Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2243548	04/03/2024
Name of Provider or Supplier	**Street Address, City, State**	
Xenobiotic Laboratories	107 Morgan Lane, Plainsboro, NJ	

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
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual, Reagent Qualification records and interview with the Laboratory Director (LD) the laboratory failed to have a complete written policy and procedure for Quality Control Verification (QCV) from 3 /15/24 to 4/3/24. The findings include: 1. The QCV procedure did not state how many runs should be performed for verification of Quality Control (QC) material. 2. The QCV procedure did not state what the acceptability criteria and the rejection criteria was for the verification of QC material 3. The LD confirmed on 4/3/24 at 1:15pm, the QCV procedure did not include the aforementioned information.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on the surveyor review of the Final Reports (FR), and interview with the Laboratory Director (LD), the laboratory failed to have accurate Reference Interval (RI) for Endocrinology tests form March 2023 to the date of survey. The findings

	include: 1. A review of three FRs revealed that patient results could have been reported as "13. RRNE Reference Range Not Established". 2. The LD confirmed on 4 /3/24 at 10:00 am that laboratory failed to have accurate RI.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records and interview with the Laboratory Director (LD), the LD failed to ensure that PS procedures performed for Endocrinology, Immunology testing performed on the Cobas e801 analyzer were adequate from March 2023 to the date of survey. The findings include: 1. There was no documented evidence that a Reference Range was verified. 2. The LD confirmed on 4/3/24 at 11:15 am that PS records were not adequate.