396 - 8.064 mmol/L); Cl 89.2 (75.32 - 86.08 mmol/L); Glu 318 (270 - 308 mg/dL, per QC test report); BUN 58 (43.4 - 56.6 mg/dL); TP 8.5

(7.18 - 8.22 g/dL). 8. 11/18/22 @ 08:21: Level 1 ALT 38 (46-60 U/L); AST 38 (42.4 - 55.6 U/L); ALP 82 (57.2 - 74.8 U/L). 9. 11/18/22 @ 10:01: Level 1 Na 149.9 (128.52 - 146.88 mmol/L); K 4.43 (3.716 - 4.384 mmol/L); Cl 115.3 (99.68 - 113.92 mmol/L). 10. 11/18/22 @ 10:44: Level 1 Na 151.7 (128.52 - 146.88 mmol/L); K 4.49 (3.716 - 4.384 mmol/L); Cl 116.7 (99.68 - 113.92 mmol/L). 11. 11/18/22 @ 10:48: Level 1 Na 150.0 (128.52 - 146.88 mmol/L); K 4.44 (3.716 - 4.384 mmol/L); Cl 115.5 (99.68 - 113.92 mmol/L). 12. 11/18/22 @ 10:55: Level 1 Na 148.9 (128.52 - 146.88 mmol/L); K 4.42 (3.716 - 4.384 mmol/L); Cl 114.6 (99.68 - 113.92 mmol/L). 13. 11/18/22 @ 08:21: Level 2 ALT 107 (120.6 - 157.4 U/L); AST 171 (185.4 - 242.6 U/L). 14. 12/01/22 @ 09:34: Level 1 ALT 38 (46-60 U/L); ALP 85 (57.2 - 74.8 U/L); Glu 101 (86 - 98 mg/dL, per QC test report). 15. 12/01/22 @ 09:49: Level 1 ALT 41 (46-60 U/L); ALP 86 (57.2 - 74.8 U/L); Glu 99 (86 - 98 mg/dL, per QC test report). 16. 12/01/22 @ 10:17: Level 1 Glu 102 (86 - 98 mg/dL, per QC test report). 17. 12/01/22 @ 10:28: Level 1 Glu 100 (86 - 98 mg/dL, per QC test report). 18. 12/01/22 @ 10:34: Level 1 Glu 100 (86 - 98 mg/dL, per QC test report). 19. 12/01/22 @ 11:11: Level 1 Glu 102 (86 - 98 mg/dL, per QC test report). 20. 12/01/22 @ 09:34 Level 2 ALT 119 (120.6 - 157.4 U/L). 21. 12/01/22 @ 09:49 Level 2 ALT 119 (120.6 - 157.4 U/L). 22. 12/02/22 @ 09:44: Level 1 Na 150.6 (128.52 - 146.88 mmol/L); K 4.45 (3.716 - 4.384 mmol/L); Cl 115.8 (99.68 - 113.92 mmol/L); Glu 78 (86 - 98 mg/dL, per QC test report); ALT 32 (46-60 U/L); Mg 0.2 (2.16 - 2.64 mg/dL). 23. 12/02/22 @ 09:55: Level 1 K 4.67 (3.716 - 4.384 mmol/L); Glu 78 (86 - 98 mg/dL, per QC test report); Mg 0.2 (2.16 - 2.64 mg/dL). 24. 12/02/22 @ 10:22: Level 1 Glu 78 (86 - 98 mg/dL, per QC test report). 25. 12/02/22 @ 10:34: Level 1 Glu 100 (86 - 98 mg/dL, per QC test report). 26. 12/02/22 @ 09:53: Level 2 Na 131.0 (114.62 - 130.98 mmol/L); Cl 86.4 (75.32 - 86.08 mmol/L). 27. 12/02/22 @ 10:22: Level 2 Na 132.6 (114.62 - 130.98 mmol/L); Cl 87.9 (75.32 - 86.08 mmol/L). 28. 12/02/22 @ 10:31: Level 2 Na 132.6 (114.62 - 130.98 mmol/L); Cl 87.6 (75.32 - 86.08 mmol/L). 29. 12/03/22 @ 10:04: Level 1 Na 147.4 (128.52 - 146.88 mmol/L); K 4.40 (3.716 - 4.384 mmol/L). 30. 12/03/22 @ 10:23: Level 1 Na 147.0 (128.52 - 146.88 mmol/L). 31. 12/03/22 @ 10:04: Level 2 Na 131.8 (114.62 - 130.98 mmol/L); K 8.09 (7.396 - 8.064 mmol/L); Cl 87.5 (75.32 - 86.08 mmol/L). 32. 12/03/22 @ 11:00: Level 2 Na 131.8 (114.62 - 130.98 mmol/L); K 8.16 (7.396 - 8.064 mmol/L); Cl 87.3 (75.32 - 86.08 mmol/L). 33. 12/04/22 @ 08:02: Level 2 ALP 330 (346.6 - 453.4 U/L). 34. 12/04/22 @ 09:04: Level 2 ALP 332 (346.6 - 453.4 U/L). 35. 12/07/22 @ 06:51: Level 1 ALT 45 (46-60 U/L). 36. 12/10/22 @ 08:52: Level 1 ALT 44 (46-60 U/L); ALT 44 (46-60 U/L); ALT 44 (46-60 U/L). 37. 12/11/22 @ 08:56: Level 1 Mg 2.2 (2.16 - 2.64 mg/dL). 38. 12/12/22 @ 10:03: Level 1 K 4.49 (3.716 - 4.384 mmol/L). 39. 12/14/22 @ 09:26: Level 2 Mg 4.1 (4.32 - 5.28 mg/dL). 40. 12/14/22 @ 10:11: Level 2 Mg 0.5 (4.32 - 5.28 mg/dL). C. Interview with testing personnel #1, as listed on CMS-209, on January 4, 2023, at 1015 hours acknowledged they didn't write everything down that they did. II. Based on review of manufacturer's instructions, calibration records, and interview, the laboratory failed to document corrective action when the Alfa-Wasserman was requiring calibrations 3 - 15 times more frequent per month than specified by the manufacturer for Carbon Dioxide, Glucose, BUN, Calcium, Albumin, Total Bilirubin, Total Protein, Magnesium, Cholesterol, HDL, and Triglycerides from 11/01/22 - 11/11/22. Findings follow. A. Review of the package inserts for Carbon Dioxide, PN 909060-11 REV C 9/17, and BUN, PN 909060-6 REV D 9/17, under Calibration stated, "Calibration Frequency: 7 days". Review of the package inserts for Glucose, PN 909060-16 REV F 1/21, Calcium, PN 909060-7 REV D 9/17, Albumin, PN 909060-1 REV D 9/17, Total Bilirubin, PN 909060-25 REV D 5/19, Total Protein, PN 909060-28 REV D12/17, Magnesium, PN 909060-22 REV D 6/17, Cholesterol, PN 909060-9 D 6/19, HDL, PN 909060-18 REV F 8/19, and Triglycerides, PN 909060-29 REV C 3/18, under Calibration stated, "Calibration Frequency: 30 days".

	B. Review of the Calibration Report from 11/01/22 to 11/11/22 showed calibrations were performed every 2 days: 11/01/22, 11/03/22, 11/05/22, 11/07/22, 11/09/22, and 11/11/22. C. Interview with testing personnel #1, as listed on CMS-209, on January 3, 2023, at 1515 hours acknowledged the instrument was asking for calibrations every other day in November. They called Alfa-Wasserman, and someone came out and changed that on December 13, 2022, but they did not document the issue. KEY: Na = Sodium K = Potassium CL = Chloride CO2 = Carbon Dioxide Glu = Glucose BUN = Blood Urea Nitrogen TP = Total Protein ALT = Alanine Transferase AST = Aspartate Aminotransferase ALP = Alanine Aminotransferase Mg = Magnesium HDL = High Density Lipoprotein
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 observation, review of proficiency test records, patient testing records, temperature charts, manufacturer's instructions, verification of performance specification records, QC (Quality Control) records, an email concerning tech support help, interview and email, the Technical Consultant failed to provide the required technical oversight of the laboratory for two of two months reviewed. Findings follow. 1. The Technical Consultant failed to provide technical and scientific oversight of the laboratory for two of two months reviewed (refer to D6036). 2. The technical consultant failed to ensure verification of the test procedures performed and the establishment of the laboratory's test performance characteristics for 18 out of 18 analytes reviewed (refer to D6040). 3. The Technical Consultant failed to enroll in proficiency testing for Sodium, Potassium, Chloride, Carbon Dioxide, Glucose, BUN (Blood Urea Nitrogen), Total Bilirubin, Calcium, Protein, Albumin, ALP (Alkaline Phosphatase), ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), Cholesterol, HDL (High-Density Lipoprotein), Triglycerides, Uric Acid, and Magnesium performed on the Alera Alfa-Wasserman for two of two months reviewed (refer to D6041). 4. The Technical Consultant failed to ensure patient testing was reported when 2 levels of QC were acceptable (refer to D6042).
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on observation, review of proficiency test records, patient testing records, temperature charts, manufacturer's instructions, verification of performance specification records, QC (Quality Control) records, interview and email, the Technical Consultant failed to provide technical and scientific oversight of the laboratory for two of two months reviewed. Findings follow. 1. The laboratory failed to enroll in proficiency testing for Sodium, Potassium, Chloride, Carbon Dioxide, Glucose, BUN (Blood Urea Nitrogen), Total Bilirubin, Calcium, Protein, Albumin,

	ALP (Alkaline Phosphatase), ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), Cholesterol, HDL (High-Density Lipoprotein), Triglycerides, Uric Acid, and Magnesium performed on the Alera Alfa-Wasserman for two of two months reviewed (refer to D2000). 2. The laboratory failed to monitor the refrigerator used to store patient specimens located in the lab with the Alera Alfa-Wasserman for two of two months reviewed from 11/01/2022 - 01/04/2023 (refer to D5413 I). 3. The laboratory failed to monitor the room temperature in the lab for two of two months reviewed from 11/01/2022 - 01/04/2023 (refer to D5413 II). 4. The laboratory failed to perform accuracy and precision for Sodium, Potassium, Chloride, ALP, Uric Acid, and Magnesium on the Alera Alfa-Wasserman for six of 18 chemistry analytes reported in the lab from 11/01/2022 - 01/03/2023 (refer to D5421 I). 5. The laboratory failed to verify the precision obtained for Cholesterol on the Alera Alfa-Wasserman during the verification of performance specifications for 1 of 2 levels measured (refer to D5421 II). 6. The laboratory failed to perform a reportable range study for Sodium, Potassium, Chloride, Carbon Dioxide, Glucose, BUN (Blood Urea Nitrogen), Total Bilirubin, Calcium, Protein, Albumin, ALP, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), Cholesterol, HDL (High-Density Lipoprotein), Triglycerides, Uric Acid, and Magnesium on the Alera Alfa-Wasserman for 18 of 18 chemistry analytes reported in the lab from 11/01/2022 - 01/03/2023 (refer to D5421 III). 7. The laboratory failed to verify the normal reference range for Sodium, Potassium, Chloride, Carbon Dioxide, Glucose, BUN, Total Bilirubin, Calcium, Protein, Albumin, ALP, ALT, AST, Cholesterol, HDL, Triglycerides, Uric Acid, and Magnesium on the Alera Alfa-Wasserman for 18 of 18 chemistry analytes reported in the lab from 11/01/2022 - 01/03/2023 (refer to D5421 IV). 8. The laboratory failed to ensure two levels of QC were performed before reporting out patient results for Cholesterol, Triglycerides, and HDL using the Alera Alfa-Wasserman on 2 out of 4 days of testing (refer to D5447). 9. The laboratory failed to ensure two levels of QC were acceptable before reporting out patient results for chemistries using the Alera Alfa-Wasserman on 11 out of 30 days of testing (refer to D5481). 10. The laboratory failed to document corrective action taken when it repeated QC for chemistries using the Alera Alfa-Wasserman on 40 out of 76 occurrences over a period of 30 days reviewed (refer to D5783 I).
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on review of patient testing records, verification of performance specification records, manufacturer's instructions, interview, and email, the technical consultant failed to ensure verification of the test procedures performed and the establishment of the laboratory's test performance characteristics for 18 out of 18 analytes reviewed. Findings follow. 1. The Technical Consultant failed to ensure accuracy and precision were performed for Sodium, Potassium, Chloride, ALP (alkaline phosphatase), Uric Acid, and Magnesium on the Alera Alfa-Wasserman for six of 18 chemistry analytes reported in the lab from 11/01/2022 - 01/03/2023 (refer to D5421 I). 2. The Technical Consultant failed to verify the precision obtained for Cholesterol on the Alera Alfa-Wasserman during the verification of performance specifications for 1 of 2 levels measured (refer to D5421 II). 3. The Technical Consultant failed to ensure the

	reportable range study was established for Sodium, Potassium, Chloride, Carbon Dioxide, Glucose, BUN (Blood Urea Nitrogen), Total Bilirubin, Calcium, Protein, Albumin, ALP, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), Cholesterol, HDL (High-Density Lipoprotein), Triglycerides, Uric Acid, and Magnesium on the Alera Alfa-Wasserman for 18 of 18 chemistry analytes reported in the lab from 11/01/2022 - 01/03/2023 (refer to D5421 III). 4. The Technical Consultant failed to ensure the normal reference range was established for Sodium, Potassium, Chloride, Carbon Dioxide, Glucose, BUN, Total Bilirubin, Calcium, Protein, Albumin, ALP, ALT, AST, Cholesterol, HDL, Triglycerides, Uric Acid, and Magnesium on the Alera Alfa-Wasserman for 18 of 18 chemistry analytes reported in the lab from 11/01/2022 - 01/03/2023 (refer to D5421 IV).
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: Based on review of patient testing records, proficiency testing (PT) records, interview, and email, the Technical Consultant failed to enroll in proficiency testing for Sodium, Potassium, Chloride, Carbon Dioxide, Glucose, BUN (Blood Urea Nitrogen), Total Bilirubin, Calcium, Protein, Albumin, ALP, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), Cholesterol, HDL (High-Density Lipoprotein), Triglycerides, Uric Acid, and Magnesium performed on the Alera Alfa-Wasserman for two of two months reviewed (refer to D2000).
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 QC (quality control) records, testing records, an email concerning tech support help, and interview, the Technical Consultant failed to ensure patient testing was reported when 2 levels of QC were acceptable. Findings follow. 1. The laboratory failed to ensure two levels of QC were performed before reporting out patient results for Cholesterol, Triglycerides, and HDL (High-Density Lipoprotein) using the Alera Alfa-Wasserman on 2 out of 4 days of testing (refer to D5447). 2. The laboratory failed to ensure two levels of QC were acceptable before reporting out patient results for chemistries using the Alera Alfa-Wasserman on 11 out of 30 days of testing (refer to D5481).
D6056	CLINICAL CONSULTANT CFR(s): 493.1415

	The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part. This CONDITION is not met as evidenced by: Based on review of the pre-survey paperwork, personnel credentials, and interview the laboratory had no clinical consultant available to provide clinical consultation to the laboratory's clients for the tests performed for two of two months of testing from 11/01/2022 - 01/03/2023. (Refer to D6057).
D6057	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1417 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493. 1405(b)(1), (2), or (3)(i); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: Based on review of the pre-survey paperwork, personnel credentials, and interview the laboratory failed to employ personnel to provide clinical consultation for the laboratory that met the qualifications of laboratory clinical consultant for the chemistry tests performed for two of two months of testing from 11/01/2022 to the date of the survey 01/03/2023. Findings follow: A. Review of the CMS form 209 Laboratory Personnel Report dated 01/03/2023 showed the Laboratory Director also served as Clinical Consultant. B. Review of the Laboratory Director's educational credentials showed she had achieved a Bachelor of Science with a Major in Biology and Major concentration in Medical Technology. Review of her transcripts showed PhD coursework in Forensic Science. C. Phone interview with the Laboratory Director on January 3, 2023, at 1045 hours confirmed she had PhD coursework, but it was incomplete. She said she served as a Clinical Consultant for a lab in Georgia.