Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2016741	08/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Desert Pain And Rehab Specialists	11047 N 19th Ave, Phoenix, AZ	

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
D3027	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(1) Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years. This STANDARD is not met as evidenced by: Based on lack of test requisitions for review and interview with the facility personnel, the laboratory failed to retain test requisitions and test authorizations for at least two years. Findings include: 1. The laboratory performs patient testing in the sub-specialty of Toxicology, with an approximate annual test volume of 176,400. 2. No records of test requistions were presented for review during the survey conducted on August 21, 2019 for testing that was performed prior to August 1, 2019. 3. The facility personnel acknowledged that the laboratory was only keeping the test requisitions for about a month and then shredding them.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) results for Urine Drug Testing for the first event of 2019 and interview with the technical supervisor, the laboratory failed to provide an adequate explanation of the unacceptable results received for urine creatinine for each of three PT specimens tested. Findings include: 1. The laboratory performs PT for urine drug analysis as a form of accuracy check to satisfy the

	requirements under the CLIA regulations. 2. The corrective action presented for review for the unacceptable results indicated above did not address the laboratory's assessment of the specific results received on the CAP survey. The only comment indicated was that there was no explanation for the unacceptable results. 3. The technical supervisor acknowledged that the explanation should have included the high standard deviation for each of the three PT samples and the conclusion that the integrity of the PT samples may have been the cause of the unacceptable grade.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of established and verified performance specification documentation for the Sciex 4000 LC/MS analyzer used for urine drug confirmation testing and interview with the technical supervisor, the laboratory failed to provide documentation regarding the stability of specimens tested on the analyzer. Findings include. 1. The laboratory performs drug screen confirmations on urine specimens using the Sciex 4000 LC/MS analyzer, with an approximate annual test volume of 176,400. 2. Review of patient test records for patient L.Y. indicated the specimen was collected on 02/27/2018 and tested on the LC/MS analyzer on 03/22/2018. 3. The Technical Supervisor stated that urine specimens tested on the LC/MS analyzer have a 31 day stability, however no documentation was presented for review during the survey to indicate the laboratory performed a specimen stability study prior to testing patient specimens on the analyzer. 4. The Technical Supervisor acknowledged that the laboratory failed to provide documentation to prove that urine specimens have a 31 day stability for testing performed on the Sciex 4000 LC/MS analyzer.
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 calibration certificates for the centrifuge and the balance supplied to the laboratory by the maintenance company, Trident Calibration Labs and interview with the technical supervisor, the laboratory failed to have the balance and centrifuge calibrated for the year 2018. Findings include: 1. The calibration certificates indicated that the maintenance company calibrated the equipment indicated above on 12/01

	/2017. 2. The calibration due date indicated on the calibration certificates was 12/01 /2018. 3. There was no documentation supplied by the laboratory that indicated the equipment was calibrated in 2018 or 2019 up to the survey date. 4. The technical supervisor acknowledged that the last time the centrifuge and balance were calibrated was on 12/01/2017.