

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 32D0537331	(X3) Date Survey Completed 08/15/2019
Name of Provider or Supplier De Baca Family Practice Clinic	Street Address, City, State 546 N 10th St, Fort Sumner, NM	
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
D6042	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4)</p> <p>(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;</p> <p>This STANDARD is not met as evidenced by: Based on the review of 2018-2019 proficiency test records, manufacturer instructions, 2018 chemistry quality control, calibration, and interview with laboratory staff, the technical consultant failed to ensure a quality control program was established and followed by the laboratory. Findings are: A. Review of 2018-2019 proficiency testing records including corrective actions revealed no documentation of the technical consultant's participation in the process. The laboratory either failed to perform adequate corrective actions for TSH (Thyroid Stimulating Hormone) failures or failed to evaluate the acceptability of the samples not graded by the proficiency agency. See D5213 B. Review of the quality control records including package inserts revealed the laboratory adopted new ranges based on the simple precision data analysis performed by the manufacturer of the Nanotek FRIEND immunoassay test system. There was no documentation that the data was reviewed by the Technical Consultant or the Laboratory Director prior to adopting the new ranges. See D5441</p>