

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 32D0537459	(X3) Date Survey Completed 05/08/2019
Name of Provider or Supplier Rio Pecos Medical Associates	Street Address, City, State 305 W Country Club Road, Roswell, 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 deficiency was cited as the result of a recertification survey completed on 05/08/19 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 records and interview with the Technical Consultant, the laboratory failed to perform and document run-to-run precision studies for the new Cell Dyne Emerald Hematology Analyzer prior to patient testing. Findings are: A. Review of the 2017 validation records indicated no documentation that the laboratory had performed run-to-run precision studies. 1. The manufacturer's technical representative installed and performed carryover, simple precision, calibration, and control range verification on 10/04/17 which was reviewed and approved by the Laboratory Director on 10/16/17. 2. Male/Female reference ranges and critical value ranges carried over from previous analyzer on 10/04/17. 3. Patient correlation studies were performed 10/04-10/09/17 by laboratory staff and approved by the Laboratory Director on 12/16/17. B. During interview on 05/08/19 at 10:32 am, the Technical Consultant didn't recall performing run-to-run precision studies.</p>