Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2135687	06/17/2026
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Comprehensive Laboratory Llc	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A recertification survey was completed on 6/17/26. Immediate Jeopardy existed for the following condition level deficiencies: 42 C.F.R. 493.1290 Condition: Postanalytic Systems 42 C.F.R. 493.1441 Condition: Laboratory Director
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the General Supervisor (GS) the laboratory failed to retain QC assay sheets for Toxicology tests run on the Beckman Coulter AU680 analyzer from 5/6/26 to 6/17/26. The GS confirmed on 6/17/26 at 10:00 am that the QC assay sheets were not retained.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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: a) Based on surveyor Procedure Manual (PM) and interview with the General Supervisor (GS), the laboratory failed to have to follow the procedure "Concordance

	/Method Comparison protocol" used in Verification of Performance Specifications performed on the Beckman Coulter AU680 for Toxicology testing from 7/11/18 to 6 /16/26. The findings includes: 1. The PM stated "The sample population should include at least 20% positive Specimens". 2. Amphetamine had one positive specimen out of twenty seven. 3. Barbituate had two positive specimens out of twenty seven. 4. The GS confirmed on 6/16/26 at 12:45 PM the laboratory did not follow the procedure "Concordance/Method Comparison protocol" used in Verification of Performance Specifications. b) Based on surveyor Procedure Manual (PM) and interview with the General Supervisor (GS), the laboratory failed to have to follow the procedure "Drugs of Abuse Concordance Data Summary" used in Verification of Performance Specifications performed on the Beckman Coulter AU480 for Toxicology testing from 7/11/18 to 6/16/26. The finding includes: 1. The work sheet on pages 5-4 through 5-6 in the PM that included an "Overall Agreement" for all toxicology analytes was not completed. 2. The GS confirmed on 6/16/26 at 12:45 PM the laboratory did not follow the procedure "Drugs of Abuse Concordance Data Summary" used in Verification of Performance Specification.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control (QC) records and interview with General Supervisor (GS), the laboratory failed to verify commercially assayed QC material with each new lot and/or shipment of Toxicology QC used on the Beckman Coulter AU680 analyzer from 5/6/26 to 6/17/26. The findings include: 1. There was no documented evidence that QC material was verified for Bio-Rad Liquichek Qualitative Urine Toxicology as follows: a) Negative QC Lot # 74741 b) Positive QC lot # 74742 2. The GS confirmed on 6/17/26 at 11:20 am that all assayed QC material was not verified before putting in use.
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in 493.1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by:

	Based on surveyor review of Final Reports (FR), Procedure Manual (PM) Analyzer Raw Data (RD), Performance Specifications (PS) and interview with the General Supervisor (GS), the laboratory failed to meet the Post Analytic system requirements for reporting laboratory test results from 3/3/26 to 6/17/26. The findings include: 1. The laboratory failed to ensure that laboratory results are accurately and reliably transmitted through the Laboratory Information System (LIS) for Fentanyl tests. Cross refer to D5801.
D5801	TEST REPORT CFR(s): 493.1291(a) (a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on surveyor review of Final Reports (FR), Procedure Manual (PM) Analyzer Raw Data (RD), Performance Specifications (PS) and interview with the General Supervisor (GS), the laboratory failed to ensure that laboratory results are accurately and reliably transmitted through the Laboratory Information System (LIS) for Fentanyl tests from 3/3/26 to 6/17/26. The findings include: 1. PS and the PM had a cut off value of 1 ng/mL for Fentanyl test run on the Beckman Coulter AU680. 2. The LIS and the Beckman coulter AU680 analyzer had a cutoff value of 100 ng/mL for Fentanyl. 3. A review of Eighty Five patients tests results revealed that Fifty Three were over the established cut of value of 1 ng/mL and were reported as negative for Fentanyl. 4. Approximately 900 Fentanyl tests are performed monthly. 5. The GS confirmed on 6/16/26 at 12:00 pm, the laboratory failed to ensure that laboratory results were accurately and reliably transmitted through the LIS.
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 an interview with the General Supervisor (GS), the Laboratory Director (LD) failed to provide overall management and direction to the laboratory to ensure that laboratory testing is performed satisfactorily and in compliance with the CLIA regulations from 3/3/26 to 6/17/26. 1. The LD failed to ensure that Performance Specifications (PS) procedures performed for testing performed on the Beckman Coulter AU680 analyzer were adequate: Cross refer to D6086. 2. The LD failed to ensure the Quality Assessment (QA) and Quality Control (QC) programs were maintained to assure the quality of laboratory services. Cross refer to D6093.

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 General Supervisor (GS), the Laboratory Director (LD) failed to ensure the PS for the Beckman Coulter AU680 analyzer were adequate before patient testing from 3/3/26 to 6/17/26 . The findings include: 1. No documented evidence that a Laboratory Information System (LIS) verification was performed. 2. The GS confirmed on 6/17/26 at 12:30 pm, the LD not ensure the PS records were adequate.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment 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: A) Based on surveyor review of the Quality Control (QC) records and interview with the General Supervisor (GS), the Laboratory Director (LD) failed to maintain a QC program to assure the quality of laboratory service from 10/17/19 to 6/17/26. The finding includes: 1. Monitoring QC Levy Jennings (LJ) charts for Toxicology testing performed on the Beckman coulter AU680 with Bio-Rad Liquichek Qualitative Urine Toxicology Control levels one and two did not have all applicable data to monitor and assess QC. a. QC levels one and two did not have dated daily values for each analyte. b. QC levels one and two had one mean value for each analyte calculated from a months worth of data. 2. There were no QC lot numbers documented on LJ charts. 3. There were no QC lot numbers entered into the Beckman coulter AU480. 4. The laboratory did not have the Manufactures Package insert (MPI) for Bio-Rad Liquichek Qualitative Urine Toxicology Controls for lot # 74741 currently in use. 5. The GS confirmed on 6/17/26 at 2:45 PM, the QC program was not maintained. B) Based on surveyor review of Final Reports (FR), Procedure Manual (PM) Analyzer Raw Data (RD), Performance Specifications (PS) and interview with the General Supervisor (GS), the Laboratory Director (LD) failed to ensure that the Quality Assurance program was maintained for laboratory services provided from 3/3/26 to the 6/17/26. Cross Refer to D5800