

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D2122307	(X3) Date Survey Completed 09/28/2018
Name of Provider or Supplier Rocky Mountain Men's Clinic 1 - Denver	Street Address, City, State 1780 S Bellaire St, Ste 355, Denver, 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
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on a review of patient test results and staff interview, the laboratory's final report failed to indicate at least two unique identifiers for positive patient identification, the test report date, and the units of measurement or interpretation for 2 of 2 reports reviewed. Findings include: a. The laboratory tests patient serum specimens for testosterone and prostatic specific antigen (PSA) levels using the Qualigen FastPack Immunoassay System. b. The final patient report did not contain at least two patient identifiers, the test report date, and the units of measure or interpretation of the test results. c. Staff stated they were unaware of these regulatory requirements, and confirmed the patient test report did not include all information required by the federal CLIA regulations.</p>