Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0999705	03/21/2023
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 survey conducted 03/21/2023 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on surveyor observations, manufacturers instructions, review of the environmental temperature logs from January 2023 to March 2023, and confirmed in interview, the laboratory failed to ensure the proper storage conditions for two of three Biorad controls for the Roche Cobas chemistry analyzer per the manufacturer's instructions. Findings were: 1. Surveyor observations on 03/21/2023 at 1120 hours in the laboratory, freezer #4 contained the following Biorad controls Biorad liquichek specialty Immunoassay Lot 64962, exp 02/28/2025 Biorad liquichek immunology lot 85703, exp 08/31/2024 2. Review of the package inserts for the above controls under Storage and Stability, it stated "this product will be stable until the expiration date when stored unopened at -20 to -70C." Biorad liquichek specialty Immunoassay Lot 64962, exp 02/28/2025 (2023-02, 5450-00S) Biorad liquichek immunology lot 85703, exp 08/31/2024 (2023-02, 3200-00S) 3. The laboratory temperature logs from January to March 2023 had improper acceptable temperature range of -15C to -50 C for the freezer. Based on a random review of the temperature logs from January to March 2023, there were ten of sixty days with temperature higher than -20C. 02/13/2023 -19

	C 02/15/2023 -18C 02/21/2023 -19C 02/28/2023 -19C 03/07/2023 -19C 03/08/2023 -19C 03/10/2023 -18C 03/13/2023 -18C 03/17/2023 -19C 03/20/2023 -18C 4. Based on a review of the laboratory CMS 116, the laboratory performed 419540 chemistry tests annually. 5. An interview with the laboratory director on 3/21/2023 at 1240 hours in his office confirmed the above findings.
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 records from 2022 to 2023 and confirmed in interview, the laboratory failed to have documentation of monitoring quality control values over time for Roche quality controls for two of two analytes (Folate and Lipase) reviewed. Findings were: 1. Based on review of the 2022 to 2023 quality controls for Folate and lipase, the laboratory used the following lots of quality control. Folate level 1 - lot 59576300 level 2 - lot 59576500 Lipase level 1 - lot 49417300 level 2 - lot 53571900 2. No documenation was available for review of the laboratory monitoring the above quality controls over time. 3. Based on review of the CMS116, the laboratory performed 419540 chemistry tests annually. 4. An interview with the laboratory director on 3/21/2023 at 1245 hours in his office confirmed the above 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: Based on a review of laboratory policy, laboratory documents, laboratory quality control (QC) records, patient results, and confirmed in an interview, the laboratory failed to evaluate 168 patient test results to the last acceptable QC when QC failed to meet the laboratory's established criteria for acceptability for chemistry testing on the Roche Cobas 6000 chemistry analyzer reviewed in November and December 2022. The findings include: 1. Review of the laboratory policy titled "Quality Control"

	section "QC failure and patient remediation" stated the following instructions: "If any QC troubleshooting other than rerunning the original or new control is performed it is necessary to evaluate all patients results back to the last successful QC run for the analyte in question. Verify that patient test results are not clinically significantly affected. This will vary depending upon the analyte in question and severity of the QC failure. Contact the lab director if help is needed with this determination. All specimens with questionable results must be verified by rerun and clients must be notified of any corrections. Report any patient investigations on the Quality Assessment Problem Identification Form." 2. Review of the laboratory document titled "Cobas QC - QC Issue & Solution" had the following quality control issues whose resolutions were beyond rerunning the original or new control: November 2022: 11/16/2022 - A1C Corrective action: Repeated QC - Calibrated - new QC - Worked 22 patients were run since the last acceptable QC on 11/15/2022, the following 10 are a random sampling: 866871 866877 866915 866923 867020 867021 867082 867105 867078 866934 11/16/2022 - Ferritin Corrective action: Calibrated - OK 7 Patients ran since the last acceptable QC on 11/15/2022: 866871 866938 867032 867039 867082 867088 867103 December 2022: 12/2/2022 - ALT Corrective action: Calibrated - controls worked 72 patients were run since the last acceptable QC on 12/1/2022, the following 10 are a random sampling: 869095 869130 869189 869192 869220 869224 869231 869229 869308 869375 12/27/2022 - ALT Corrective action: recalibrate - ok 59 patients were run since the last acceptable QC on 12/22 /2022, the following 10 are a random sampling: 872461 872492 872524 872526 872538 872547 872537 872621 872677 872679 12/28/2022 - Ferritin Corrective action: recalibrate - okay 3 patients ran since the last acceptable QC on 12/27/20222 872768 872853 873023 12/29/2022 - Ferritin Corrective action: recalibrate - okay 5 patients ran since the last acceptable QC on 12/28/2022 873081 873088 873222 873226 873284 Surveyor queried if patient remediation had been performed and documented and none was provided. 3. In an interview on 3/21/2023 at 13:05 hours, in the conference room, the laboratory director confirmed that patient remediation to the last acceptable QC had not been performed for the above QC failures. KEY: ALT - alanine transaminase A1C - hemoglobin A1C
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 laboratory's CMS209, laboratory personnel records from 2022 and 2023 and confirmed in interview, the technical consultant failed to evaluate the competency of three of three testing personnel (testing person #1, 2, 3) for moderate complex testing in the specialties of chemistry, immunology and hematology. Findings included: 1. Review of the CMS209 confirmed that there were three testing personnel who performed nonwaived testing in chemistry, immunology, and hematology (TP#1, 2, 3). 2. Based on review of laboratory competency assessments from 2022, TP#3 performed the competency assessment for TP#1 (hire date 07/12 /2021) on 07/07/2022. No documentation was available for review to qualify TP#3 as a technical consultant. 3. Based on review of laboratory competency assessments from 2022, TP#1 performed the competency assessment for TP#3 (hire date 06/05/2018). No documentation was available for review to qualify TP#1 as a technical consultant.

	4. Based on review of laboratory competency assessments from 2022 and 2023, TP#1 and TP#3 performed the competency assessment for TP#2 (hire date 06/08/2022) in 08 /22/2022 and 02/102023. 5. An interview with the laboratory director on 03/21/2023 at 0950 hours confirmed the above findings. He also stated that there were no policy for competency assessments but agreed that the lab needed one.