

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D2114374	<b>(X3) Date Survey Completed</b>  05/15/2019
<b>Name of Provider or Supplier</b>  Apollo Clinical Laboratories, Inc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2000</b>	<p><b>ENROLLMENT AND TESTING OF SAMPLES</b> CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Owner and Technical Supervisor, the laboratory failed to tests the College of American Pathologists C-B 2018 General Chemistry/Therapeutic Drugs PT samples in the same manner as patients' specimens. Cross refer to D 2013.</p>
<b>D2013</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(4)</p> <p>The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of</p>

patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Proficiency Test (PT) record, observation of Chemistry instrument, refrigerator and freezer and interview with the Owner, Technical Supervisor (TS) and Testing Personnel (TP), the laboratory failed to analyze Chemistry PT samples obtained from the College of American Pathologists (CAP) on the Advia 1800 analyzer for the 2nd event of 2018. The findings include: 1. The Instrument Printout (IP) had analyzer serial # CA 129100919090919 but serial # on the analyzer was CA 1291010621062. 2. The laboratory printed all PT sample results on the final report which had 'Quality Laboratory Service' (QLS) name and Brooklyn, NY address. 3. On the day of survey the TP # 2 listed on CMS form 209 stated general supervisor 'brings reagents and control material from QLS laboratory to perform PT samples.' 4. Observation of the refrigerator and freezer confirmed that the laboratory did not have any reagents or controls to perform chemistry testing. 5. The laboratory was not approved and was not performing serum chemistry tests for patients. 6. The owner and TS stated on 5/15/19 at 2:30 pm that general supervisor was out of the country and will discuss with him on his return.

**D2015**

**TESTING OF PROFICIENCY TESTING SAMPLES**

CFR(s): 493.801(b)(5)(6)

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Proficiency Testing (PT) records and interview with the Technical Supervisor (TS), the laboratory failed to maintain the Work Records (WR) and Attestation Statements (AS) signed by the analyst and laboratory director for Routine Chemistry, Endocrinology, Urinalysis, Coagulation and Hematology tests performed with the College of American Pathologists in 1-2019 events. The findings include: 1. The laboratory did not document handling, processing and each step in the testing and reporting of PT samples. 2. There were no printouts to substantiate reported results. 3. The Advia 1800-Chemistry, Centaur- Endocrinology, Atlas Clinitek-Urinalysis, Sysmex 1500-Coagulation and Advia 2120i-Hematology analyzers were checked to ensure PT was performed but no data was found in any of

the analyzers to verify PT was done. 4. The CAP evaluation sheets for all PT were signed off and reviewed by the general supervisor. 5. The TS confirmed on 5/15/19 at 2:15 pm that the laboratory did not maintain any records for PT.

**D5309**

**TEST REQUEST**  
CFR(s): 493.1241(e)

If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately.

This STANDARD is not met as evidenced by:  
Based on review of Test Requisition (TR), and interview with the Owner, the laboratory failed to ensure that information from TR was transcribed accurately into the laboratory information system for all tests from 12/7/17 to the date of the survey. The Owner confirmed on 5/15/19 at 11:00 am that the laboratory did not ensure TR information was transcribed accurately.

**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 review of the Procedure Manual (PM) and interview with the Owner, the laboratory failed to established a written procedure on how transcribed information from test requisition into the laboratory information system will be monitored from 12/7/17 to the date of survey. The Owner confirmed on 5/15/19 at 11:30 am that the laboratory did not have the procedure mentioned above.

**D5403**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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.

(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

(a) Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to established a written Quality Control (QC) program for the Adiva 1800 analyzer from 12/7/17 to the date of survey . The TP # 2 listed on CMS form 209 confirmed on 5/15/19 at 11:15 am that the laboratory did not have a written QC program. (b) Based on surveyor review of the PM, the statistics for unassayed control materials and interview with the TP, the laboratory failed to established a written procedure to establish unassyed control material values for the Adiva 1800 analyzer from 12/7/17 to the date of survey . The TP # 2 listed on CMS form 209 confirmed on 5/15/19 at 11:15 am that the laboratory did not have a written procedure to establish statistical parameters for unassayed control materials. (c) Based on the lack of the PM and interview with the TP, the laboratory failed to have a Corrective Action (CA) procedure for failed Quality Control values from 12/7 /17 to the date of the survey . The TP # 2 listed on CMS form 209 confirmed at 1:45 pm on 5/15/19 the laboratory did not have the CA procedure. 35471 (d) Based on surveyor review of the PM and interview with the Technical Supervisor (TS), the laboratory failed to have a procedure to verify new lots of reagents, prepared mobile phases, and standards before it is put in use for Ethyl Glucuronide (EtG) and Ethyl Sulfate (EtS) Toxicology Urine Toxicology tests from 8/1/18 to the date of the survey. The TS confirmed on 5/15/19 at 2:50 pm that laboratory did not have the above procedure.

**D5411**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on surveyor observation of Calibration Material (CM) in use, review of the Advia Chemistry Serum Toxicology Calibrators Kit Manufacture Package Insert (MPI) and interview with the Testing Personnel (TP), the laboratory Failed to follow MPI for the Advia 1800 analyzer from January 1, 2019 to the date of survey. The findings include: 1. The MPI stated "Intended use in the Qualitative or Semiquantitive calibration of ADVIA chemistry systems for the serum Tricyclic Antidepressant". 2. The laboratory was testing Urine specimens not Serum for Tricyclic Antidepressant. 3. Approximately 77 patients were run and reported with expired CM . 4. The TP # 2 listed on CMS form 209 confirmed on 5/15/19 at 11:00 am that the laboratory did not follow the MPI

**D5415**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper

use.

This STANDARD is not met as evidenced by:

Based on surveyor observation of the Quality Control (QC) material and interview with the Testing Personnel (TP), the laboratory failed to put new expiration dates on all controls used for urine Toxicology and routine chemistry performed on the Adiva 1800 analyzer from 12/7/2017 to the date of survey. The TP confirmed on 5/15/19 at 1:00 pm the laboratory failed to put new expiration dates on the control material.

**D5805**

**TEST REPORT**

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

a. Based on surveyor review of the Final Report (FR) and interview with the Owner, the laboratory failed to ensure that the FR included the name and address of the laboratory where testing was performed from 12/7/17 to the date of survey. The owner confirmed on 5/15/19 at 11:50 pm that FR did not have the name and address of testing facility. b. Based on surveyor review of the FR and interview with the Owner, the laboratory failed to report Urine Drug confirmation test results accurately from 12/7/17 to the date of survey. The finding includes: 1. The laboratory performed non Food and Drug Administration cleared tests and there was no statement stating the test had not been cleared or approved by the U.S. Food and Drug Administration" on the FR. 2. The owner confirmed on 5/15/19 at 1:00 pm that Urine Drug confirmation tests were not reported accurately.

**D6076**

**LABORATORY DIRECTOR**

CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of the Procedure Manual (PM), the laboratory records, tour of the laboratory and interview with the owner, the Laboratory Director (LD) failed to provide overall management, oversight and direction to the owner for laboratory testing. The findings include: 1. The LD failed to ensure that Performance Specification were performed correctly. Cross refer to D 6086 2. The LD failed to ensure proficiency testing samples were tested as patient samples. Cross refer to D 6089 3. The LD failed to ensure that quality controls programs were maintained. Cross Refer to D6093

**D6086**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that 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 Technical Supervisor (TS), the Laboratory Director failed to ensure that PS were adequate to perform urine Ethyl Glucuronide (EtG) and Ethyl Sulfate (EtS) Toxicology tests on the AbSciex Triple Quad 4500 from 8/1/18 to the date of survey. The findings include: 1. The laboratory failed to perform a sample stability study. 2. There was no validation performed to establish the expiration date of reagents, working solutions, Internal Standard, controls and calibrators used. 3. A method comparison was not performed. 4. Carryover studies were not performed. 5. The laboratory did not perform Interference or Matrix Effect studies. 6. The laboratory failed to have a source for the PS from clinical scientific literature. 7. The TS confirmed on 5/15/19 at 2:30 pm that EtG and EtS confirmation tests were not adequate.

**D6089**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Proficiency Testing (PT) records and interview with the Owner, the Laboratory Director (LD) failed to ensure PT samples for C-B 2018 Chemistry/Therapeutic Drugs event were tested in the same manner it tests patients samples. Cross Refer to D 2000 and D 2013.

**D6093**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Quality Control (QC) records and interview with the Testing Personnel (TP), the Laboratory Director failed to ensure that the laboratory maintained a QC program from 12/7/17 to the date of the survey. The findings include: 1. The monthly Levy Jennings charts for the Adiva 1800 had two out of three levels of controls printed. 2. The laboratory did not notice that all level of QC charts were not printed. 3. There was no evidence of QC review on the monthly Levy Jennings charts. 4. The TP # 2 listed on CMS form 209 confirmed on 5/15/19 at 2:00 pm the laboratory did not ensure a QC program was maintained.