

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 36D1093278	<b>(X3) Date Survey Completed</b> 01/23/2019
<b>Name of Provider or Supplier</b> Advanced Spine & Pain Management	<b>Street Address, City, State</b> 7691 Five Mile Road, Suite 303, Cincinnati, OH	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2007</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS 209 form, proficiency testing (PT) records, and an interview with the Practice Administrator (PA), the laboratory failed to examine or test PT samples by all personnel who routinely perform testing in the laboratory. Patients tested with the 2018 PT UDS kit 31085722 3 08 39 event B have the potential to be affected by this deficient practice. Findings Include: 1. Review of one out of seven of the laboratory's 2017-2018 College of American Pathology (CAP), PT attestation pages revealed the PA participated in PT testing for the 2018 UDS kit 31085722 3 08 39 event B. 2. Review of the laboratory's CMS-209 form, approved, signed, and dated by the Laboratory Director on 01/22/2019, did not indicate the PA listed as Testing Personnel. 3. A competency assessment document was provided for the PA for the AO400 instrument, however it was dated 09/25/2018. The PT test date was 07/18/2018. The competency assessment document was not signed by the PA. 4. The PA stated they stepped-in to help out when short staffed for the 2018 UDS kit 31085722 3 08 39 event B. The interview occurred on 01/23/2019 at 12:22 PM.</p>
<b>D2015</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the</p>

proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the Practice Administrator (PA), the laboratory failed to document the handling, preparation, processing, examination and each step in the testing and reporting of proficiency testing (PT) results. All patients tested with the PT events below have the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's College of American Pathologist (CAP), 2017 DMPM attestation page for kit 29968175 3 05 18 and 2017 UDS attestation page for kit 29968220 7 07 77 found no Lab Director signature. 2. Review of the attestation page for the 2017 UDS CAP kit 29968239 8 07 43 found a signature from a former Testing Personnel on the Director or designee attestation line. 3. Review of the original attestation page for the 2018 DMPM CAP kit 31662577 1 05 72 found no Testing Personnel signature on the (original) attestation page. Two other attestation pages for the 2018 DMPM CAP kit 31662577 1 05 72 kit were found with only typed names for the attestation of both the Laboratory Director and Testing Personnel. 4. Review of the attestation page(s) for the 2018 UDS CAP kit 31086008 7 07 71 found two separate pages. One attestation page contained the Testing Personnel signature only. Another page contained the Laboratory Director's signature only. 5. Review of the attestation page for the 2018 UDS CAP kit 31085436 2 07 28 found only typed names, no signature as required by CAP. 6. The PA confirmed all PT attestation pages are sent to the Lab Director for review and submission. The interviews occurred on 01/23/2019 at 12:15 PM.

**D5200**

**GENERAL LABORATORY SYSTEMS**  
CFR(s): 493.1230

Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on record reviews and interviews with the Laboratory Director and Practice Administrator, the laboratory failed to meet the applicable general laboratory systems requirements to monitor and evaluate the overall quality of the general laboratory systems and correct identified problems. All patients have the potential to be affected by this deficient practice. Findings Include: 1. The laboratory failed to establish and follow written policies and procedures to assess and document the competency of TP and the General Supervisor. (Refer to D5209) 2. The laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the general laboratory systems specified in 493.1239. (Refer to D5291) 3. The laboratory failed to review assessment

policies, procedures and notes to ensure continuous improvement as specified in 493.1239. (Refer to D5293)

**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 and an interview with the Practice Administrator (PA), and the Laboratory Director (LD), the laboratory failed to establish and follow written policies and procedures to assess the competency of the General Supervisor (GS) based on the responsibilities of the position. All patients from 01/21/2019 until the competency assessment has been completed have the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's Form CMS-209, approved, signed, and dated by the LD on 01/22/2019, found one individual listed as GS. 2. Review of the laboratory's competency assessment policy and procedure titled "Personnel Competency Assessment Policy", lists six elements of evaluation. 3. Review of the "General Supervisor Competency Assessment" document signed and dated by the LD on 01/21/2019, lists eight responsibilities only. No signature and date from the GS was found. 3. The surveyor requested the General Supervisor's competency assessment document listing the six elements of evaluation as stated in the policy and procedure. The LD and PA were unable to provide the requested documentation. The interviews occurred on 01/23/2019 at 10:57 AM.

**D5291**

**GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT**

CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on policy and procedure review, record review, and an interview with the Laboratory Director (LD), the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems. All patients tested have the potential to be affected by this deficient practice. Findings include: 1. Review of the quality assessment policy and procedure titled, "Quality Assurance Protocol", found the following statement: "Staff Training and Documentation" "Each laboratory staff member is trained for their respective duties prior to testing patient samples." 2. Review of documentation found no General Supervisor training for 2017-2018. 3. One competency assessment document was provided for Testing Personnel #2 labeled as "initial competency" for the API3000, however no dates or Testing Personnel signature were recorded. 4. No initial competency assessments for Testing Personnel #2 for the AO400 instrument and respective lab duties were found. 5. Review of the quality assessment policy and procedure titled, "Quality Assurance Protocol", found the following statement: "Quality Assurance/Quality Improvement Meetings" "2. The

meetings will define issues; the plans of actions to address the issues, implementation of the plans of action, and summarize the outcomes for which the laboratory has tried to improve its function." 6. Meeting notes provided on the date of inspection found no implementation of a plan of action, or a summary of an outcome for which the laboratory has tried to improve its function. 7. An interview with the LD confirmed quality assessment was not performed as stated in the policy and procedures. The interview occurred on 01/23/2019 at 1:10 PM.

**D5293**

**GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1239(b)(c)

(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's quality assessment documentation and an interview with the Laboratory Director (LD), the laboratory failed to review the effectiveness of their quality assessment program of the general laboratory systems. All patients have the potential to be affected by this deficient practice. Findings were as follows: 1. Review of the laboratory's January 11, 2018 quality assessment documentation, provided on the date of the inspection, revealed an email with twelve action items listed after the LD quality assessment meeting/visit. 2. Action items #2 requesting a new humidifier, #6 stating the LD will sign all policy and procedures, and #11 requesting the creation of a LD visit log book were stated in the email. 3. Three checklists from the LD visits on 03/01-02/2018, 09/24-25/2018, and 01/21-22/2019 were provided on the date of the survey. 4. Review of each LD visit checklist found several unchecked boxes and miscellaneous notes regarding laboratory issues. 5. The Surveyor requested the laboratory's 2018-2019 quality assessment documentation for the general laboratory systems for the problems identified by the LD. The LD was unable to provide the requested documentation on the date of the inspection. The interview occurred on 01/23/2019 at 1:33 PM.

**D5311**

**SPECIMEN SUBMISSION, HANDLING, AND REFERRAL**  
CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:  
Based on policy and procedure review and an interview with the Practice Administrator (PA), the laboratory failed to establish and follow a written procedure for the handling and shipping of urine specimens received from another facility. All patients have the potential to be affected by this deficient practice. Findings were as follows: 1. Review of the laboratory's policy and procedure manual titled, "Advanced

Spine and Pain Care Policy and Procedure Manual", did not find any mention of a policy and procedure for the conditions and handling of urine specimens during shipping. 2. The surveyor requested a policy and procedure for all urine specimen shipments received from 2017 up to the date of the survey, to include sample transport conditions, from the PA. The PA verified there was no policy and procedure which included the conditions and handling of urine specimens received and was unable to provide the requested information. The interview occurred on 01/23/2019 at 12:42.

**D6079**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(a)(b)

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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:  
Based on document reviews, and policy and procedure reviews, it was determined the Laboratory Director (LD) failed to be responsible for the overall operation and administration of the laboratory including assuring compliance with applicable regulations. All patients have the potential to be effected by this deficient practice. Findings include: 1. The LD failed to ensure written policies and procedures were available to the laboratory personnel for urine specimens shipped from another laboratory . (See D5311) 2. The LD failed to ensure competency assessments were performed on 1 of 2 testing personnel. (See D5209) 3. The LD failed to ensure all proficiency testing was performed by testing personnel who routinely run patient samples. (See D2007) 4. The LD failed to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems.(See D5291) 5. The LD failed to review the effectiveness of the quality assessment program of the general laboratory systems.(See D5293)

**D6106**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(14)

The laboratory director must 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 review of the laboratory's policy and procedure manual and an interview with the Laboratory Director (LD), the Laboratory Director failed to ensure that approved policies and procedures were available to all personnel responsible for any aspect of the testing process. All patients have the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policy and procedure manual titled, "Advanced Spine and Pain Care Policy and Procedure Manual", did not find any indication the Laboratory Director approved the policies

and procedures prior to the implementation of patient testing and after becoming the laboratory director in 2018, via a signature and date. 2. The LD confirmed the policies and procedures were not signed after becoming laboratory director in 2018 and prior to patient testing. The interview occurred on 01/23/2019 at 10:57 AM.

**D6120**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for 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; (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 the laboratory's documents, and an interview with Laboratory Director (LD), the Technical Supervisor (TS) failed to evaluate the competency of testing personnel to ensure the staff maintain their competency to perform test procedures and report test results promptly, accurately, and proficiently. All patients have the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's competency assessing policy titled "Personnel Competency Assessment Policy", found the following statement: "These assessments will occur at the onset of testing, following training, after 6 months of employment, and then annually on the anniversary of their hire date." 2. One competency assessment document was provided for TP#2 labeled as "initial competency" for the API3000, however no dates or Testing Personnel signature was recorded. 3. The surveyor requested the initial competency assessments for the AO400 instrument, general lab duties, and the dates the above assessment was performed. The TS was unable to provide the requested information. The interview occurred on 01/23/2019 at 10:50 AM.

**D6127**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the Laboratory Director (LD), the Technical Supervisor (TS) failed to evaluate and document the performance of Testing Personnel (TP) who was responsible for high complexity testing procedures at least semiannually during the first year the individual tested patient specimens. All patients have the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's 2018 training and competency assessment documentation, provided on the date of the inspection, found TP#2 did not have a semi-annual competency assessment record. 3. The LD confirmed TP#2 did not have a semiannual competency assessment within the first year of testing. The interviews occurred on 01/23/2018 at 10:50 AM.

**D6141**

**GENERAL SUPERVISOR**

CFR(s): 493.1459

The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of CMS form 209, document reviews, and an interview with the Laboratory Director (LD), the laboratory failed to have one or more General Supervisors who were qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. All patients from March 2018 to January 20 2019 have the potential to be affected by this deficient practice. Findings Include: 1. Review of CMS form 209 showed Testing Personnel #1 also listed as the General Supervisor. 2. Review of the "LC/MS/MS - Specific Checklist" for the API 3000 found TP#1 listed as the General Supervisor and Testing Personnel under the "Title". Further review revealed an employee and LD signature date of 01/21 /2019, two days prior to the laboratory survey. 3. The surveyor requested qualification documents and competency assessment records for the General Supervisor prior to 01 /21/2019 from the LD. The LD stated there was no General Supervisor after the previous General Supervisor had terminated employment at this location in March of 2018. the interview occurred 01/23/2019 at 10:32 AM.