

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D2135687	<b>(X3) Date Survey Completed</b>  05/15/2018
<b>Name of Provider or Supplier</b>  Advanced Comprehensive Laboratory Llc	<b>Street Address, City, State</b>  67-71 East Willow St, Millburn, 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>D2015</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(5)(6)</p> <p>(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.</p> <p>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 Attestation Statements (AS) for Urine Toxicology (UT), Oral Fluid Drug Testing (OFD), Urine Drug Adulterant/Integrity (DAI), Forensic Urine Drug Testing Confirmation (UDC) and Urine Drug Testing Screening (UDS) PT events in 2017 and 1-2018 with the College of American Pathologists (CAP). The findings include: 1. The AS was not found at the time of the survey for OFD - D 2017. 2. The Laboratory Director did not sign the AS for: a. UT - C 2017 b. UDC - D 2017 c. DAI - A 2018 d. UDS - A 2018 3. Testing Personnel did not sign the AS for UT - C 2017. 4. The TS confirmed on 5/15 /18 at 10:45 am that all PT records were not maintained.</p>
<b>D5211</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing</p>

performed as specified in 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 Technical Consultant (TC), the laboratory failed to evaluate coded results for Forensic Urine Drug Testing Confirmation (UDC), Oral Fluid Drug Testing (OFD), Urine Drug Adulterant/Integrity (DAI) and Urine Drug Screening (UDS) obtained with the College of American Pathologists (CAP) in the 2017 and 1-2018. The findings include: 1. The laboratory did not evaluate Code 26 (Educational challenge) as follows: a. 2017 - OFD- Diazepam Qualitative sample OFD -16 and Qualitative sample OFD - 19, Methylenedioxyamphetamine, Nordiazepam and Temazepam Qualitative samples OFD-16-20 b. 2018 - DAI - A Interpretation samples DAI 01-03 and OFD - A Oxycodone, Cocaine and Alprazolam Qualitative and Quantitative samples OFD 01-05, Delta 9 - THC - COOH, Buprenorphine and Norbuprenorphine Qualitative samples OFD 01-05 c. 2018 - UDS Amphetamine/Methamphetamine sample UDS - 05 2. The laboratory did not evaluate Code 30 ( Scientific Committee Decision) for UDS - Ethanol samples UDS 01 - 05. 3. The TC confirmed on 5/15/18 at 10:45 am that the laboratory failed to evaluate coded results.

**D5221**

EVALUATION OF PROFICIENCY TESTING PERFORMANCE  
CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

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 evaluate results when the laboratory received an unacceptable score in PT for Forensic Urine Drug Testing Confirmation (UDC), Urine Toxicology(UT) and Oral Fluid (OFD) Forensic Drug Testing performed with the College of American Pathologists (CAP) in 2017 and 1-2018. The finding includes: 1. There was no review or evaluation documented when the laboratory received an unacceptable result for Urine and Oral Fluid Toxicology Results as follows: a. UT - C 2017 sample UT-14 b. UDC - D 2017 Phencyclidine samples UDC - 32 and 36 c. OFD - D 2017 Benzoylcgonine sample OFD-16 d. CAP off cycle survey UDC Codeine UDC-56, Methamphetamine UDC-58, Delta-9-THC-COOH UDC-60, Phencyclidine UDC-52 e. Urine Drug Screening - UDS 2018 - Delta-9-THC-COOH sample UDS-01 2. The TS confirmed on 5/15/18 at 10:00 am that the laboratory did not perform and document an evaluation of unacceptable PT performance.

**D5401**

PROCEDURE MANUAL  
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual (PM), Patient Data (PD) and

	<p>interview with the Technical Supervisor (TS), the laboratory failed to follow the established procedure for Chromatography review in May 2018. The finding includes: 1. The PM stated under Procedure section 4: if the Ion Ratio (IR) is outside the acceptable limit, the peak cannot be confirmed as the analyte and must be repeated. 2. Observation of the PD on the instrument revealed the IR failed but there was no documented evidence of a repeat. 3. The TS confirmed on 5/15/18 at 2: 05 pm that the PM was not followed.</p>
<p><b>D5467</b></p>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(9)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual, Calibrators, Controls and interview with the Technical Supervisor (TS), the laboratory failed to use different lot numbers of calibrators to make the calibrator and controls from October 2017 to the date of the survey. The TS confirmed on 5/15/18 at 2:10 pm the laboratory did not use different lot numbers of calibrators.</p>
<p><b>D5791</b></p>	<p><b>ANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1289(a)(c)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor review of the Procedure Manual and interview with the Technical Supervisor (TS), the laboratory failed to establish written procedures to monitor and assess Quality Control for Toxicology tests performed on the AB Sciex from October 2017 to the date of the survey. The findings include: 1. The laboratory did not establish a procedure to validate the expiration date for prepared reagents, calibrators, standards and controls. 2. Expiration dates were arbitrarily given as follows: a. Controls and calibrators - one year b. Working calibrator - two weeks c. QC frozen and then thawed - 2 weeks after thawing d. Mobile Phase - 1 week e. Injection needle wash - 1 month 3. The TS confirmed on 5/15/18 at 12:00 pm the laboratory did not validate expiration dates.</p>
<p><b>D5807</b></p>	<p><b>TEST REPORT</b> CFR(s): 493.1291(d)</p> <p>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.</p>

This STANDARD is not met as evidenced by:  
Based on surveyor review of the Final Report and interview with the Technical Supervisor, the laboratory failed to identify the source of the Cutoff Ranges used for Urine Drug Confirmation tests from October 2017 to the date of survey. The TS confirmed on 5/15/18 at 2:20 pm that the source of the Cutoff ranges was not known.

**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 Toxicology Performance Specification (PS) records and interview with the Technical Supervisor (TS), the laboratory director failed to ensure that accuracy was performed on qualitative tests performed on the AU 680 analyzer was adequate in January 2018. The findings include: 1. The laboratory had no positive agreement for qualitative method comparison for, Cocaine, Phencyclidine, Propoxyphene, Methamphetamine, and Ethanol. 2. The laboratory used two quantitative test methods when performing qualitative method comparison. 3. The TS Confirmed on 5/15/18 at 11:00 am that accuracy was not performed.

**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 (LD) failed to ensure PS were adequate to perform Toxicology testing on the AB Sciex from July 20, 2017 to the date of survey. The findings include: 1. A review of the Linearity, Accuracy, Carryover records for Buprenorphine revealed that Accuracy was unacceptable for the target value of two but two was used for the "lowest standard that met the ion's ratio's acceptance criteria (LOD)". 2. The linearity study for Buprenorphine revealed it to be linear from 5 -1000 but the LOD was two. 2. The Parallel Study performed for Fentanyl did not have any results or documentation of acceptance. 3. The Parallel Study for Buprenorphine was performed with one spiked sample. 4. There was no documentation to substantiate studies for interfering substance were performed. 5. There was no documented evidence to show the validation of the Hydrolysis Control was performed. 6. There was no documented evidence to show the results of the carryover study. 7. The method comparison reviewed at the time of the survey was performed using the Beckman Au 680 a

qualitative method not quantitative. 8. The TS confirmed on 5/15/18 at 1:40 pm that the LD did not ensure the PS were adequate.