Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D2146205	08/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Rocky Mountain Men's Clinic 2 - Colorado Springs	1465 Kelly Johnson Blvd, Suite 120, Colorado Springs, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, proficiency testing (PT) records and staff interview, the laboratory failed to ensure PT attestation statements were signed by the appropriate personnel for the chemistry testing module in 2018. Findings include: a. The laboratory's policy for proficiency testing states, "Laboratory director and all staff performing the testing should sign in the attestation spaces provided on the data sheet." b. PT records for the 1st Event of 2018 did not contain signed attestation statements by the laboratory director or testing personnel. c. On 8/20/18 at around 12 p.m., the testing personnel confirmed the attestation statements had not been signed by appropriate personnel as required by laboratory policy.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test

	system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, proficiency testing (PT) records and staff interview, the laboratory failed to document each step in the testing and reporting of results by not retaining a duplicate copy of the PT results sent to the PT provider for the 1st Event of 2018. Findings include: a. The laboratory's policy for proficiency testing states, "Retain all data sheets, attestation sheets, worksheets, and instrument printouts for two years." b. PT records for the 1st Event of 2018 did not contain a copy of the test results reported to the PT provider. c. On 8/20/18 at around 12 p.m., the testing personnel confirmed the laboratory staff did not maintain a copy of all records required for proficiency testing in 2018.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the quality assurance (QA) Plan, review of personnel competency assessment records and staff interview, the laboratory failed to establish and follow written policies for assessing the competency of 2 of 2 testing personnel in 2018 for testing Prostate Specific Antigen (PSA) and testosterone on the Qualigen Fast Pack IP System. Findings include: a. The QA Plan states personnel should be qualified and trained in performance. b. There is no documentation on the intervals and criteria of assessing competency for testing personnel. c. The competency assessments for 2 of 2 testing personnel (#2 and #3 on Form CMS-209) signed by the laboratory director on 8 /17/2018 does not contain all required elements for assessing competency. d. There is no documentation of assessing competency for 2 of 2 testing personnel (#2 and #3) prior to patient testing on 4/26/18. c. On 8/20/18 at around 11 am, the testing personnel confirmed there was no established policies to follow for assessing competency on testing personnel.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the quality assessment (QA) plan, personnel competency records and staff interview, the laboratory failed to establish an ongoing mechanism to monitor and assess problems to ensure competency is performed on all testing personnel who test for Prostate Specific Antigen (PSA) and testosterone using the Qualigen Fast Pack IP System in 2018. Findings include: a. The QA plan states

	personnel will be trained and qualified. b. There were no initial competencies for 2 of 2 testing personnel (#2 and #3 on Form CMS-209) prior to reporting patients in April 2018. c. Competency assessments performed on 2 of 2 testing personnel (#2 and #3) were signed off by the laboratory director on 8/17/18 and failed to include: direct observation of routine patient test performance; monitoring the recording and reporting of test results; review of intermediate test results, worksheets, quality control records, proficiency testing results, and preventative maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and assessment of problem solving skills. d. On 8/20/18 at around 11 am, the testing personnel confirmed the laboratory failed to establish and follow their QA plan and did not evaluate testing personnel for competency in 2018.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of general laboratory systems quality assessment (QA) documentation and staff confirmation, the laboratory failed to establish a mechanism to: a) review the effectiveness of corrective actions taken to resolve problems, b) revise policies and procedures necessary to prevent recurrence of problems, c) discuss analytic systems QA reviews with appropriate staff and, d) document all QA activities in the general laboratory systems in 2018.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: 1) Based on review of the procedure manual and staff interview, the laboratory failed to have an available written procedure for testing Prostate Specific Antigen (PSA) and testosterone on the Qualigen Fast Pack IP System, reviewed and signed by the laboratory director, for staff to follow in 2018. Staff stated they were unaware a test procedure must be in place for testing personnel to follow. 2) Based on review of the procedure manual, quality control (QC) records, and staff interview, the laboratory failed to follow their written procedure to ensure QC material is tested prior to reporting PSA and testosterone results in 2018 and approximately 1500 patients are tested annually on the Qualigen Fast Pack IP System. Findings Include: a. The laboratory's procedure states, "Two valid levels of quality control results must be obtained by running Qualigen Control 1 & 2 control prior to running patient samples

	and after any daily maintenance has been performed." b. No quality control material was run prior to reporting patients from 4/26/18 to 8/11/2018 and 199 patients were reported. c. On 8/20/2018, testing personnel stated they were unaware of testing 2 levels of quality control material prior to testing patients until 8/14/18 and notified the laboratory director that QC must be performed daily. d. On 8/20/2018, testing personnel confirmed the laboratory failed to follow the written procedure and did not test two quality control material prior to reporting patients in 2018.
D5805	TEST REPORT CFR(s): 493.1291(c) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's survey CLIA application Form CMS-116, 1 patient test report and staff interview, the laboratory failed to include the facility name where Prostate Specific Antigen (PSA) and testosterone is performed since testing began in April 2018. Findings include: a. The facility name and address listed on CLIA application Form CMS-116 received by the state agency on 8/20/18 was Rocky Mountain Men's Clinic. b. During the onsite survey, the final patient test report showed the facility name of "AMDS Labs." c. On 8/20/18 at around 12 pm, the testing personnel confirmed no patient report for Rocky Mountain Men's Clinic had shown this facility's name where PSA and testosterone results were performed since testing began in April 2018.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the quality assessment (QA) plan, proficiency testing (PT) records, verification records, quality control (QC) records, patient result logs, corrective action documentation and staff interview, the laboratory director failed to provide the overall management and direction to ensure PT records are maintained and signed (Ref D6004), failed to ensure instrument verification records were approved prior to patient use (Ref D6013), failed to have testing personnel follow established procedures (Ref. D6014), and failed to ensure established QC procedures are followed in 2018 (Ref. D6020).
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)

	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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on a review of the quality assessment (QA) plan, proficiency testing (PT) records, corrective action documentation, and staff confirmation, the laboratory director failed in 2018 to provide for the overall operation and failed to ensure compliance with all applicable regulations. Findings include: a. Appropriate personnel failed to sign attestation statements for all PT events in 2018 (Ref D2009). b. The laboratory failed to retain a duplicate copy of the PT results sent to the PT provider in 2018 (Ref to D2015).
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of the verification records, patient test reports, and staff interview, the laboratory director failed to review and sign his approval of the verification data of Prostate Specific Antigen (PSA) and testosterone before testing patient specimens using the Qualigen Fast Pack IP System in 2018. Findings include: a. Analyte verification records for PSA and testosterone performed on 4/24/18 showed accuracy, precision and verification for reportable range. b. There was no laboratory director signature approving the verification activities for the Qualigen Fast Pack IP System for PSA and testosterone. c. Patient resulting for PSA and testosterone began on 4/26 /18. d. On 8/20/18 at around 11 am, a testing personnel confirmed the laboratory director did not approve the verification of the Qualigen Fast Pack IP System prior to reporting patients.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on review of the quality assessment (QA) plan, quality control (QC) records, corrective action documentation and staff interview, the laboratory director failed to ensure that laboratory personnel are performing Prostate Specific Antigen (PSA) and testosterone testing following the established procedures in an accurate and reliable manner in 2018. (Ref. D5401)
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the quality assessment (QA) plan, quality control (QC) records, corrective action documentation and staff interview, the laboratory director failed to ensure that QC values were performed prior to reporting patient results and that corrective action documentation is maintained in 2018 (Ref. D5401).
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the Quality Assurance (QA) manual, personnel competency assessment records and staff interview, the technical consultant failed to evaluate and assure that 2 testing personnel maintain competency to conduct prostate specific antigen (PSA) and testosterone testing using the Qualigen Fast Pack IP System in 2018 that includes; direct observation of routine patient test performance; monitoring the recording and reporting of test results; review of intermediate test results, worksheets, quality control records, proficiency testing results, and preventative maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and assessment of problem solving skills. Findings Include: a. The laboratory director also serves as the technical consultant. b. No documentation existed that 2 testing personnel had competency assessment performed in 2018 to include all competency assessment criteria by the technical consultant. c. On 8/20/18 at around 11 am, the testing personnel confirmed that competency assessment was not performed on 2 testing personnel in 2018 that includes all required assessment criteria.