Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0999705	12/16/2021
Name of Provider or Supplier	**Street Address, City, State**	
Accutox, Inc/Stat Lab	105 Ih 10 South, Beaumont, 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	An onsite recertification survey was performed on 12/15/21 to 12/16/21. The laboratory was surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780 resulting in the following IMMEDIATELY JEOPARDY findings: D5300 493.1240: Pre-Analytic Systems The immediate jeopardy conditions were abated as evidenced by a letter signed by the laboratory director on 12/16/21. See the attached letter. and the following CONDITION LEVEL findings: D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: . Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) Micrographs , laboratory policy, and confirmed in interview, the laboratory failed to test PT samples the same number of times that it routinely tests patient samples for four out of six hematology events reviewed for 2020 and 2021. The findings include: 1. Review of the AccuTox, Inc. StatLab Proficiency Testing policy stated the following: "Run the proficiency testing exactly as you would run a patient. It is okay to repeat a questionable result if you would normally repeat a patient, but it is not okay to run all rests in duplicate." 2. Review of the API Hematology events for 2020 and 2021 list the following testing personnel (TP) performing identification (testing) as documented on the micrographs. 2020 - Hematology 2nd Event - Testing performed by TP7 and TP6 Blood Cell Identification (BCI)-08, BCI-10 2020 - Hematology 3rd Event - Testing performed by TP1 and TP7 BCI-11, BCI-12, BCI-13,

	BCI-14, BCI-15 Erythrocyte Cell Identification (ECI)-11, ECI-12, ECI-13, ECI-14, ECI-15 Urine Sediment (US)-05, US-06 Urine Eosinophils (UE)-03 2021 - Hematology 1st Event - Testing performed by TP1 and TP7 BCI-01, BCI-02, BCI-03, BCI-04, BCI-05 ECI-01, ECI-02, ECI-03, ECI-04, ECI-05 US-01, US-02 UE-01 2021 - Hematology 3rd Event - Testing performed by TP1 and TP3 BCI-12, BCI-13, BCI-14 ECI-11, ECI-12, ECI-13 US-05, US-06 UE-03 3. In an interview on 12/15/2021 at 11:45 hours, in the office, the laboratory director stated that the hematology micrographs should have only been performed by one testing personnel, and that patient slides are not reviewed by more than one testing personnel before resulting. .
D2093	ROUTINE CHEMISTRY CFR(s): 493.841(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on review of laboratory policy, American Proficiecny Institute (API) proficiency testing (PT) results, and confirmed in interview, the laboratory failed to return proficiency testing results to the proficiency testing program within the time frame specified resulting in a score of 0% for the one of six core chemistry PT events reviewed in 2020 and 2021. The findings include: 1. Review of laboratory policy titled "Proficiency Testing" paragraph 6 has the following statement: "Be sure to have all results in by the date on forms. Late results will not be graded." 2. Review of the laboratories PT 'Performance Review and Corrective Action form' had the following statement regarding PT result submissions, and subsequent 0%, for the 2020 Chemistry Core 3rd Event: "Toxicology was performed but not reported. All results were within the peer group range." 3. Review of API PT score sheet for the 2020 Chemistry Core 3rd Event had the following seven analyte failures, graded with a 0%, as a result of the missed submission: Carbamazepine Digoxin Lithium Phenobarbital Phenytoin Theophylline Valproic Acid 4. In an interview with on 12/15/2021 at 10:00 hours in the office, the lab director stated that the PT event missed the submission deadline, and that there had been some disorganization in the past.
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 laboratory policy, proficiency testing (PT) Failure Investigation forms, and confirmed in interview, the laboratory failed to follow its policy for the remediation of patient specimens for two out of six Chemistry PT events reviewed. The findings include: 1. Review of the AccuTox, Inc. StatLab Proficiency Testing

	policy stated the following: "When the results are returned, review for any missed analyte. Fill out a Proficiency Failure Investigation form. 1. Rerun proficiency specimens. 2. Rerun patient specimens that contain the same tests as the missed proficiency tests. 3. Determine if patient testing has been compromised. 4. Attach copies of the Q.C. done on the day of original testing. 5. Analyze what went wrong so it will not happen again." 2. Review of the American Proficiency Institute (API) routine scores list the following failures with no documented patient remediation on the Proficiency Failure Investigation form for two out of six Chemistry PT events reviewed: 2020 - Chemistry 2nd Event: Glucose (non-Waived) - 40% 2021 - Chemistry 3rd Event: CK, ISO - 60% 3. In an interview on 12/15/2021 at 11:45 hours in the office, the laboratory director confirmed that patient remediation was not performed for PT failures as stated by the laboratory policy, and that he would have it added to the Proficiency Failure Investigation form. .
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the manufacturer's instructions, review of the laboratory's policy and patient test records, and confirmed in interview, the laboratory failed to meet the requirements for preanalytic systems. Refer to D5309, D5311
D5309	TEST REQUEST CFR(s): 493.1241(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately. This STANDARD is not met as evidenced by: Based on review of the laboratory and patient test records from June to November 2021, and confirmed in interview, the laboratory failed to ensure the date and time of collection transcribed onto the laboratory information system (LIS) matched the information on the patient final report for five of twenty chemistry and hematology samples reviewed. Findings included: 1. Random review of the laboratory and patient test records from June to November 2021 revealed the following five of twenty Complete Metabolic Panel (CMP) and Complete Blood Count (CBC) patient final reports whose time of collection did not match the time of collection on the requisition. Accn #804034: date and time of collection 10/22/21 at 1007 hours on requisition; final report date and time of collection 10/22/21 at 1107 hours Accn #788004: date and time of collection 07/09/21 at 1009 hours on requisition; final report date and time of collection 07/09/21 at 1129 hours Accn #806147: date and time of collection 10/22/21 at 0943 hours on requisition; final report date and time of collection 10/22/21 at 1031 hours Accn #799886: date and time of collection 09/15/21

	at 0900 hours on requisition; final report date and time of collection 09/15/21 at 1044 hours Accn #794580: date and time of collection 08/17/21 at 1216 hours on requisition; final report date and time of collection 08/17/21 at 1319 hours 2. An interview with the laboratory director via phone on 1/14/22 at 0845 hours confirmed the above findings. He acknowledged that the time on the requisition should be entered correctly in their LIS and should match on the final report.
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 manufacturer's instructions, laboratory and patient test records from July to December 2021, and confirmed in interview, the laboratory failed to follow its policy and process Ammonia specimens within 30 minutes for 13 of 15 samples reviewed. Findings included: 1. Review of the laboratory policy Ammonia with an effective date of 1/28/20 under specimen collection and preparation revealed "perform analysis within 20-30 minutes of venipuncture or freeze separated plasma immediately." 2. Review of the laboratory policy Specimen Collection Manual under specimen requirements revealed "Ammonia: stability, 30 minutes on ice" 3. Random review of patient laboratory and final reports from July 2021 to December 2021 revealed the following 13 Ammonia specimens that were collected and received and analyzed beyond the 30 minutes stability. Acc# 812223: collected date 12/08/21 at 1058 hours; received 12/08/21 at 1146 hours; elapsed time 48 minutes Acc# 801318: collected date 9/22/21 at 1226 hours; received 9/22/21 at 1411 hours; elapsed time 1 hour, 45 minutes Acc# 806147: collected date 10/22/21 at 0943 hours; received 10/22 /21 at 1031 hours; elapsed time 48 minutes Acc# 796707: collected date 08/26/21 at 0650 hours; received 08/26/21 at 0755 hours; elapsed time 1 hour, 5 minutes Acc# 799164: collected date 09/09/21 at 0750 hours; received 9/09/21 at 0912 hours; elapsed time 1 hour, 22 minutes Acc# 803546: collected date 10/07/21 at 0721 hours; received 10/07/21 at 0821 hours; elapsed time 1 hour Acc# 809766: collected date 11 /18/21 at 0721 hours; received 11/18/21 at 0809 hours; elapsed time 48 minutes Acc# 801407: collected date 9/23/21 at 0734 hours; received 9/23/21 at 0821 hours; elapsed time 47 minutes Acc# 807788: collected date11/04/21 at 0656 hours; received 11/04 /21 at 0802 hours; elapsed time 1 hour, 6 minutes Acc# 805920: collected date 10/21 /21 at 0726 hours; received 10/21/21 at 0824 hours; elapsed time 58 minutes Acc# 810752: collected date11/29/21 at 1100 hours; received 11/29/21 at 1403 hours; elapsed time 3 hours, 3 minutes Acc# 789241: collected date 07/19/21 at 01330 hours; received 07/19//21 at 1414 hours; 44 minutes Acc# 801414: collected date 09/23/21 at 0822 hours; received 09/23/21 at 0915 hours; elapsed time 53 minutes 4. An interview with the laboratory director on 12/16/21 at 1150 hours in the office confirmed the above findings. He acknowledged that the laboratory does not reject specimens that are received beyond the 30 minute stability.
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 policy, laboratory records, and confirmed in interview, the laboratory quality assessment policies failed to identify and correct problems in the preanalytic systems. Refer to D5309, D5311
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: I. Based on review of laboratory procedure, patient test results, and confirmed in interview, the laboratory failed to have specific instructions for result interpretation of the slide review procedure for three out of nine CBC (complete blood count) patients reviewed for random dates in August, October, and December 2021 1. Review of laboratory policy titled 'Criteria For Performing Manual Scan/Differential' section 'A Slide Will Be Made for Review' paragraph 2 stated: "If there are any clinically significant findings or abnormal/immature WBCs are present or if the provider has requested the specimen will be sent to St. Elizabeth Hospital or Diagnostic Pathology Associates for review. Examples of clinically significant findings: 1. Banded neutrophils >10 2. Any abnormal or immature WBC other than banded neutrophils. 3. NRBCs >5 (see Corrected WBC Due to Presence of NRBCs procedure) 4. And RBC morphology not included in the Peripheral Blood Smear Guidelines. (Sickle cells, parasites, etc.)" 2. Review of patient final reports revealed the following three out of nine patients with slide review criteria: 79339 - Tested 8/11/2021 - Notes: 'Slide Reviewed-Few Bands Seen' 793229 - Tested 8/11/2021 - Notes: 'Slide Reviewed - Platelets Decreased - Reactive Lymphs-Noted' 793246 - Tested 8/11/2021- Notes: ' Slide Reviewed - Occ'l Band' 3. Surveyor queried the laboratory director on 12/16 /2021 at 10:00 hours, about the specific criteria for the reflex in regards to slides with banded neutrophil including the number of cell fields reviewed before resulting, and

the quantitative definition for the qualitative results reported (i.e 'occ'l, and 'few'). The laboratory director stated that no specific number of cell fields had been established for review, and that no quantitative definitions for qualitative results were established. 4. In an interview on 12/16/2021 at 10:05 hours in the laboratory, the laboratory director confirmed that the above testing instructions and definitions were missing from the procedure manual. II. Based on review of the manufacturer's instructions, laboratory documents, and confirmed in interview, the laboratory failed to have a policy in place for the lot to lot method correlation for two of two coagulation test prothrombin time (PT) and activated partial thromboplastin time (APTT) for three of three reagent lot roll over reviewed in 2020 and 2021 and normal patient ranges for one of one new lot prothrombin time (PT) reagent reviewed for 2021. The findings include: 1. Review of the Siemens Dade Innovin IFU (2013-11) section 'Definitions of Symbols' had the following statement; " ** The mean normal PT (MNPT) is defined as the mean value of the normal range. It must be determined specifically for each thromboplastin lot using the method used to analyze the patient samples and, where appropriate, using the coagulation analyzer used for the analysis. Follow appropriate laboratory guidelines for the establishment of an MNPT, it applicable. For US customers the appropriate CLSI guideline is recommended." 2. Review of laboratory lot roll over documents for 2020 and 2021 have the following three reagent lot roll overs documented: 2020: One Reagent Lot Rollover for Dade Innovin PT reagent: Date of testing: 3/2/2020 New Lot: Innovin 54755B, Expiration: 6/6/2022 Old Lot: Innovin 549750E, Expiration: 3/7/2022 2021: Two reagent lot rollovers for Dade Innovin PT, and Dade Actin APTT reagent: Date of Testing: 6/14/2021 New Lot: Innovin 549783, Expiration 7/14/2023 New Lot: Dade Actin 562649B, Expiration 2 /10/2023 Old Lot: Innovin 54755B, Expiration 6/6/2022 Old Lot: Dade Actin 55699A, Expiration 8/4/2021 2. Surveyor queried 12/15/2021 at 14:30 hours for documentation of coagulation reagent lot rollover. The laboratory director provided a file folder with loose leaf papers of 22 patient questionnaires, patient results, a geometric mean printout, and a printout of untitled instructions that stated: "New Innovin: Run 10 patients on both old and new lot of Innovin. Results must agree within +/- 5%. Also Collect and run 20 normal patients (10 Male, 10 Female). Calculate the NPM [Normal Patient Mean] using the NPM spreadsheet. Enter the new NPM and ISI in the CA 500. New Actin: Run 10 patients on both old and new lot of Actin. Results must agree within +/- 5%. New Ci-trol: Run new and old lot of QC 2x5 days." 3. Further review of the laboratory records revealed documentation for the NPM. "Innovin Lot# 549783 Expires 07/14/2023 - ISI = 1.08 PT: 11.6, 10.4, 11.0, 9.9, 9.7, 10.5, 9.4, 10.2, 10.4, 10.3, 9.9, 10.1, 9.4, 9.9, 10.3, 9.9, 9.8, 9.6, 9.9, 10.0, 9.9 Mean - 10.1 Geo Mean - 10.1 Date Performed 6/14/2021 Signed by the laboratory director" 4. Surveyor queried 12/15/2021 at 14:55 hours, if the above untitled instructions were the laboratories policy for the coagulation reagent lot rollover; the laboratory director stated they were loose instructions, and that a policy had not been established. 5. Review of the CMS116 section VIII Non-Waived Testing lists the total annual volume for the specialty Hematology at 115,606. 6. In an interview on 12/15 /2021 at 14:57 hours, in the laboratory office, the laboratory director confirmed that a formal policy was not in place for the lot to lot method correlation for PT and APTT reagent change. III. Based on review of coagulation reagent and quality control instructions for use (IFU), laboratory documents, the CMS116, and confirmed in interview, the laboratory failed to have a policy in place to establish the acceptable ranges for new quality control (QC) lot reagents for two of two QC lot reagents reviewed in 2021, for the two coagulation test prothrombin time (PT) and activated partial thromboplastin time (APTT). Findings included: 1. Review of the Siemens Dade Ci-Trol Coagulation Control Level 1 IFU (2015-10) section "Specific Performance Characteristics" stated: "Studies of Ci-Trol Level 1 in normal clinical

	laboratory usage show an intralaboratory variation in a total CV of approximately 3% for prothrombin times and approximately 4% for activated partial thromboplastin times. Since laboratory control materials are used for the effective monitoring of performance of a coagulation test, each laboratory should establish its own level of performance to monitor quality assurance." 2. Review of the Siemens Dade Ci-Trol Coagulation Control Level 3 IFU (2015-10) section "Specific Performance Characteristics" stated: "Studies of Ci-Trol Level 3 in normal clinical laboratory usage show an intralaboratory variation in a total CV of approximately 5% for prothrombin times and approximately 4% for activated partial thromboplastin times. Since laboratory control materials are used for the effective monitoring of performance of a coagulation test, each laboratory should establish its own level of performance to monitor quality assurance." 3. Review of laboratory documents for the following two QC reagent in use for 2021: Ci-Trol Control 1, Lot# 564804, EXP 5/19/2022 Ci-Trol Control 3, Lot# 556523, EXP 7/2/2022 4. Surveyor queried 12/15/2021 at 14:30 hours for documentation of the establishment of the new lot Ci-Trol QC ranges. The laboratory director provided a file folder with lose leaf papers of 22 patient questionnaires, patient results, untitled instructions, a geometric mean printout and the following two "New Lot Of PT Reagent Worksheet" that stated the following: a. New Reagent of PT Reagent Worksheet "Quality Control: New Innovin Lot# 549755B Exp 6/6/2022 Level 1 Control Range - Lot# 564804E EX: 5/19/2022 - 10.4 Level 2 Control Range - Lot# 556523A EX: 7/2/2022 - 46.9 Reviewed & Approved By: [laboratory director] Date: 3/3/2020" b. Old Reagent of PT Reagent Worksheet "Quality Control: Old Innovin Lot# 549750E Level 1 Control Range - Lot# 564804E EX: 5/19/2022 - 10.7 Level 2 Control Range - Lot# 556523A EX: 7/2/2022 - 45.8 Reviewed & Approved By: [laboratory director] Date: 3/3/2020" 5. Surveyor queried 12/15/2021 at 14:45 hours for the laboratory procedure for the establishment of new coagulation QC ranges. The laboratory director stated that no policy was available. 6. Review of the CMS116 section VIII Non-Waived Testing lists the total annual volume for the specialty Hematology at 115,606. 7. In an interview on 12/15/2021 at 15:00 hours, in the office, the laboratory director confirmed that the laboratory had no policy in place for the establishment of acceptable control ranges for new coagulation QC.
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 calibrator and quality control records from 2020-2021 and confirmed in interview, the laboratory failed to document calibration verification semiannually for 10 of 10 analytes on the Roche Cobas chemistry analyzer for 2020 and 2021. Findings were: 1. Random review of the laboratory Roche Cobas calibration records from 2020 - 2021 revealed the following 10 of 10 analytes used 2 or less calibrators. BUN CA GLUC3 LIPC MG2 NH3 TBIL HDL CREA TP 2. Review of the laboratory quality control records from 2020 to 2021 revealed the above analytes are tested with two levels of quantitative controls each day of patient testing. 3. Review of the calibration verification records from 2020 - 2021 revealed the laboratory failed to document 1 of 2 calibration verifications for 10 of 10 analytes reviewed in 2020 and 2021. BUN CA GLUC3 LIPC MG2 NH3 TBIL HDL CREA TP 4. Review of the laboratory records revealed the laboratory performed 302,734 chemistry tests annually. 5. An interview with the laboratory director on 12/16/21 at 1030 hours in the office confirmed the above findings. Key: BUN - blood urea nitrogen CA - Calcium GLUC3- Glucose LIPC - Lipase MG2- Magnesium NH3 - Ammonia TBILI - Total Bilirubin CREA - Creatinine TP - Total Protein
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory quality control and patient test records from September 2020 to November 2021, and confirmed in interview, the laboratory failed to establish quality control procedures that can detect immediate errors for four of twenty analytes (Estradiol, Vitamin B12, Prealbumin, and Ammonia) on the Roche Cobas 6000 chemistry analyzer. Findings were: 1. Random review of the quality control records for the Estradiol, Vitamin B12, Prealbumin, and Ammonia testing from September 2020 to November 2021 revealed the laboratory used the following acceptable ranges: Liquicheck Immunoassay Plus lot 85231, exp 2/28/22 Estradiol 18-50.4 pg/mL Vitamin B12: 230 - 358 pg/mL Liquicheck Immunology Control lot 68931, exp 8/31/21 Prealbumin 10.3 - 16.3 mg/dL lot 68933, exp 8/31/21 Prealbumin 27.6 - 39.8 mg/dL Liquicheck Ethanol/Ammonia Control lot 54313, exp 6/30/21 Ammonia 151.8 - 434.62 ug/dL 2. Review of the laboratory records available revealed no documentation of a control procedure to establish the above ranges and to ensure it was able to detect immediate errors. 3. Review of the laboratory records revealed the

	laboratory performed 302,734 chemistry tests annually. 4. An interview with the laboratory director on 12/16/21 at 1030 hours confirmed the above findings. He acknowledged that the ranges used above were too wide and should be re-evaluated.
D5461	CONTROL PROCEDURES CFR(s): 493.1256(d)(6)(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--Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on review of reagent change log, the CMS-116, and confirmed in interview, the laboratory failed to perform quality control (QC) after a complete change of reagents for the Sysmex xs-1000i hematology analyzer for 23 of 23 months reviewed. The findings include: 1. Review of the reagent change log for January through December 2020, and January through November 2021 list the following number of times a reagent was changed on the Sysmex xs-1000i hematology analyzer. 2020 - January through December Sulfolyser - 16 times CellPack - 27 times Stromatolyser - 4DS - 13 times Stromatolyser - 4DL - 8 times 2021 - January through November Sulfolyser - 18 times CellPack - 30 times Stromatolyser - 4DS - 17 times Stromatolyser - 4DL -9 times 2. Review of the CMS116 section VIII Non-Waived Testing lists the total annual volume for the specialty Hematology at 115,606 patients tested annually. 3. In an interview on 12/16/2021 at 10:00 hours in the laboratory, a testing personnel confirmed that QC was not ran after reagent change on the Sysmex xs-1000i hematology analyzer. .
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: Based on review of the manufacturer's instructions, review of laboratory and patient test records from July 2021 to November 2021, and confirmed in interview, the laboratory failed to establish the acceptance criteria of two of seven quality control materials for Vitamin B12, FSH, and Prealbumin testing on the Roche Cobas 6000

	chemisty analyzer. Findings included: 1. Review of the manufacturer's instructions under assignment of values revealed "the mean values and corresponding +/- 3 SD ranges in the Assignment of Values Data Charts were derived from replicate analysis and are specific for this lot of product...it is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides." Liquicheck Immunoassay Plus (2021-03, 4203-00) Liquicheck Immunology Control (2021-03, 3200-00) 2. Review of the quality control records for Vitamin B12, FSH, and Prealbumin testing from July 2021 to November 2021 revealed the laboratory used the following quality controls and corresponding acceptable ranges: Liquicheck Immunoassay Plus (Vitamin B12) lot 85271: 224-327 pg/mL lot 85272: 449-595 pg /mL lot 85273: 585-757 pg/mL Liquicheck Immunoassay Plus (FSH) lot 85271: 5.75-7.41 mIU/mL lot 85272: 15.8-20.2 mIU/mL lot 85273: 40.9-52.2 mIU/mL Liquicheck Immunology Control (Prealbumin) lot 68971: 11.2-16.1 mg/dL lot 68972: 21.9-30.5 mg/dL lot 68973: 31.1-42.6 mg/dL 3. Review of the laboratory records available revealed no documentation of the laboratory establishing the above acceptable ranges. No policy was provided for review. 4. Review of the laboratory records revealed the laboratory performed 302,734 chemistry tests annually 5. An interview with the laboratory director on 12/16/21 at 1030 hours in the office confirmed the above findings. He acknowledged that the laboratory used the package insert ranges and did not establish their own.
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 instrument verification records, review of patient final reports, and confirmed in interview, the laboratory director failed to provide overall management and direction of the laboratory. (refer to D6007and D6020)
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 a review of laboratory pre-analytic systems it was revealed that the laboratory director failed to ensure that testing systems performed in the laboratory provided quality laboratory services for all aspects of test performance in chemistry. Refer to D5311

D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: . Based on review of laboratory policy, review of corrective action forms, and confirmed in interview, the laboratory director failed to ensure that proficiency testing (PT) results were returned within the timeframes established by the PT program for four out of sixteen PT events reviewed for 2020 and 2021. The findings include: 1. Review of the laboratory 'Proficiency Testing' policy stated the following: "Record all results on the answer form and sign the attestation statement for each analyte performed. Results are entered on the internet at www.api-pt.com. Be sure to have all results in by the date on the forms. Late results will not be graded. 2. Review of the laboratories PT 'Performance Review and Corrective Action form' revealed the following statements regarding PT result submissions, and subsequent failures in 2020 and 2021. 2020 - Hematology 1st Event: Performance review and corrective action form, signed by LD 4/24/2020 "Failed to report UA01 & UA02 Protein, glucose, and specific gravity." 2020 - Chemistry Core 3rd Event: Performance Review and Corrective action form, signed by the LD 10/8/2020 "Toxicology was performed but not reported." 2021 - Chemistry Core 3rd Event: Performance Review and Corrective action form, signed by the LD 10/18/2021 "Failed to submit core verification by deadline." 2021 - Chemistry Miscellaneous 1st Event: Performance Review and Corrective action form, signed by the LD 6/14/2021 "Failed to submit results." 3. In an interview with on 12/15/2021 at 10:00 hours in the office, the Lab Director stated that several PT events have missed the submission deadline, and that there had been some disorganization in the past. .
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 laboratory quality control (QC) records and confirmed in interview, the laboratory director failed to ensure the laboratory maintained a quality control program. Refer to D5441, D5469