Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0999705	05/07/2019
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
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 surveyor observation, review of laboratory quality assesment documentation and staff interview, the laboratory failed to establish procedures for monitoring specimen acceptability and rejection. Findings: 1. In the course of the survey, documentation of rejected specimens was requested. In an interview at the site on 05-07-2019, testing person 1 (CMS form 209) stated specimen rejections were noted in the laboratory information system and that no manual log was maintained. 2. An electronic report of specimen rejections for the previous year was requested. In an interview at the site on 05-07-2019, the laboratory director (CMS form 209) stated that although the data needed was stored in the information system, no one at the site was able to produce such a report. .
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 review of method verification documentation for the Sysmex XS-1000i hematology analyzer and staff interview, the laboratory failed to verify that the manufacturer's reference intervals were appropriate for the facility's patient population. Findings: 1. Method verification documentation for the Sysmex XS-1000i hematology analyzer was reviewed. In studies provided principally by the manufacturer's field service representative, accuracy, precision and reportable range were addressed. 2. No evidence of reference range verification was included. In an interview at the site on 05-07-2019, the laboratory diretor stated he was not aware that the study had not been performed. .
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: . Based on review of laboratory documentation for verification of the accuracy of calculations performed in the laboratory information system and staff interview, the laboratory failed to verify the accuracy of calculations for international normalized ratio (INR) and creatinine clearance performed by the Lab Daq information system. Findings: 1. Laboratory documentation for comparison of instrument printouts to Lab Daq reports was reviewed. The section for INR calculations showed the following: Specimen INR INR reported 636869 4.69 4.89 636886 1.09 1.07 636885 1.32 1.30 636857 3.34 3.43 636864 2.01 2.02 2. The section for creatinine clearance showed the following: Specimen Creat.Clearance Lab Daq results 628817 38.04 39.64 627576 8.98 9.36 632002 21.66 22.85 634041 31.00 32.15 3. In an interview at the site on 05-07-2019, the laboratory director, who also serves as technical consultant (CMS form 209) stated he believed he had used the wrong calculations in the verification process.