Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2142238	05/21/2018
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Orthopedics And Sports Medicine	801 W Bayou Pines Dr, Lake Charles, 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	AN INITIAL CERTIFICATION SURVEY was performed at Advanced Orthopedics and Sports Medicine - CLIA # 19D2142238 on May 21, 2018. Advanced Orthopedic and Sports Medicine was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1403 CONDITION: Laboratory Director performing moderate complexity testing. 42 CFR 493.1409 CONDITION: Technical Consultant. 42 CFR 493.1421 CONDITION: Testing Personnel.
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 laboratory policy and procedure manual, and interview with personnel, the laboratory failed to establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory failed to establish written policies and procedures that include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel involved in any phase of laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting or test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing

	samples or external proficiency testing samples. f) Assessment of problem solving skills. 2. Interview with personnel 2 on May 21, 2018 confirmed the laboratory failed to have a complete policy and procedure manual.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory failed to include the gender of the patient, and the specimen collection time on the patient test requisition for nine (9) of nine (9) patients received. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory did not include a policy for test requisitions that included: a) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. b) The patient's name or unique patient identifier. c) The sex and age or date of birth of the patient. d) The test(s) to be performed. e) The source of the specimen, when appropriate. f) The date and, if appropriate, time of specimen collection. g) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. 2. Review of a random selection of patient test requisitions from February 12, 2018 through May 15, 2018 revealed the laboratory failed to include the gender of the patient, and the specimen collection time on the patient test requisition for the following nine (9) patients for Urine Drug Screen (UDS) testing. NOTE: UDS testing includes: Amphetamine (Amph), Barbiturate (Barb), Benzodiazepine (BZO), Cocaine (COC) Ecstasy, Methadone (Meth), Opiate (OPI), and Cannabinoids (THC): On February 12, 2018 Patient 1. On February 26, 2018 Patient 2. On March 5, 2018 Patient 4. On March 23, 2018 Patient 3. ON April 6, 2018 Patient 6. On April 26, 2018 Patient 5. On May 3, 2018 Patients 7 and 8. On May 15, 2018 Patient 9. 3. Interview with personnel 2 on May 21, 2018 revealed the laboratory began UDS testing on February 11, 2018. Personnel 2 also revealed that samples for UDS are collected inhouse and at another location. Personnel 2 did confirm the laboratory failed to document the gender of the patient and the collection time of the specimen.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d)

	If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to establish detailed written instructions for the facilities the laboratory provides services for to maintain the integrity of samples and ensure accurate and reliable testing. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed instructions for specimen types, and the collection containers for the sample. However the laboratory failed to address: a) Collection techniques/methods to ensure that the appropriate specimen is collected and that the integrity of the sample meets the manufacturer's instructions b) Test Systems and methodologies. storage requirements and transportation needs for the Siemens Viva E Analyzer for Urine Drug Screen (UDS) testing which includes: Amphetamine (Amph), Barbiturate (Barb), Benzodiazepine (BZO), Cocaine (COC) Ecstasy, Methadone (Meth), Opiate (OPI), and Cannabinoids (THC): c) If the samples needed to be centrifuged to meet the manufacturer's instructions to maintain the integrity of the samples. d) Transportation of the samples to the laboratory at appropriate temperatures: if the samples needed to be maintained at room temperature, refrigerated or frozen. 2. Interview with personnel 2 on May 21, 2018 revealed he was unaware the laboratory was receiving samples from and outside source. Personnel 2 confirmed the laboratory manual does not include all the information required to maintain the integrity of patient samples.
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 ensure the laboratory policy and procedure manual contained complete policies and procedures. Findings: 1. Review of the laboratory policy and procedure manual revealed the laboratory failed to have policies and procedures for: Test Requisitions: what mandated information needs to be on the test requisition: a) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. b) The patient's name or unique patient identifier. c) The sex and age or date of birth of the patient. d) The test(s) to be performed. e) The source of the specimen, when appropriate. f) The date and, if appropriate, time of specimen collection. g) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. Performance specifications to include: a) Detailed policies and procedures for testing personnel that instructed testing personnel what to do for studies for accuracy, precision (day-to-day, run-to-run, and

	within-run variation, as well as operator variance), reportable and reference ranges and analytical sensitivity and specificity. a) Acceptability criteria for each of the studies for accuracy, precision, reportable and reference ranges and analytical sensitivity and specificity. a) Policies and procedures for when data from the studies for precision, accuracy, reportable range, reference range, analytical sensitivity and analytical specificity fail to meet acceptability criteria. Description of the course of action to take if the Siemens Viva E Analyzer becomes inoperable. Personnel Competency to include written policies and procedures that include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel performing laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting or test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills: and that assessments are to be performed semi annually the first year and annually thereafter. 2. Interview with personnel 2 on May 21, 2018 confirmed the policy and procedure manual was incomplete
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 observation and record review, the laboratory failed to include on the report for Urine Drug Screen tests a statement that states the results are preliminary results and the disclaimer contained in the Siemens Viva E package inserts on the report for Urine Drug Screen testing. Findings 1. Observation by surveyors during the tour of the laboratory on May 21, 2018 revealed the laboratory maintained a Siemens Viva E Analyzer for testing Amphetamine (Amph), Barbiturate (Barb), Benzodiazepine (BZO), Cocaine (COC) Ecstasy, Methadone (Meth), Opiate (OPI), and Cannabinoids (THC). 2. Review of the Siemens Syva Emit Assay sheets for Amph, Barb, BZO, COC, Ecstasy, Meth, OPI, and THC revealed that these "assays provides only preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgement should be applied to any drug-of-abuse test results, particularly when preliminary positive results are used." 3. Review of a random selection of patient test records from February 12, 2018 through May 15, 2018 for Urine Drug Screen testing performed on the Siemens Viva E revealed the laboratory failed to state the results are preliminary and failed to add the disclaimer stated above for the following nine (9)

	patients. On February 12, 2018 Patient 1. On February 26, 2018 Patient 2. On March 5, 2018 Patient 4. On March 23, 2018 Patient 3. ON April 6, 2018 Patient 6. On April 26, 2018 Patient 5. On May 3, 2018 Patients 7 and 8. On May 15, 2018 Patient 9. 4. Interview with personnel 2 on May 21, 2018 revealed laboratory personnel were unaware the laboratory had to assure that the reports stated the results were just preliminary results and that a disclaimer had to to be on each report. Personnel 2 confirmed patient reports failed to state results were preliminary and failed to include the disclaimer.
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, 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 that all personnel have the appropriate education and experience to accurately report patient test results. Refer to D6029. 2 The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D6031.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of laboratory personnel records and interview with laboratory personnel, the Laboratory Director failed to ensure that all personnel have the appropriate education and experience to accurately report patient test results. Findings: 1. The Technical Consultant failed to possess a current license issued by the State of Louisiana. Refer to D6035. 2. The laboratory failed to provide documentation that testing personnel met the educational qualifications for performing moderate complexity testing for one (1) of one (1) testing personnel. Refer to D6065.
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 laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Findings: 1. Review of the laboratory policy and procedure manual revealed the laboratory failed to have policies and procedures for: Test Requisitions: what mandated information needs to be on the test requisition: a) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. b) The patient's name or unique patient identifier. c) The sex and age or date of birth of the patient. d) The test(s) to be performed. e) The source of the specimen, when appropriate. f) The date and, if appropriate, time of specimen collection. g) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. Performance specifications to include: a) Detailed policies and procedures for testing personnel that instructed testing personnel what to do for studies for accuracy, precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference ranges and analytical sensitivity and specificity. a) Acceptability criteria for each of the studies for accuracy, precision, reportable and reference ranges and analytical sensitivity and specificity. a) Policies and procedures for when data from the studies for precision, accuracy, reportable range, reference range, analytical sensitivity and analytical specificity fail to meet acceptability criteria. Description of the course of action to take if the Siemens Viva E Analyzer becomes inoperable. Personnel Competency to include written policies and procedures that include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel performing laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting or test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills: and that assessments are to be performed semi annually the first year and annually thereafter. 2. Interview with personnel 2 on May 21, 2018 confirmed the policy and procedure manual was incomplete
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 observation, record review, and interview with personnel, the Technical Consultant (Personnel 2) failed to meet the qualifications and provide technical oversight of the laboratory. Findings: 1. The Technical Consultant (Laboratory Director) failed to meet the qualifications for a Technical Consultant of moderate complexity testing. Refer to D6035. 2. The Technical Consultant failed to provide technical and scientific oversight for the laboratory. Refer to D6036.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with personnel, the Technical Consultant (Personnel 2) failed to meet the qualifications for a Technical Consultant of moderate complexity testing. Findings: 1. Review of Personnel Records for the Technical Consultant revealed the Technical Consultant failed to possess a current State License. 2. Interview with Personnel 2 on May 21, 2018 revealed he was unaware that he needed to possess a Louisiana State License to fulfill the position of Technical Consultant. Personnel 2 confirmed he did not have a Louisiana State License.

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, record review and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight for the laboratory. Findings: 1. Review of the FORM CMS 209 submitted to the surveyor on May 21, 2018 revealed that Personnel 2 fulfilled the duties for Technical Consultant. 2. Observation, record review and interview with personnel revealed the Technical Consultant failed to address the following problems identified in the laboratory: a) The laboratory failed to establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. Refer to D5209. b) The laboratory failed to include the gender of the patient, and the specimen collection time for nine (9) of nine (9) patients received. Refer to D5305. c) The laboratory failed to establish detailed written instructions for the facilities the laboratory provides services for to maintain the integrity of samples and ensure accurate and reliable testing. Refer to D5317. d) The laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures. Refer to D5401. e) The laboratory failed to include on the report for Urine Drug Screen tests a statement that states the results are preliminary results and the disclaimer contained in the Siemens Viva E package inserts on the report for Urine Drug Screen testing. Refer to D5805. 3. Interview with Personnel 2 on May 21, 2018 confirmed it was his responsibility to assure that all the items cited above were in place prior to patient testing.
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 record review and interview with laboratory personnel, the laboratory failed to ensure testing personnel met the qualifications of education and licensure to perform moderate complexity testing. Findings: 1) The laboratory failed to have evidence that testing personnel performing non-waived testing met the educational qualifications for performing moderate complexity testing, for one (1) of one (1) testing persons. Refer to tag D6065. 2) Interview with personnel 2 on May 21, 2018 confirmed the above findings
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 record review and interview with personnel, the laboratory failed to provide documentation that testing personnel met the educational qualifications for performing moderate complexity testing for one (1) of one (1) testing personnel. Findings: 1. Review of personnel records on May 21, 2018 revealed the laboratory failed to maintain documentation of at least a High School Diploma or equivalent for moderate complexity laboratory testing for Personnel 3. 2. Interview with Personnel 2 on May 21, 2018 confirmed the laboratory did not maintain documentation of education for Personnel 3.