Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D2085729	03/07/2019
Name of Provider or Supplier	**Street Address, City, State**	
Auzenne Pain Institute	4803 29th Ave Ste A, Meridian, MS	

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
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of Siemens Viva-ProE system maintenance logs from 6-28-17 through 3-7-19 and lack of documentation of weekly maintenance for eighteen months, the laboratory failed to document, as performed, the weekly maintenance, as defined by the manufacturer, from 6-28-17 until 1-2-19. Findings include: Review of Siemens Viva-ProE system maintenance logs from 6-28-17 through 3-7-19 revealed the following weekly maintenance procedure was not documented as performed for eighteen months, from 6-28-17 until 1-2-19: Weekly Perform rinse probe procedure.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of urine drug screen test reports from the Siemens Viva-ProE system and interview on 3-7-19 at 10:30 a.m. with the general supervisor and Testing

	Personnel #2, listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, the laboratory's record system does not include the identity of the personnel who performed urine drug screen testing on the Siemens Viva-ProE system. Findings include: Review of urine drug screen test reports from the Siemens Viva-ProE system revealed no documentation of the identity of the personnel who performed urine drug screen testing on the Siemens Viva-ProE system. The general supervisor and Testing Personnel #2 confirmed there is no documentation of the identity of testing personnel performing urine drug screen testing on the Siemens Viva-ProE system and stated that both Testing Personnel #2 and Testing Personnel #3 perform testing on the Siemens Viva-ProE system.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the CMS 209 personnel form and personnel records since the last survey on 5-8-17, the technical consultant failed to evaluate the competency and document the performance of Testing Personnel #2 and Testing Personnel #3, responsible for moderate complexity urine drug screen testing on the Siemens Viva-ProE system, at least semiannually during the first year these individuals tested patient specimens. Findings include: Review of the CMS 209 personnel form and personnel records since the last survey on 5-8-17 revealed the technical consultant failed to evaluate the competency and document the performance of Testing Personnel #2 at least semiannually since the Siemens Viva-ProE system was put in use for patient testing on 6-28-17 and failed to evaluate the competency and document the performance of Testing Personnel #3 at least semiannually since this individual began moderate complexity testing after orientation on 11-30-17.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of the CMS 209 personnel form and personnel records since the last survey on 5-8-17, the technical consultant failed to evaluate the competency and document the performance of Testing Personnel #2 and Testing Personnel #3, responsible for moderate complexity urine drug screen testing on the Siemens Viva-ProE system, at least annually. Findings include: Review of the CMS 209 personnel form and personnel records since the last survey on 5-8-17 revealed the technical consultant failed to evaluate the competency and document the performance of Testing Personnel #2 and Testing Personnel #3 at least annually since these individuals began performing moderate complexity urine drug screen testing on the Siemens Viva-ProE system.

D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must 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: 1. Based on interview on 3-7-19 at 10:30 a.m. with the general supervisor and Testing Personnel #2, listed on the CMS 209 personnel form, observation of Immunalysis Oxycodone Urine HEIA reagent in use by the laboratory for testing on the Siemens Viva-ProE system on 3-7-19 at 11:00 a.m., review of the Food and Drug Administration (FDA) categorization database and personnel records, the laboratory director failed to ensure Testing Personnel #2 and Testing Personnel #3 had the appropriate education to perform high complexity urine oxycodone testing on the Siemens Viva-ProE system. 2. Based on personnel records and lack of documentation of training for urine drug screen testing on the Siemens Viva-ProE system for Testing Personnel #2 and Testing Personnel #3, the laboratory director failed to ensure these testing personnel received appropriate training for moderate complexity urine amphetamine, benzodiazepine, cocaine, opiate, and cannabinoid testing on the Siemens Viva-ProE system.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on interview on 3-7-19 at 10:30 a.m. with the general supervisor and Testing Personnel #2, listed on the CMS 209 personnel form, observation of Immunalysis Oxycodone Urine HEIA reagent in use by the laboratory for testing on the Siemens Viva-ProE system on 3-7-19 at 11:00 a.m., review of the FDA categorization database and personnel records, the laboratory failed to ensure Testing Personnel #2 and Testing Personnel #3 met the qualification requirements of 493.1489 of this subpart to perform high complexity urine oxycodone testing on the Siemens Viva-ProE system. Findings include: Review of the FDA categorization database revealed the Immunalysis Oxycodone Urine HEIA reagent observed in use by the laboratory on 3-7-19 at 11:00 a.m. is not yet classified for use on the Siemens Viva-ProE, and is therefore, considered high complexity. Interview on 3-7-19 at 10:30 a.m. with the general supervisor and Testing Personnel #2, listed on the CMS 209 personnel form, revealed Testing Personnel #2 has been performing oxycodone testing on the Siemens Viva-ProE system since the system was put in use for patient testing on 6-28-17, and Testing Personnel #3 has been performing oxycodone testing since orientation on 11-30-17. Review of personnel records for Testing Personnel #2 and #3 revealed no documentation to qualify these individuals as high complexity testing personnel.
D6171	TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) 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 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; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

	This STANDARD is not met as evidenced by: Based on interview with the general supervisor and Testing Personnel #2, listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, on 3-7-19 at 10:30 a.m., observation of Immunalysis Oxycodone Urine HEIA reagent in use by the laboratory for testing on the Siemens Viva-ProE system on 3-7-19 at 11:00 a.m., review of the Food and Drug Administration (FDA) categorization database and personnel records, the laboratory failed to ensure Testing Personnel #2 and Testing Personnel #3 met the qualification requirements of 493.1489 of this subpart to perform high complexity urine oxycodone testing on the Siemens Viva-ProE system.