Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2256857	11/28/2023
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Surgical Technology Llc	400 Rushing Dr, Herrin, 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
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 technical consultant; the laboratory failed to have a competency policy/procedure in place to assess employee competency on the i-STAT analyzer used for Chem 8+ and Activated Clotting Time (ACT) cartridges as required per 493.1235. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the lack of a competency assessment policy/procedure in place as required per 493.1235. 2. On survey date 11-28-2023, at 12:20 pm, the technical consultant confirmed the laboratory failed to have a competency policy/procedure in place to assess employee competency.
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 technical consultant; 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 six of six patient testing dates reviewed for Chem 8+ and Activated Clotting Time (ACT) cartridges on the i-STAT analyzer. 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 laboratory failed to provide the surveyors with required room temperature monitoring as per 493.1252 for six of six patient testing dates reviewed (02/20/2023, 03/13/2023, 06/08/2023, 09/18/2023, 10/31/2023, 11/20 /2023). 3. On survey date 11-28-2023, at 2:00 pm, the technical consultant confirmed the laboratory failed to provide room temperature monitoring documentation.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the technical consultant; the laboratory failed to include all the required components of a laboratory test report including a) the facility's address for six of six i-STAT Chem 8+ and Activated Clotting Time (ACT) test reports and b) the reference range for three of three ACT test reports reviewed as required by 493.1291. Findings Include: 1. Upon review patient test reports, six of six reports (10922, 11310, 14840, 16814a, 17127, 16814b) for Chem 8+ testing on the iSTAT analyzer found the laboratory failed to indicate the facility address on the laboratory's test report. 2. Review of three of three patient test reports (10922, 16814a, 16814b) for ACT testing on the i-STAT analyzer found the laboratory failed to indicate the ACT reference range on the laboratory's test report. 3. On survey date 11-28-2023, at 1:37 pm, the technical consultant confirmed the patient test reports failed to include all the required components of a laboratory test report, including a facility address on six of six Chem 8+ patient test reports and an ACT reference range on three of three ACT patient test reports.
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 technical consultant; the laboratory failed to have competency assessments performed by a qualified technical consultant for six of eight individuals responsible for moderate complexity testing including Chem 8+ and Activated Clotting Time (ACT) cartridges on the i-STAT analyzer at least semiannually during the first year the individuals tested patient specimens as per 493.1413. Findings: 1. Upon record review, six of eight testing personnel (TP)'s competency assessments in their first year of testing patient specimens were not performed by a qualified technical consultant. Testing Personnel: Individual performing competency: TP #1 TP #6 TP #4 TP #6 TP #5 TP #6 TP #6 TP #4 TP #7 TP #6 TP #8 TP #6 2. An interview with the technical consultant at 2:00 pm on 11/28/2023 confirmed the findings that six of eight of the testing personnel's competency assessments in their first year of testing patient specimens were not performed by a qualified technical consultant.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of personnel records, lack of academic records, the CMS-209 (Laboratory Personnel Report), and interview with the technical consultant; the laboratory failed to have qualifying academic records for one of eight testing personnel (TP) to meet the qualification requirements of 493.1423 (see D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of personnel records, lack of academic records, the CMS-209 (Laboratory Personnel Report), and interview with the technical consultant; the laboratory failed to have qualifying academic records for one of eight testing personnel (TP) listed on the CMS-209 for moderate complexity testing including Chem 8+ and Activated Clotting Time (ACT) cartridges on the i-STAT analyzer as required per 493.1423. Findings include: 1. No academic records were made available to qualify moderate complexity TP #3 listed on the CMS-209 form dated 11/28/2023.

	2. Interview with technical consultant on 11/28/2023 at 2:00 pm revealed they were unable to retrieve the qualifying documents at the time, but they would email the surveyors once the records were obtained. As of 12/19/2023 at 1:05 pm, no records had been received by the surveyors for one of eight testing personnel.