Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2057982	11/14/2018
Name of Provider or Supplier	**Street Address, City, State**	
Isaac Spine Joint & Pain Institute	3320 Perimeter Hill Dr, Nashville, TN	

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	13995 A revisit survey was conducted on Isaac Spine, Joint, and Pain Institute for all previous deficiencies cited on November 14, 2018. All deficiencies have been corrected, and no new noncompliance was found. The facility is in compliance with all regulations surveyed.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on random chart audit reviews and interview with the Technical Supervisor determined the laboratory failed to retain instrument records for 2016 and 2017. The findings include: 1. Random chart audits for two patients in 2016 and three patients in 2017 revealed no instrument records for the Microgenics Corporation (MCG) 240 screening instrument and the Atmospheric Pressure Ionization (API) 4000 Liquid Chromatography-Mass Spectrometry (LC-MS) confirmation instrument for 2016 and 2017. 2. Interview with the Technical Supervisor on November 14, 2018, at 1:15 P.M. confirmed the laboratory failed to retain instrument records for the MCG 240 screening instrument and the API 4000 LC/MS confirmation testing instrument in 2016 and 2017.
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 a random chart audit reviews and interview with the Technical Supervisor determined the laboratory failed to perform and document monthly maintenance for the MGC 240 screening instrument in December 2016. Findings include: 1. A random chart audit review of two patients in December 2016 revealed no monthly maintenance for the MGC 240 screening instrument was perfomed and documented in December 2016. 2. Interview with Technical Supervisor on November 14, 2018, at 12: 00 P.M., confirmed the laboratory failed to perform and document the monthly maintenance for the MC 240 screening instrument in December 2016.
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: Based on review of personnel records, and interview with the Technical Supervisor determined the Laboratory Director failed to ensure that all testing personnel have the appropriate education, experience, and training for patient testing in 2016, 2017, and 2018. The findings include: 1. Review of personnel records failed to include level of education for testing personnel numbers one (Date of Hire [DOH]1/9/17) and three (DOH 10/16/17). 2. Review of personnel records failed to include training records for testing personnel numbers one (DOH 1/9/17), two (DOH 2016), and three (DOH 10/16 /17). 3. Review of personnel records failed to include competency assessments for testing personnel numbers one, two, and three. 3. Interview with the Technical Supervisor on November 14, 2018, at 9:30 AM, confirmed the Laboratory Director failed to ensure that all testing personnel have the appropriate education, training, demonstrate competency to perform and report accurate results for patient testing in 2016, 2017 and 2018.
D6149	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(b)(1) The director or technical supervisor may delegate to the general supervisor the responsibility for assuring that all remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications. This STANDARD is not met as evidenced by: Based on review of the Quality Control records for December 2016 and interview with the Technical Supervisor/General Supervisor determined the Laboratory Supervisor failed to ensure that all remedial actions were taken when the Buprenorphine negative control coefficient of variation (CV) was above acceptable limits for December 2016. The findings include: 1. Review of the Quality Control records for the screening instrument, MGC 240, for December 2016, revealed the low negative control for Buprenorphine was rerun five times with no corrective action

	taken to determine the problem. 2. Review of the Quality Control records for the screening instrument, MGC 240, for December 2016, revealed the monthly CV for the Buprenorphine negative control was 22 percent (%) with the acceptable limit of less than 20 %. 3. Interview with the Technical Supervisor/General Supervisor on November 14, 2018, revealed the Buprenorphine negative control was rerun until it was within acceptable limits and the CV% for December 2016 was above acceptable limits and no corrective action was taken and documented.