

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 32D0537046	(X3) Date Survey Completed 05/23/2018
Name of Provider or Supplier Las Cruces Physician Services Llc DbA	Street Address, City, State 2970 N Main, Las Cruces, 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
D0000	The following deficiencies were cited as the result of a recertification survey on 05/23 /2018 for 42 CFR part 493 Laboratory Requirements.
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on the review of validation studies and interviews with laboratory staff, the laboratory failed to perform the run-to-run precision studies for Vitamin D, Thyroid Stimulating Hormone (TSH) and Prostate Specific Antigen (PSA) using the Qualigen FastPack test system. Findings are: 1. Review of the validation studies revealed that the laboratory performed simple precision (within-run) for PSA on 11/22/16, TSH on 05/24/17, and Vitamin D on 02/16/17. 2. During interview on 5/23/18 at 2:20 pm, testing person #1 stated that that his training was performed via a webcam and the validation studies were performed on the same day, 11/22/16. He then submitted the results to the manufacturer for review. 3. During interview on 5/23/18 at 2:20 pm, the technical consultant confirmed the laboratory did not perform run-to-run precision studies for the Qualigen FastPack test system when it was installed in November 2016. She further stated that she was not present when the initial validation studies (PSA) were performed.</p>
D6030	LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(12)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on the review of personnel records and interview with laboratory staff, the laboratory director failed to ensure the laboratory maintained documentation of competency evaluations for 1 (TP #1) of 3 testing personnel. Findings are: Review of the personnel file for testing person #1 revealed no documentation of the 2015 annual competency. This was noted during the previous survey but was not cited because the office manager had recently left. The interim office manager stated on 5/24/16 at 4:00 pm that she did not know what had happened to the 2015 competencies.