Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D1034225	10/24/2022
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Clinical Laboratory	1405 Airline Drive, Metairie, LA	

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 performed at Advanced Clinical Laboratory, CLIA # 19D1034225, on October 24, 2022. Advanced Clinical Laboratory was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.801 CONDITION: Enrollment and testing of samples 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing; Laboratory Director
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 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. This CONDITION is not met as evidenced by: Based on review of the laboratory's proficiency test recods, test menu, and interview with personnel, the laboratory failed to enroll in an HHS approved proficiency testing program for blood cell identification. Findings: 1. Initial review of the laboratory's test menu on October 24, 2022 at 9:40 am revealed the laboratory did not include manual differentials on their list of tests performed. 2. In interview on October 24, 2022 at 10: 30 am the Technical Consultant stated the laboratory performs manual differentials for Complete Blood Count testing. 3. Review of the laboratory's 2021 and 2022 proficiency test records revealed the laboratory was not enrolled in an HSS approved proficiency testing program for blood cell identification. 4. In further interview on Ocotber 24, 2022 at 3:59 pm, the Technical Consultant confirmed the laboratory was

	not enrolled in a proficiency testing program for blood cell identification. 5. Review of the laboratory's updated test menu revealed the laboratory performs 1,057 manual differentials annually.
D3039	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory's calibration records and interview with personnel, the laboratory failed to retain one (1) of three (3) calibration records reviewed for the Complete Blood Count (CBC) analyzer for at least two (2) years. Findings: 1. Review of the laboratory's calibration records for the CBC analyzer revealed the laboratory did not retain the records for May 2022. 2. In interview on October 24, 2022 at 3:37 pm, the Technical Consultant stated the laboratory keeps the latest calibration records. The Technical Consultant confirmed the laboratory did not retain the CBC analyzer's calibration records for May 2022.
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 review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to establish a complete policy and procedure manual. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a written quality control procedure for blood culture bottles that included visual inspections. 2. In interview on October 24, 2022 at 10:25 am, the Technical Consultant confirmed the laboratory did not have a procedure for visual inspections of blood culture bottles.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, policies/procedures, and interview with personnel, the laboratory failed to ensure policies were updated to include current test procedures Findings: 1. Review of the laboratory's policies and procedures revealed policies related to urine drug screens (UDS) were included with current tests policies /procedures, not discontinued. 2. In interview on October 24, 2022 at 11:00 am Testing Personnel 1 stated UDS testing was discontinued in December 2019. Testing

	Personnel 1 confirmed the laboratory's policies and procedures were not updated to current tests.
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 observation by surveyor, review of the manufacturer's package insert, and interview with personnel, the laboratory failed to document the visual inspection of blood culture bottles prior to use per manufacturer's requirements. Findings: 1. Observation by surveyor during the laboratory tour on October 24, 2022 at 10:15 am revealed the laboratory utilizes BacT/ALERT Adult Blood Culture Collection Kits (lot number 2206270017). 2. Review of the manufacturer's package insert revealed "Inspect each blood culture bottle before use to ensure integrity of bottle and sensor on bottom of bottle is intact. The sensor is normally a uniform grayish-green color and a yellow color would indicate contamination of the broth. Discard any bottle found to be damaged or with a sensor that is yellow." 3. In interview on October 24, 2022 at 10: 05 am, the Technical Consultant stated the laboratory checks the expiration dates of the blood culture bottles. The Technical Consultant confirmed the laboratory does not document visual inspections of the blood culture bottles received.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of maintenance records, and interview with personnel, the laboratory failed to ensure weekly maintenance for the Cobas e411 was performed per manufacturer's requirements for two (2) of three (3) weeks in October 2022. Findings: 1. Observation by surveyor during the laboratory tour on October 24, 2022 at 10:15 am revealed the laboratory utilizes the Cobas e411 for routine chemistry and endocrinology testing. 2. Review of the "Cobas e411 analyzer Maintenance log" revealed the following weekly maintenance tasks: a) Clean incubator and aspiration station b) Clean sipper probe 3. Further review of the "Cobas e411 analyzer Maintenance log" for October 2022 revealed the laboratory did not document weekly maintenance performance for the following weeks: Week of October 9, 2022 Week of October 16, 2022 4. In interview on October 24, 2022 at 3: 37 pm, the Technical Consultant confirmed the laboratory did not document the weekly maintenance performance for the identified two weeks.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403

	The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D6014. 2. The Laboratory Director failed to ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. Refer to D6015. 3. The Laboratory Director failed to ensure that the laboratory performed required maintenance. Refer to D6023. 4. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D6031.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to retain one (1) of three (3) calibration records reviewed for the Complete Blood Count (CBC) analyzer for at least two (2) years. Refer to D3039. 2. The laboratory failed to document the visual inspection of blood culture bottles prior to use per manufacturer's requirements. Refer to D5411.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. Refer to D2000.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6)

	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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on record review, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance. Refer to D5429.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to ensure policies were updated to include current test procedures Refer to D5407.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to retain one (1) of three (3) calibration records reviewed for the Complete Blood Count (CBC) analyzer for at least two (2) years. Refer to D3039. 2. The laboratory failed to document the visual inspection of blood culture bottles prior to use per manufacturer's requirements. Refer to D5411. 3. The laboratory failed to ensure weekly maintenance for the Cobas e411 was performed per manufacturer's requirements for two (2) of three (3) weeks in October 2022. Refer to D5429.
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in

	an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to ensure enrollment in an HHS approved proficiency testing program. Refer to D2000.