Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0492065	03/20/2019
Name of Provider or Supplier	**Street Address, City, State**	
Zimmerman Medical Clinic Laboratory	7707 Fannin St Suite 255, Houston, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory policy, American Association of Bioanalysts (AAB) proficiency testing (PT) records and confirmed in interview, the laboratory failed to test proficiency testing materials the same number of times as patient samples for CBC (complete blood count) on the Beckman Coulter ACT Diff 2 hematology analyzer. Findings were: 1. Review of he Beckman Coulter ACT Diff 2 Special Procedures and Troubleshooting manual under the service and maintenance chapter, table 6.4 stated, "X flag indicates that one of the multiple Aperture Alert criteria was not met" and the suggested action was, "1. Thoroughly mix and rerun the samples. 2. If flag does not repeat, report result. 3. If flag repeats, clean the aperture as instructed in Zapping the Aperture. 4. If after cleaning, problem

	persists, contact your Beckman Coulter Representative." 2. Review of the Beckman Coulter's Act Diff 2 analyzer's Operators manual (PN 4237495B, June 2003) revealed in the Service and Maintenance chapter is a section titled "Parameter Codes and Flags." The manufacturer's instructions stated "If any flag appears, review the results according to your laboratory's protocol." The following flags also include the following instructions: "3" = Differential parameter failed the internal regional size distributional criteria at region 3. Action = Verify results according to laboratory's protocol. "M" = Differential parameter failed the internal regional size distributional criteria at multiple regions. Action = Verify results according to laboratory's protocol. "L" = Low result. For Patient samples, result is lower than the low limit for that patient sample. Action = Follow the laboratory's protocol. "H" = High result. For Patient samples, the result is higher than the upper limit for that patient sample. Action = Follow the laboratory's protocol. "*" = If on WBC (white blood count) and Differential only, 35 fL (fluid level)' count interference check failed. Possible interference with the WBC count. Action = Thoroughly mix and rerun the sample. = Verify results according to your laboratory's protocol. 3. Review of the laboratory policy ZMC002 Coulter Act 2Diff revealed "results that contain error codes or are above the instrument linear limits are repeated. If the second run duplicates errors send samples to the reference laboratory for confirmatory analysis...some error codes may be eliminated by cleaning the instrument. See the operator's manual for instructions. "*" review results; mix and repeat "X" aperture alert: clean and repeat analysis. Send for confirmation if requested by clinician. "1,2,3,4,M" differential parameters failed the internal regional size distribution criteria in one or more regions: repeat analysis. If the error code persists and the clinician requests the sample will be sent for confirmation. 4. Review of the 2017 - 2018 AAB Hematology proficiency test records revealed no documentation of the repeat analysis for the CBCs with flags for 6 of 6 testing events: 2017 3rd event, Specimen 2 (*), 3 (*), 4 (*), 5 (*) 2017 2nd event, Specimen 2 (*) ,4 (*) , 5 (*) 2017 1st event, Specimen 1 (*), 2 (*), 3 (*), 4 (*), 5 (*) 2018 3rd event, Specimen 12 (M, *), 13 (*), 14 (M,*) 2018 2nd event, Specimen 7 (*), 10 (*) 2018 1st event, Specimen 1 (*), 3 (*), 4 (*), 5 (*) 5. Interview with the primary test person on 3/19/19 at 1330 hours in the laboratory confirmed the above findings.
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Bioanalysts Association (AAB) Chemistry proficiency testing records from 2017 and 2018, and confirmed in interview, the laboratory failed to attain a satisfactory score of at least 80% for the analyte Total Bilirubin (Tbili), Carbon Dioxide (CO2), and Uric Acid (UA). The findings were: 1. A review of the laboratory's AAB proficiency test records from 2017 and 2018 revealed the laboratory failed to attain a satisfactory score of at least 80% for the analytes Tbili on 1 of 5 events: 2017 Event 3 Tbili (20%) lab result acceptable result Specimen 1 1.8 2.4 - 3.6 Specimen 2 2.2 3.1 - 4.7 Specimen 3 0.9 1.0 - 1.8 Specimen 5 1.6 2.1 - 3.2 2. A review of the laboratory's AAB proficiency test records from 2017 and 2018 revealed the laboratory failed to attain a satisfactory score of at least 80% for the analytes CO2 on 1 of 5 events: 2018 Event 2 CO2 (40%) lab result acceptable result Specimen 1 19 21 - 32 Specimen 2 15 16 - 24 Specimen 4 12 13 - 21

	3. A review of the laboratory's AAB proficiency test records from 2017 and 2018 revealed the laboratory failed to attain a satisfactory score of at least 80% for the analytes Uric Acid on 1 of 5 events: 2018 Event 2 UA (60%) lab result acceptable result Specimen 2 4.9 3.4 - 4.8 Specimen 4 4.2 2.8 - 3.9 4. An interview with the primary testing person on 3/19/19 at 1315 hours in the laboratory confirmed the above findings.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory American Association Bioanalysts (AAB) proficiency testing records, laboratory policy, and confirmed in interview, the laboratory failed to document remedial action for PT failures for the analyte Total Bilirubin (Tbili), Carbon Dioxide (CO2), and Uric Acid (UA). Findings were: 1. A review of the laboratory's AAB from 2017 and 2018 revealed the laboratory failed to attain a satisfactory score of at least 80% for the analytes Total Bilirubin (Tbili), Carbon Dioxide (CO2), and Uric Acid (UA). Cross refer to D2087 2. Review of the laboratory policy Laboratory Proficiency Testing revealed "all results less than 100% must be investigated and remediated appropriately." 3. Review of the laboratory corrective actions for the AAB for the 2017 3rd event and 2018 2nd event revealed no documentation of remedial action for the above PT failures. 4. An interview with the primary testing person on 3/19/19 at 1315 hours in the laboratory confirmed the above findings.
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the 2017 - 2018 American Association Bioanalysts (AAB) proficiency testing (PT) results and confirmed in interview, the laboratory failed to attain at least 80% for the analyte Red blood cells (RBC) and hematocrit (HCT) for 1 of 5 Hematology events. Findings were: 1. Review of the 2017 - 2018 AAB Hematology PT results revealed the laboratory received the following scores for the analyte RBC and hematocrit. 2018 3rd event (60% RBC) Specimen 1: lab result 4.94 (acceptable range 4.36 - 4.92) Specimen 2: lab result 2.60 (acceptable range 2.28 - 2.57) 2018 3rd event (20% HCT) Specimen 1: lab result 40.9 (acceptable range 36 - 40.6) Specimen 2: lab result 19.0 (acceptable range 16.5 - 18.6) Specimen 3: lab result

	55.2 (acceptable range 48.8 - 55.0) Specimen 4: lab result 18.7 (acceptable range 16.5 - 18.6) 2. An interview with the primary testing person on 3/19/19 at 1315 hours in the laboratory confirmed the above findings.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory American Association Bioanalysts (AAB) proficiency testing records, and confirmed in interview, the laboratory failed to document remedial action for PT failures for the analyte Red Blood Cells (RBC) and Hematocrit (HCT). Findings were: 1. A review of the laboratory's AAB from 2017 and 2018 revealed the laboratory failed to attain a satisfactory score of at least 80% for the analytes RBC and HCT on 1 of 5 events. Cross refer to D2121 2. Review of the laboratory policy Laboratory Proficiency Testing revealed "all results less than 100% must be investigated and remediated appropriately." 3. Review of the laboratory corrective actions for the AAB for the 2018 3rd event revealed no documentation of remedial action for the above PT failures. 4. An interview with the primary testing person on 3/19/19 at 1315 hours in the laboratory confirmed the above findings.
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 review of the 2017 and 2018 personnel records, laboratory policies, and confirmed in interview, the laboratory failed to document the competency assessment for 1 of 1 technical consultants. Findings were: 1. Review of the laboratory records available revealed no documentation of the competency assessment for 1 of 1 technical consultant. 2. An interview with the primary testing person on 3/19/19 at 0920 hours in the laboratory confirmed the above findings.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236.

	This STANDARD is not met as evidenced by: A review of the laboratory's American Association of Bioanalytsts proficiency testing from 2017 and 2018 and confirmed in interview, the laboratory quality assessment policies and procedures failed to identify, monitor and correct problems in the general laboratory systems. Refer to D2121, 2087
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, observations, patient results, and confirmed in interview, the laboratory failed to follow their policy for specimen labeling. Findings were: 1. Review of the laboratory policy Specimen Collection revealed "specimens will not be accepted unless they are properly labeled accurately with required information: patient name, patient ID number, date and time collection, collector's ID." 2. Random review of the samples stored in the laboratory refrigerator from 3/12/19 to 3/19/19 revealed 1 of 10 CBC specimens labeled with just the patient name. Refer to CBC patient alias list. 3. Random review of the samples stored in the laboratory refrigerator from 3/12/19 to 3/19/19 revealed 10 of 10 CBC specimens with no documentation of the date and time of collection or collector's ID. Refer to CBC patient alias list. 4. Review of the laboratory patient results revealed the laboratory performed the CBC for all of the above specimens. 5. An interview with the technical consultant on 3/19/19 at 1305 hours in the laboratory confirmed the above findings. She acknowledged that the laboratory
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment plan, and staff interview, it was revealed the laboratory's quality assessment plan failed to identify and correct issues in pre-analytic systems. Refer to D5311
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 the manufacturer's instructions, laboratory policy, quality control records, laboratory test records, and confirmed in interview, the laboratory failed to follow its laboratory policy to resolve flags for quality control and CBC (complete blood count) patient testing on the Beckman Coulter Act2 Diff hematology analyzer. Findings were: 1. Review of the Beckman Coulter's Act Diff 2 analyzer's Operators manual (PN 4237495B, June 2003) revealed in the Service and Maintenance chapter is a section titled "Parameter Codes and Flags." The manufacturer's instructions stated "If any flag appears, review the results according to your laboratory's protocol." The following flags also include the following instructions: "3" = Differential parameter failed the internal regional size distributional criteria at region 3. Action = Verify results according to laboratory's protocol. "M" = Differential parameter failed the internal regional size distributional criteria at multiple regions. Action = Verify results according to laboratory's protocol. "L" = Low result. For Patient samples, result is lower than the low limit for that patient sample. Action = Follow the laboratory's protocol. "H" = High result. For Patient samples, the result is higher than the upper limit for that patient sample. Action = Follow the laboratory's protocol. "*" = If on WBC (white blood count) and Differential only, 35 fL (fluid level)' count interference check failed. Possible interference with the WBC count. Action = Thoroughly mix and rerun the sample. = Verify results according to your laboratory's protocol 2. Review of the laboratory policy ZMC002 Coulter Act 2Diff revealed "results that contain error codes or are above the instrument linear limits are repeated. If the second run duplicates errors send samples to the reference laboratory for confirmatory analysis...some error codes may be eliminated by cleaning the instrument. See the operator's manual for instructions. "*" review results; mix and repeat "X" aperture alert: clean and repeat analysis. Send for confirmation if requested by clinician. "1,2,3,4,M" differential parameters failed the internal regional size distribution criteria in one or more regions: repeat analysis. If the error code persists and the clinician requests the sample will be sent for confirmation. 3. Random review of the quality control records from November 2018 to March 2019 revealed 7 of 20 days with no documentation of the laboratory resolving flags for quality control. 2/15/19: Level L - * 2/11/19: Level L - * 1/31/19: Level H - * 1/30/19: Level L - * 1/29/19: Level L - X 1 /17/19: Level L - * 11/16/18: Level H - * 4. Random review of the laboratory test records from November 2018 to March 2019 revealed 20 of 45 patient test records with flags and no documentation of the laboratory resolving the flags prior to reporting the CBC test. 3/13/19 Patient 147674: * Patient 98998: M Patient 98998: M 2/28/19 Patient 140865: 3 1/17/19 Patient 78403: 3 Patient 127375: 3 Patient 146484: M 1/9/19 Patient 145370: M Patient 135352: 3 12/20/18 Patient 126567: M, * Patient 96317: 3 Patient 93481: M, * 12/6/18 Patient 95901: 1, * Patient 93588: 3 Patient 99685: * Patient 79769: * 11/27/18 Patient 95630: 3 Patient 119785: M Patient 91516: M Patient 98918: * 5. An interview with the primary testing person on 3/19/19 at 1450 hours in the laboratory confirmed the above findings. She was unaware she had to resolve the flags prior to reporting the results.
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 observations and confirmed in interview, the laboratory failed to ensure that expired supplies were not available for use. Findings were: 1. Observations on 3/19/19 at 1000 hours revealed 2 racks of expired blue tops (BD Vacutainer sodium citrate) lot 8099549, exp 1/31/19. 2. An interview with the primary testing person on 3/19/19 at 1010 hours confirmed the above findings. She stated that the laboratory should have discarded them.
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 the chemistry verification studies, and verified by interview the laboratory failed to perform a complete verification study for Thyroid Stimulating Hormone (TSH) on the AFIAS-6/SP analyzer. Findings were: 1. A review of the AFIAS-6/SP analyzer for TSH verification studies revealed no documentation of a normal patient ranges study to verify the reference range 0.45 - 4.50 uIU/mL. 2. A review of the AFIAS-6/SP analyzer for TSH verification studies revealed no documentation of a reportable range study to verify the manufacturer reportable range of 0.07 - 80 uIU/mL. 3. An interview with the primary testing person on 03/20/19 at 1100 hours in the laboratory confirmed the above findings.
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 review of the laboratory records and confirmed in interview, the laboratory failed to document twice annually the calibration verification for all the chemistry testing on the Alfa Wassermann ACE Axcel chemistry analyzer for 2018. Findings were: 1. Review of the laboratory records revealed the laboratory performed the following 20 analytes on the Alfa Wassermann ACE Axcel Clinical chemistry analyzer: Sodium (NA) Potassium (K) Chloride (CL) Carbon Dioxide (CO2) alkaline phosphatase (ALP) aspartate aminotransferase (AST) Alanine Aminotransferase (ALT) Total Bilirubin (TBILI) Calcium (CA) Glucose (GLU) blood urea nitrogen (BUN) Creatinine (CREA) Phophorus (PHOS) Uric Acid (UA) Albumin (ALB) Total Protein (TP) Triglyceride (TRIG) Cholesterol (CHOL) High density lipoprotein (HDL) Low density lipoprotein (vLDL) 2. Review of the calibration records for the above analytes revealed all of the analytes used 2 or less calibrators; therefore, required calibration verification twice annually. 3. Review of the laboratory records available revealed the laboratory performed calibration verification for the above analytes on 11/2018. No documentation of the first calibration verification for 2018 was available for review. 4. An interview with the 03/20/19 at 1120 hours confirmed the above findings.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory test records, quality control records, manufacturer's instructions, and confirmed in interview, the laboratory failed to document a complete INDIVIDUALIZED QUALITY CONTROL PLAN (IQCP) for the TSH testing on the AFIAS-6/SP analyzer. (risk assessment, quality control plan, quality assessment plan) Findings were: 1. Review of the laboratory IQCP for TSH on the AFIAS-6/SP analyzer revealed no documentation of the risk assessment evaluation that included all five components and all phases of testing. 2. Review of the laboratory IQCP for TSH on the AFIAS-6/SP analyzer revealed no documentation of the Quality Control Plan. 3. Review of the laboratory IQCP for TSH on the AFIAS-6/SP analyzer revealed no documentation of the Quality Assessment Plan. 4. An interview with the primary testing person on 3/20/19 at 1105 hours in the laboratory confirmed the above findings. She was unaware the laboratory was required to perform an IQCP.
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 the quality control records, laboratory patient logs, and confirmed in interview, the laboratory failed to document 2 acceptable levels of controls prior to reporting patient test results for Thyroid Stimulating Hormone (TSH) analysis on the AFIAS-6/SP analyzer. Findings were: 1. Random review of the laboratory quality control report from October 2018 - February 2019 for the AFIAS-6/SP analyzer revealed no quality control performed on the following days for TSH: 10/26/18; 11/6 /18; 11/13/18; 11/14/18; 12/6/18; 12/7/18; 12/11/18; 1/21/19; 1/28/19; 1/31/19; 2/4 /19. 2. Random review of the laboratory patient logs from October 2018 - February 2019 revealed the laboratory performed 12 patient testing without documentation of 2 acceptable levels of quality control: 10/26/18 (87074); 11/6/18 (28594); 11/13/18 (144491); 11/14/18 (99811); 12/6/18 (54339); 12/7/18 (93697); 12/11/18 (84205); 1 /21/19 (27321); 1/28/19 (145228); 1/31/19 (147605); 2/4/19 (147507). 3. An interview with the primary testing person on 3/20/19 at 1115 hours in the laboratory confirmed the above findings. She was unaware her quality control study was insufficient. She only performed external quality control monthly.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Review of the manufacturer's instructions, laboratory policy, quality control records, patient test records, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions to establish the acceptable range for the quality control testing on the Alfa Wassermann chemistry analyzer. Findings were: 1. Random review of the package inserts for the reagents used in the Alfa Wassermann chemistry analyzer revealed under quality control "each laboratory should establish its own mean and precision parameters" for 6 of 6 reagents. ACE Albumin Reagent (REF SA2001) P/N 909060-1, Rev D 9/17 ACE Uric Acid (REF SA 1025, RX1025) P/N 909060-31, Rev c 1/18 ACE Totabl Bilirubin (REF SA1008) P/N 909060-25, Rev C 9 /17 ACE Calcium-Arsenazo (REF SA1009) P/N 909060-7 Rev D 9/17 ACE Creatinine Reagent (REF SA1012) P/N 909060-12 Rev E 9/17 ACE Total Protein

	(REF SA1022) P/N 909060-28 Rev D 12/17 2. Review of the Alfa Wassermann Chemistry control (REF C1-5, C1-4) revealed under assay values "each laboratory should establish its own mean and precision parameters." 3. Review of the laboratory policy ACE Axcel Clinical Chemistry System under use of quality control material revealed "each laboratory should establish its own mean and precision parameters." 4. Review of the laboratory quality control records for the Alfa Wassermann chemistry analyzer revealed no documentation of the laboratory establishing its acceptable range for the following controls. Level 1 Chemistry Control lot 1213UNCM , exp 5/31/21 Level 2 Chemistry Control lot 937UECM, exp 5/31/21 5. Random review of the laboratory test records from 11/2018 to 03/2019 revealed the laboratory performed chemistry testing on the following dates without establishing the quality control acceptable ranges : 3/8/19 142637 140969 3/11/19 87048 119386 2/28/19 144805 98070 95655 2/21/19 119492 84286 12/20/18 89894 126567 121446 12/6/18 54339 77886 11/27/18 66920 144912 125292 6. An interview with the primary testing person on 3/19/19 at 1550 hours in the laboratory confirmed the above findings. She was unaware the laboratory was required to establish its own acceptable ranges for the chemistry quality control.
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 review of American Association of Bioanalyts (AAB) proficiency testing records and confirmed in interview, the laboratory director failed to ensure that all proficiency testing reports received were reviewed to evaluate the laboratory's performance and to identify any problems that required corrective action. Refer to D5291
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, American Association of Bioanalysts (AAB) proficiency testing (PT) records, laboratory records, and confirmed in

	interview, the laboratory director failed to ensure the laboratory performed an approved corrective action plan for PT test results with unacceptable (less than 80%) scores. Refer to D2094, D2128
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 the manufacturer's instructions, laboratory quality control (QC) records, and confirmed in interview, the laboratory failed to ensure the laboratory established and maintained a quality control program. Refer to D5445, D5447
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on a review of quality control records and staff interview, it was revealed that the technical consultant failed to ensure an appropriate quality control program was maintained throughout the testing process. refer to D5469
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the CMS form 209, personnel records from 2017 - 2018 and verified by interview, the Technical Consultant failed to perform the competency evaluations for 2 of 3 testing personnel. (TP #1, TP#2) Findings were: 1. A review of the facility's personnel files revealed 1 of 3 testing personnel (TP #1) had a 2018 competency assessment performed by TP #2, who did not meet the requirements as a technical consultant. Testing person #2 has a high school degree. 2. A review of the facility's personnel files revealed 1 of 3 testing personnel (TP #2) had a 2017 competency assessment performed by TP #3, who did not meet the requirements as a technical consultant. Testing person #3 has an associate's degree. 3. An interview with

	the primary testing person on 3/19/19 at 1005 hours in the laboratory confirmed the above findings. key: CMS - Centers for Medicaid and Medicare Services