Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2231713	11/07/2023
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Surgical Technology	1307 E Mccord, Centralia, 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
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 laboratory records and interview with the laboratory representative; the laboratory failed to enroll in appropriate proficiency testing (PT) challenges for eight of eight iStat Chem 8+ regulated analytes performed (Chloride, Creatinine, Glucose, Potassium, Sodium, Urea Nitrogen (BUN), Hematocrit, and Hemoglobin) in 2021 through date of survey (11-07-2023). Findings Include: 1. Review of the laboratory's policy and procedure manual identified the test menu: Chem 8+ - Sodium, Potassium, Chloride, Glucose, Calcium (iCA)*, Total Carbon Dioxide (TCO2)*, BUN, Creatinine, Hematocrit, and calculated Anion Gap* and Hemoglobin (*=non-regulated analytes). 2. Interview with the laboratory representative, on 11-07-23 at 11:25 am, stated that patient testing started on 10-04-2021. 3. Review of American Proficiency Institute (API) PT records revealed the laboratory failed to enroll for the correct five challenges, three times per year as required per 493.801 for eight of eight Chem 8+ regulated analytes performed in 2021 through the date of survey (11-07-23). 4. Interview with the laboratory representative, on 11-07-2023, at 11:29 am, confirmed 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 review of the laboratory records, lack of documentation, and interview with the laboratory representative; the laboratory failed to have a formal competency policy /procedure in place to assess employee competency as required per 493.1235. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the lack of an appropriate competency assessment policy/procedure in place as required per 493.1235. 2. On survey date 11-7-2023, at 10:55 am, the laboratory representative confirmed the laboratory failed to have a formal competency policy /procedure in place to assess employee competency.
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 review, lack of documentation, and an interview with the laboratory representative; the laboratory failed to maintain analytic system performance as required by 493.1250. First, the laboratory failed to monitor and document laboratory and manufacturer temperature requirements (see 5413). Secondly, the laboratory failed to verify performance for 10 out of 10 tested analytes (see 5421 and 5439). Lastly, the laboratory failed to meet the criteria for acceptability of quality control results prior to reporting patient test results (see 5481).
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and an interview with the laboratory representative; the laboratory failed to monitor and document manufacturer's required conditions essential for proper temperature of testing environment to ensure accurate

	and reliable test system operations and results as required per 493.1252 for seven of seven patient testing dates reviewed. Findings include: 1. Review of the laboratory procedure manual stated on page one, under "Supplies and Storage Requirements" the following: "Cartridges must be at room temperature (18-30 C or 64-86 F) prior to use. Allow 5 minutes for an individual cartridge and one hour for a box of cartridges to come to room temperature." 2.The facilities lack of ability to provide the surveyors with required room temperature monitoring as per 493.1252 for seven of seven patient testing dates reviewed (11-23-2021, 04-05-2022, 07-12-2022, 09-16-2022, 01-17-2023, 06-21-2023, and 10-18-2023). 3. On survey date 11-7-2023, at 3:02 pm, the laboratory representative confirmed the laboratory failed to be able to provide room temperature monitoring documentation.
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 interview with the laboratory representative, the laboratory failed to demonstrate that it can obtain accuracy, precision, reportable range, and verification of reference intervals for ten out of ten analytes reported on the iSTAT 1 system using the Chem 8+ and Activated Clotting Time (ACT) cartridges for results comparable to those established by the manufacturer as required per 493.1253. Findings include: 1. Review of the laboratory's policy and procedure manual identified the test menu, "Chem 8+ - Sodium, Potassium, Chloride, Glucose, iCA, TCO2, BUN, Creat, Hematocrit" and Activated Clotting Time (ACT). 2. Interview with the laboratory representative, on 11-07-23 at 11:25 am, stated that patient testing started on 10-04-2021 with the i-STAT 1 system. 3. Review of laboratory records found no documentation to verify accuracy, precision, reportable range, or reference intervals for the two cartridges (Chem 8+ and ACT) in use for ten of ten analytes resulted on the i-STAT 1 system (serial number: 420912). 4. On survey date 11/7/2023, at 11:18 am, the laboratory representative confirmed no analysis or interpretation of analytes tested were performed.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following

	occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory representative; the laboratory failed to perform calibration verification every six months as required per 493.1255 for iSTAT Chem 8+ testing in 2021 through 2023. Findings Include: 1. Upon the tour of the facility on 11-07-2023, at 11:06 am, the laboratory representative stated calibration verification materials and an external stimulator are to be ran every six months. 2. The calibration verification records for the iSTAT Chem 8+ cartridges on the i-STAT 1 system (Serial Number: 420912) identified calibration verifications were performed: 11-17-2021 08-05-2022 08-22-2022 10-31-2023 This showed a greater than six-month gap from the 11-17-2021 calibration verification to the 08-05-2022 calibration verification and the 08-22-2022 calibration verification to the 10-31-2023 calibration verification. 3. On an initial survey conducted on 11/07/2023 at 11: 18 am, the laboratory representative confirmed the above findings.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (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 interview with the laboratory representative, the laboratory failed to meet the criteria for acceptability of quality control (QC) results prior to reporting patient test results as required per 493.1256 for one of seven patient testing dates reviewed for glucose testing using iSTAT Chem 8+ cartridges, affecting two patient results. Findings include: 1. Review of quality control results of seven randomly selected patient testing dates was performed (11-23-2021, 04-05-2022, 07-12-2022, 09-16-2022, 01-17-2023, 06-21-2023, and 10-18-2023). 2. One of seven testing dates (7-12-2022) showed the TriControl Level 1 for glucose using the Chem 8+ cartridge was unable to obtain a quantifiable value. "Glu ***mg /dL" 3. No evidence of repeat testing or corrective action was found regarding this QC failure. 4. Review of patient testing performed identified two patients (Chart numbers: 9418 and 8029) had glucose testing results reported when QC was unacceptable. 5. On an initial survey conducted on 11/07/2023 at 3:02 pm, the laboratory representative confirmed the above findings.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)

	(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview with laboratory representative, the laboratory failed to document corrective actions taken when refrigerator (containing iSTAT cartridges and quality control materials) temperatures failed to be documented or were outside of the acceptable range for two of seven months reviewed. Findings Include: 1. The laboratory's standard operating procedure and seven monthly temperature logs from November 2021 through October 2023 were reviewed. 2. Upon review of the laboratory's "Refrigerator & Freezer Temperature Log", the log itself stated: "Record the Time, Temperatures & Initials two times (2) each business day, upon arrival (morning) and when closing the office at the end of the day (evening)." 3. Review of temperature logs revealed a) two temperatures missing from one date (6/2/2023) in June 2023 and b) two temperatures out of documented range on one date (10/24/23) in October 2023. 4. No corrective actions were noted on the above-mentioned occurrences. 5. On survey date 11/7/2023, at 3:02 pm, the laboratory representative confirmed no corrective actions were taken regarding these gaps in temperature monitoring or out of range measurements.
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 record review of proficiency testing (PT) reports and interview with the laboratory representative, the laboratory director (LD) failed to ensure successful participation in an Health and Human Services (HHS) approved PT program for the specialties of hematology and chemistry resulting in the laboratory's unsuccessful PT enrollment for the overall specialty of hematology in regard to hematocrit and hemoglobin and the following routine chemistry analytes: sodium, potassium, chloride, glucose, urea nitrogen, and creatinine (see also D6015). Secondly, the LD failed to develop and follow required corrective action policies and procedures regarding failed PT results (see 6019). Lastly, the LD failed to develop and follow required competency assessment policies and procedures to ensure testing personnel maintained competency to perform all authorized chemistry and hematology tests (see D6030).
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 the laboratory representative, the laboratory director failed to ensure successful participation in an Health and Human Services (HHS) approved proficiency testing (PT) program for the specialties of hematology and chemistry resulting in the laboratory's unsuccessful PT enrollment for eight out of eight analytes (hematocrit, hemoglobin, sodium, potassium, chloride, glucose, urea nitrogen, and creatinine). Findings Include: 1. Review of the laboratory's policy and procedure manual identified the test menu: Chem 8+ - Sodium, Potassium, Chloride, Glucose, Calcium (iCA)*, Total Carbon Dioxide (TCO2)*, BUN, Creatinine, Hematocrit, and calculated Anion Gap* and Hemoglobin (*=non-regulated analytes). 2. Review of American Proficiency Institute (API) PT records revealed the laboratory failed to enroll for the correct five challenges, three times per year as required per 493.801 for eight of eight regulated analytes performed. See D2000. 3. Interview with the laboratory representative, on 11-7-2023, at 11:29 am, confirmed the above findings.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review, lack of documentation, and interview with the laboratory representative, the laboratory director failed to ensure that an approved corrective action plan is followed when any PT results are found to be unacceptable or unsatisfactory for one out of ten analytes for event two of calendar year 2022 as required by 493.1407. Findings include: 1. Review of PT records found no corrective action documentation for the unsatisfactory Total CO2 score (at 50%) for event two of calendar year 2022. 2. Survey interview performed 11/7/2023 at 11: 54 am with laboratory representative confirmed above findings.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for

	monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of the laboratory records, lack of documentation, and interview with the laboratory representative; the laboratory director failed to ensure policies and procedures were established and maintained to monitor the competency of six out of six testing personnel authorized to perform moderate complexity testing in the specialty of hematology and subspecialty of routine chemistry as required by 493. 1407. Findings Include: 1. Review of the laboratory's policy and procedure manual identified a lack of a competency assessment policy. See D5209. 2. Review of employee records revealed a lack of competency assessment performed by the qualified technical consultant according to the CMS-209 for six of six employees (see D6046). 3. Interview with the laboratory representative on 11-07-2023 at 10:55 am, confirmed the above findings.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) 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. This STANDARD is not met as evidenced by: Based on review of employee competency assessments and interview with the laboratory representative; the laboratory failed to have competency assessments performed by a qualified technical consultant for six of six individuals responsible for moderate complexity testing semiannually during the first year the individuals tested patient specimens as per 493.1413. Findings: 1. Upon record review, six of six testing personnel's competency assessments in their first year of testing patient specimens were not performed by a qualified technical consultant. 2. An interview with the laboratory representative at 10:53 am on 11/07/2023 confirmed the findings that six of six of the testing personnel's competency assessments in their first year of testing patient specimens were not performed by a qualified technical consultant.