

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D1091624	(X3) Date Survey Completed 10/29/2019
Name of Provider or Supplier Desert Pain Specialists, Pc	Street Address, City, State 617 East Riverside Drive, Suite 301, St George, UT	
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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on twice annual test verification records review, lack of corrective action documentation, and interview with staff, the laboratory failed to document corrective actions taken for two out of three consecutive Norbuprenorphine results that were not within the acceptable range of variation for blind testing samples the first SLP intralaboratory accuracy testing event of 2018 and the first SLP intralaboratory event of 2019. Findings include: 1. The test results for Norbuprenorphine for the first SLP of 2018 was 175.6 and the 1st event of 2019 was 164.5. Both were above the acceptable range. 2. The laboratory failed to document corrective actions taken for the two out of three failures. 3. In an interview conducted on 10/30/2019 at approximately 1:30 P.M. staff stated they replaced the norbuprenorphine standard used for creating the standard curve that is the known value in calculating unknown specimen concentration but did not record the corrective action as part of the test's verification corrective actions or quality assessment documentation.</p>
D6175	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(1)</p> <p>Each individual performing high complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.</p>

This STANDARD is not met as evidenced by:

Based on reagent records review, procedure manual review and interview with staff, the testing person failed to follow the laboratory's procedure for making mobile phase B reagent each day of high pressure liquid chromatography tandem mass spectrometry (LCMS) toxicology testing. The laboratory performed testing approximately 3 days per week. Findings include: 1. Reagent records review document Mobile Phase B reagent was made fresh every 48 hours. 2. The LCMS procedure stated Mobile Phase B reagent is to be made each day of testing and remained stable for 48 hours. 3. In an interview with staff on 10/29/2019 at approximately 1:30 P.M. staff confirmed they made Mobile Phase B reagent every 48 hours.