

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2084339	(X3) Date Survey Completed 01/06/2020
Name of Provider or Supplier Desert Laboratories, Llc	Street Address, City, State 1343 N Alma School Rd, Ste 150, Chandler, 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
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) evaluation forms submitted to the laboratory by the PT agency for 2018 and 2019 and interview with the laboratory personnel, the laboratory failed to document the evaluation and verification activities performed by the laboratory for analytes under the specialty of Chemistry that received exception codes instead of an actual grade. Findings include: 1. The proficiency testing agency indicated exception codes [26] and [28] pertaining to a number of analytes on the PT evaluation forms indicating an educational challenge and unable to quantitate respectively. 2. The PT agencies participant summary booklets contain a table of exception code numbers, the exception code description and the action required for each code listed. 3. There was no documented evaluation or explanation presented during the survey for each analyte that received an exception code instead of an actual grade. 4. The laboratory personnel acknowledged that the laboratory did not document an evaluation or explanation for each analyte that received an exception code instead of an actual grade.</p>
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p>

This STANDARD is not met as evidenced by:

A. Based on review of room humidity logs where the TSQ Quantum Access LC/MS is utilized for patient testing and interview with the laboratory personnel, the laboratory failed to provide corrective actions on a number of days when the humidity readings were outside of the manufacturer's required ambient humidity range. Findings include: 1. The humidity readings were outside of the 40% - 80% range on 3 days out of 21 days in March 2019 and 2 days out of 22 days in November 2019. 2. There was no written corrective action for the out of range humidity readings. 3. Both months were signed off by the technical supervisor even though no corrective actions were documented on the form in the column labeled corrective actions. B. Based on review of quality control (QC) results for the toxicology QC samples run on the AU 400 E chemistry analyzer and interview with the technical supervisor, the laboratory failed to follow the policy related to the rerunning of control samples and provided no corrective action or retraining documentation. Findings include: 1. Out of range control results for toxicology QC samples run on the analyzer on 11/13/2019 that were flagged at 1 standard deviation (SD) out of range were rerun. 2. The laboratory's policy states to rerun QC samples when they out of range by more than 2 SD. 3. The technical supervisor acknowledged that the testing personnel were not following the laboratory's policy and that there was no corrective actions documented including retraining of testing personnel.