

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0999705	(X3) Date Survey Completed 02/06/2025
Name of Provider or Supplier Accutox, Inc/Stat Lab	Street Address, City, State 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	The laboratory was found to be in compliance with 42 CFR Part 493, Requirements for Laboratories as a result of a recertification survey completed on 2/6/2025.
D5429	<p> MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) </p> <p> (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. </p> <p> This STANDARD is not met as evidenced by: Based on manufacturers instructions, laboratory records, and confirmed in interview, the laboratory failed to ensure the performance of all necessary main maintenance on the Roche Cobas 6000 for records reviewed in 2023 and 2024. The findings included: 1. Review of the Roche Cobas 6000 manufacturers included the following instrument maintenance to be completed for the c501 module and the e 601 module on the Roche Cobas 6000 chemistry analyzer: Cobas c 501 module Maintenance Log: Every 2 months Replace: ISE measuring cartridges Quarterly: Replace: ISE pinch valve tubing and ISE supper tubing Clean: Ultrasonic mixers Cobas e 601 module Maintenance Log Every 3 Months Replace: Pinch valve tubing 2. Review of the laboratory maintenance checklists for 2023 and 2024 did not include documentation of the following maintenance tasks: 2023 On the C 501 module, of the Roche Cobas 6000, the following quarterly maintenance was not documented for 2023: Replace: ISE pinch valve tubing Replace: ISE sipper tubing Clean: Ultrasonic mixers On the E 601 module, of the Roche Cobas 6000, the following maintenance to be performed every three months was not documented for 2023: Replace: Pinch valve tubing 2024 On the C 501 module of the Roche Cobas 6000, the ISE Measuring cartridges, to be replaced every two months, was last documented replaced on 6/4/2024. No additional documentation that the ISE Measuring cartridges were replaced from July 2024 through December 2024. On the C 501 module of the Roche Cobas 6000, the following quarterly maintenance was not documented in 2024: Replace: ISE pinch </p>

valve tubing Replace: ISE sipper tubing Clean: Ultrasonic mixers On the E 601 module of the Roche Cobas 6000, the following maintenance to be performed every three months, was not documented in 2024: Replace: Pinch valve tubing 3. In an interview on 1/6/2025 at 10:55 hours, in the laboratory, testing personnel (TP) 1 and TP2 confirmed that the laboratory had not documented and performed all necessary maintenance on the Roche Cobas 6000 chemistry analyzer.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

(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 laboratory policy, laboratory documentation, and confirmed in interview, the laboratory failed to ensure calibration verification was performed and evaluated every six months on the Cobas Roche 6000 chemistry analyzer in 2024 for 60 of 60 analytes that require calibration verification. The findings included: 1. Review of the laboratory policy titled "Roche Cobas 6000 Calibration Verification Procedure" included the following instruction: "Calibration verification is to be performed on each analyte on the instrument/test system at least every six months or more frequently if specified in the manufacturer's instructions ..." 2. Review of the Roche Cobas 6000 test menu included 60 total analytes with a two-point calibration. Surveyor asked for the calibration verification documentation for 2024 and the evaluation could be provided. 3. In an interview on 2/6/2025 at 11:30 hours, in the office, the laboratory director stated that the calibration verification had not been completed. The missed the first calibration verification of 2024 and had tested the samples at the end of 2024 but no evaluation for acceptability had been completed.

D5793

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies, laboratory checklists, chemistry calibration records, instrument maintenance, laboratory QC, and confirmed in interview, the laboratory failed to ensure that the analytic quality assessment (QA) was effective enough to prevent the recurrence of problems identified in the laboratory for records reviewed in 2024 for the Roche Cobas 6000 chemistry analyzer. The findings included: 1. Review of the laboratory policy titled "Quality Assessment" included the following points: " ... 13. Temperatures and instrument maintenance will be monitored monthly by the designee. 14. QC is reviewed every month by the Lab Directory. Problems will be discussed with the staff. ... 19. Calibration verification will be performed once every 6 months on the Roche Cobas 6000.." 2. Review of the laboratory "Quality Assessment Checklist" included the following items to be checked monthly: " _All controls/calibrations were performed and were within acceptable limits Prior to reporting patient results. __All controls/calibrations were performed and were acceptable limits Prior to reporting patient results. ___All instrument maintenance was performed, documented, and reviewed by director or designee. ___Out of control analytes are documented in LabDaq with corrective actions and initials of performing tech. (reran, calibrated, fresh control, etc.)" 3.a. Review of the laboratory maintenance logs for the Roche Cobas 6000 included the following missed maintenance in 2024: On the C 501 module of the Roche Cobas 6000, the following ISE Measuring cartridges, to be replaced every two months, was last documented on 6 /4/2024. No additional documentation that maintenance was performed from July 2024 through December 2024. On the C 501 module of the Roche Cobas 6000, the following quarterly maintenance was not documented in 2024: Replace: ISE pinch valve tubing Replace: ISE sipper tubing Clean: Ultrasonic mixers On the E 601 module of the Roche Cobas 6000, the following maintenance to be performed every three months, was not documented in 2024: Replace: Pinch valve tubing 3.b. Review of the laboratory "Quality Assessment Checklist", signed by the laboratory director, indicated a monthly review of laboratory maintenance from February 2024 - December 2024. 4.a. Review of laboratory policy titled "Quality Control" included the following information: "Two or three levels of control are required to be run once each day of use depending on the specific analyte. Controls may consist of either Roche or Bio-Rad QC products. QC is deemed acceptable if all QC results are within +/- 2SD for analytes with two levels of control or two out of three levels are within +/- 2SD and one level is within +/- 3SD for analytes with three levels of control." 4.b. Review of chemistry QC included the following instances reviewed, in September 2024, where quality control was outside of acceptable limits: Date: Test, Control Level, QC Flag 9/3/2024 Rheumatoid Factor, Immuno 2 Normal, Flag >3SD 9/9/2024 Creatinine, Level 2, Flag >3SD 9/13/2024 Valproic Acid, Immuno Plus High, Flag >3SD 4.c. Review of the laboratory "Quality Assessment Checklist", signed by the laboratory director, indicated a monthly review of laboratory QC for September 2024 on 10/14/2024. Surveyor asked for additional quality assurance activities for the investigation of the quality control being greater than 3 S.D. from the mean, with no documented corrective action, and none could be provided. 5. In an interview on 2/6 /2025 at 13:30 hours, in the office, the laboratory director confirmed that the quality assessment checklist failed to identify the missed maintenance and lacked the additional QA documentation had not occurred for QC that was outside of acceptability.