

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D2081924	(X3) Date Survey Completed 06/28/2018
Name of Provider or Supplier Rocky Mountain Pathology Consultants, Pc	Street Address, City, State 10841 S Crossroads Dr, Suite 4, Parker, CO	
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on the lack of proficiency testing (PT) records and staff interview, the laboratory failed in 2017 and 2018 to enroll in an HHS-approved PT program for the infectious mononucleosis, HIV-1/2, and Helicobacter pylori tests for which it seeks certification in 2017 and 2018. Findings include: a. The laboratory tests patient serum specimens for infectious mononucleosis, HIV-1/2, and Helicobacter pylori. b. No documentation existed to show that the laboratory had enrolled in an approved PT program for these moderate complexity tests in 2017 and 2018. c. The CMS Casper Report 0096D showed no PT scores for these tests for 2017 or 2018. d. Staff stated that they were unaware that these test systems are moderate complexity when serum specimens are used. e. Staff confirmed the laboratory had not enrolled or participated in a PT program for the moderate complexity infectious mononucleosis, HIV-1/2, and Helicobacter pylori testing in 2017 or 2018 as required by subpart I of the federal CLIA regulations.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p>

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on a review of the operator's manual, maintenance records, and staff interview, the laboratory failed in 2017 and 2018 to ensure the humidity in the laboratory met the manufacturer's required operating conditions for the Beckman Coulter AU480 chemistry analyzer. Approximately 400 patient specimens are tested annually. Findings include: a. The laboratory tests patient specimens for immunoglobulin A (IgA) and homocysteine using the Beckman Coulter AU480 chemistry analyzer. b. The operator's manual for the Beckman Coulter AU480 chemistry analyzer stated the testing environment in the laboratory must have 40-80% ambient relative humidity. c. Monthly maintenance log sheets listed the acceptable range for the room humidity as 20-80%. d. On 6-28-18 at around 2 p.m., staff stated they were unaware the humidity range listed on their maintenance log sheets was incorrect for meeting the requirements for the chemistry analyzer. e. On 6-28-18 at around 2 p.m., staff confirmed the laboratory had the incorrect humidity range listed on their log sheets and confirmed they had not ensured a testing environment of at least 40% relative humidity as required by the operator's manual for the Beckman Coulter AU480 chemistry analyzer.