Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2114374	06/10/2025
Name of Provider or Supplier	**Street Address, City, State**	
Apollo Clinical Laboratories, Inc	2124 Morris Avenue, Union, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records, and interview with the Technical Supervisor (TS), the laboratory failed to verify the accuracy and reliability of Toxicology testing twice a year in the calendar years 2023 and 2024. The findings includes: 1. The laboratory participated in College of American Pathologists (CAP) PT "Module Drug Monitoring for Pain Management" two events in 2023 and 2024 that did not include all 89 metabolites performed on the Absciex 4500 analyzer . 2. The laboratory participated in CAP PT Module "Oral Fluid for Drugs of Abuse" two events in 2023 and 2024 that did not include all 53 metabolites performed on the Absciex 4500 analyzer . 3. The TS confirmed on 6/10/25 at 1:30 pm that the laboratory did not verify the accuracy of Toxicology testing twice a year.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as

	established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Patient Test Records (PTR), Performance Specifications for the Absciex 4500 analyzer and interview with the Technical Supervisor (TS), the laboratory did not have accurate specimen stability procedures for Toxicology tests from 11/1/22 to 6/10/25. The findings include: 1. The PM states Urine and Oral fluid temperature stability are as follows: a) Ambient >14 days b) Refrigerated (2-8C) c) Frozen (-20 to - 5C) 2. The PS for Urine and Oral Fluid stated analytes were shown to be stable at refrigerated temperature (2-8C) for 7 days and stable in the autosampler for 3 days. 3. Surveyor review of Ten PTR revealed samples were tested within 7 days. 4. The TS confirmed on 6/10/25 at 11:40 am, laboratory did not have accurate specimen stability procedures in the PM.
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. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with Techincal Supervisor (TS), the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems from 5/15/19 to 6/10/25. The finding includes: 1. The laboratory failed to have a procedure to verify new lots of controls before they were put in use on the Adiva analyzer. 2. The TS confirmed on 6/10/25 at 10:40 am that the laboratory failed to have a procedure to verify new lots of controls before they were put in use.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records and interview with the Techincal Supervisor (TS). the Laboratory Director (LD) failed to ensure that PS procedures performed for Ethyl glucuronide (ETG) testing performed on the Adivia analyzer were adequate from 5/15/19 to 6/10/25. The findings include:

	1. There was no documented evidence that PS was performed for ETG prior to the start of patient testing. 2. The TS confirmed on 6/10/25 at 11:15 am, the PS records were not adequate.