Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2172502	03/10/2021
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Surgical Technology, L L C	4200 Williamson Pl - Ste 1a, Mount Vernon, IL	

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
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. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and an interview with the laboratory director (LD); the laboratory failed to retain quality control and patient test records for the Activated Clotting Time - Kaolin (ACT-K) testing performed for at least 2 years. Findings include: 1. The laboratory's procedures manual, quality control (QC) logs and worksheets, and patients' electronic medical records (EMR) were reviewed. 2. The laboratory's manual revealed the following: *The Abbott i-STAT analyzer was used to perform ACT-K testing. *Upon completion of the test, a printout is generated with the test result. 3. Review of 8 selected patients EMR reports revealed the following: *Patients ACT-K printouts were photographed and uploaded into the EMR. *The printout results of the 8 patients were discarded. 4. Further review showed the photographed printouts of 4 out of 8 Patients (XA2, XA4, XA7, and XA8) failed to include the patients' name or any other identifier. 5. Review of the QC records from 10/07/2020 through 03/03/2021, showed the laboratory saved a total of 19 days of QC printout results. 6. The laboratory failed to establish a written policy and procedure that instructs the retention of controls and patient test printouts for at least 2 years. 7. On an Initial survey conducted on 03/10/2021 at 3:10 PM, the LD confirmed with the above findings.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish

	and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review, the Laboratory Personnel Report (CMS 209), and an interview with the laboratory director (LD), the laboratory failed to establish written policies and procedures that meet the personnel requirements in subpart M to assess employees performing Coagulation testing, affecting 4 out of 4 testing personnel (TP). Findings: 1. The CMS 209, personnel records, and procedures manual were reviewed. 2. The laboratory used the Abbott i-STAT handheld analyzer for Activated Clotting Time - Kaolin (ACT-K) testing. 3. The CMS 209 listed 4 employees (TP1, TP2, TP3, and TP4) performing the ACT-K test. 4. Review of the laboratory's competency procedure revealed the following: *The procedure failed to include and demonstrate the review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; *Direct observation of performance of instrument maintenance and function checks; *The assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and *The assessment of problem solving skills. 5. The laboratory failed to ensure the competency procedures used to evaluate TP meet the laboratory personnel requirements. 6. On an Initial survey conducted on 03/10/2021 at 3:20 PM, the LD confirmed the above findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record and manual review, manufacturer's instructions, and an interview with the laboratory director (LD), the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283 for performing Hematology testing in the laboratory. Findings Include: 1. The laboratory failed to meet the following analytic systems requirements: *Failed to follow written procedures for all assays and tests. See D5401. *Failed to establish manufacturer's performance specifications. See D5421. *Failed to perform calibration verification procedures bi-annualy. See D5437 *Failed to establish control procedures. See D5441.
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 record review and an interview with the laboratory director (LD), the laboratory failed to follow the written procedures manual for the tests performed in the specialty of Hematology, affecting 250 patients. Findings: 1. The Abbott's i-STAT operator's and procedures manual and quality control documents were reviewed. 2. The laboratory used the manufacturer's i-STAT manual as it's procedure manual for Activated Clotting Time - Kaolin (ACT-K) testing. 3. Review of the operator's manual revealed the laboratory failed to implement the following procedures and logs which are required by the manufacturer: *i-STAT System Incoming Cartridge (quality control) QC log; *i-STAT System QC Log: Expiration Date and Storage Conditions; *i-STAT Cartridge Quality Control Action log; *i-STAT Electronic Simulator Log for Analyzer; *i-STAT Electronic Simulator Action Log; *i-STAT Analyzer Thermal Probe Check *i-STAT QC Log: Incoming QC; *i-STAT QC Action Log; *i-STAT QC Log: Expiration Date and Storage Conditions: Refrigerated; *i-STAT QC Log: Expiration Date and Storage Conditions: Room Temperature 4. Further review revealed no documentation of the electronic simulator, thermal probe check, refrigerator and room temperatures had been recorded since testing began on 09/30 /2019. 5. On an Initial survey conducted on 03/10/2021 at 3:25 PM, the LD confirmed the above findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and an interview with the laboratory director (LD), the laboratory failed to demonstrate that it could obtain performance specifications comparable to those established by the manufacturer before reporting patient test results in the specialty of Hematology, affecting 250 patients. Findings: 1. The Abbott i-STAT operator's and procedures manual, quality control (QC) documents, and test volume worksheets were reviewed. 2. The laboratory used the i-STAT handheld analyzer for Activated Clotting Time - Kaolin (ACT-K) testing. 3. The manufacturer's instructions were provided for verifying the reportable range of the ACT-K by performing a linearity procedure. 4. The laboratory failed to follow the manufacturer's instructions by performing the linearity procedure prior to testing patients. 5. The test volume worksheet revealed the laboratory reported 250 patient test result during the time period of 03/2020 through 03/2021. 6. On an Initial survey conducted on 03/10 /2021 at 3:15 PM, the LD confirmed the above findings.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or

	specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on record review and an interview with the laboratory director (LD). the laboratory failed to follow the manufacturer's instructions to perform calibration verification (CV) procedures every 6 months on the analyzer used for Activated Clotting Time - Kaolin (ACT-K) testing, during the year of 2020. Findings Include: 1. The Abbott's i-STAT operator's and procedures manual and quality control (QC) log sheets were reviewed. 2. The laboratory used the manufacturer's i-STAT manual as it's procedure manual for Activated Clotting Time - Kaolin (ACT-K) testing. 3. The manual instructs the laboratory to perform the following: *"In the United States, laboratory regulations (CLIA) require that for tests categorized as Non-Waived, a calibration verification procedure be performed and documented at least once every six months." 4. Review of QC logs revealed no documentation of calibration verifications being performed since ACT-K testing began on 09/30/2019. 5. The laboratory failed to follow written procedures to perform calibration verifications bi-annually. 6. On an Initial survey conducted on 03/10/2021 at 3:15 PM, the LD confirmed the above findings.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and an interview with the laboratory director (LD), the laboratory failed to establish control procedures that monitor the accuracy and precision of the complete analytic process for testing performed in the specialty of Hematology, affecting 250 patients. Findings: 1. The i-STAT operator's and procedures manual, quality control (QC) logs and data sheets, and patients' electronic medical records (EMR) were reviewed. 2. The laboratory used the i-STAT handheld analyzer for Activated Clotting Time - Kaolin (ACT-K) testing. 3. Review of the QC documents and 8 selected patients final reports revealed the following: *The laboratory began documenting QC procedure results for ACT-K testing on 11/06/2019. *QC was not performed on 11/05/2019; 11/12/2019; 01/21/2020; 03/11/2020; 03/20/2020; 06/12/2021; 06/30/2020; and 09/18/2020. *Eight (8) out of 8 patients

	tested on the above dates, results were reported into their EMR. 4. Further review of the QC records from 10/07/2020 through 03/03/2021, showed the laboratory documented 19 days of QC results. 5. The laboratory test volume worksheet documents 250 patients were tested from 03/2020 through 03/2021. 6. The laboratory failed to establish and implement QC procedures for ACT-K testing when the procedure was not included in the manufacturer's manual, prior to testing patients. 7. On an Initial survey conducted on 03/10/2021 at 3:15 PM, the LD confirmed the above findings.
D5807	TEST REPORT CFR(s): 493.1291(d) 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. This STANDARD is not met as evidenced by: Based on record review and an interview with the laboratory director (LD); the laboratory failed to ensure reference ranges or normal values are included in the final test report, affecting 8 out of 8 patients. Findings: 1. The patients' final report of 8 randomly selected patients were reviewed. 2. The laboratory failed to include the "reference intervals" or "normal" values for the Activated Clotting Time - Kaolin (ACT-K) tests the laboratory reports. 3. On an Initial survey conducted on 03/10/2021 at 3:15 PM, the LD confirmed the above findings.
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 records review, manuals, and an interview with the laboratory director (LD), the LD failed to have a director who is providing overall management and direction in accordance with 493.1407. Findings: 1. The LD failed to enroll the laboratory in an approved program for each of the specialties. See D6015. 2. The LD failed to ensure that quality control (QC) and quality assurance (QA) programs are established and maintained to identify failures as they occur. See D6022. 3. The LD failed to employ a technical consultant. See D6028.
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, lack of documentation, and an interview with the laboratory director (LD), the LD failed to enroll the laboratory in an approved proficiency testing (PT) program for the Hematology tests performed in the laboratory prior to testing patients, during the year of 2020. Findings: 1. The American Proficiency Institute (API) proficiency testing (PT) program documents, the i-STAT operator's and procedures manual, and quality control (QC) log sheets were reviewed. 2. The i-STAT manual instructs the laboratory on the PT program enrollment requirement for it's moderately complex testing. 3. The QC logs revealed the laboratory began patient testing for Activated Clotting Time- Kaolin (ACT-K) after 09/30/2019. 4. The API-PT program documents showed the laboratory became enrolled for i-STAT ACT testing on 03/03/2021. 5. Further review showed the laboratory failed to enrolled in any other approved PT program during the year of 2019 and 2020. 6. On an Initial survey conducted on 03/10/2021 at 3:20 PM, the LD confirmed the above findings.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and an interview with the laboratory director (LD); the LD failed to ensure that quality control (QC) and quality assurance (QA) procedures are established and maintained to assure the quality of laboratory services are provided and failures identified as they occur in the specialty of Hematology, prior to testing patients. Findings: 1. The LD failed to establish written control procedures for its Activated Clotting Time - Kaolin (ACT-K) testing. 2. The LD failed to ensure QC documents are maintained and reviewed. 3. The LD failed to establish written QA procedures to monitor, assess, and when indicated, correct problems identified in the test system.
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) 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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: Based on record review, the Laboratory Personnel Report (CMS 209), and an

	interview with the laboratory director (LD); the LD failed to employ laboratory personnel with the appropriate education and experience to provide consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities. Findings: 1. The LD failed to meet the qualifications of TC and fulfill the responsibilities of the TC. 2. The LD failed to employ qualified personnel to perform the responsibilities of a technical consultant (TC).
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on record review and an interview with the laboratory director (LD), the laboratory failed to a technical consultant (TC) who meets the qualification requirements of 493.1411 and provide technical oversight in accordance with 493. 1413 for testing performed in the subspecialty of Hematology. Findings: 1. The laboratory failed to employ a qualified TC to provide technical oversight for the Hematology testing performed in the Surgery laboratory. See D6034.
D6034	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: Based on record review and an interview with the laboratory director (LD), the laboratory failed to employ a technical consultant (TC) who qualified by education and experience can provide technical consultation for the Coagulation testing performed in the laboratory, affecting 250 patients. Findings: 1. The laboratory personnel files, procedures manual, and quality control (QC) documents were reviewed. 2. The TC responsibilities are the following: *Providing technical and scientific oversight of the laboratory. *Selecting of test methodology appropriate for the clinical use of the test results; *Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; *Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; *Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory ' s established performance specifications; *Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; *Identifying training needs and assuring that each

	individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; *Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. 3. The LD failed to ensure the above responsibilities were performed in the laboratory since testing began on 09/30/2019. 4. The LD failed to employ a qualified individual who could fulfill the responsibilities of TC in the laboratory.