Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D1048217	(X3) Date Survey Completed 01/28/2019
Name of Provider or Supplier Rocky Mountain Urgent Care/Family Medicine	**Street Address, City, State** 13650 E Mississippi Ave, Ste 110, Aurora, 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	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 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. This CONDITION is not met as evidenced by: Based on the lack of proficiency testing (PT) records and staff interview, the laboratory failed to enroll in an HHS-approved PT program for 2018 and 2019 in the specialty of bacteriology for the molecular testing of Chlamydia trachomatis and Neisseria gonorrhoeae for which it seeks certification since testing began in September 2018. Findings include: a. The laboratory tests patient specimens for Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG) using the Cepheid GeneXpert CT/NG molecular diagnostic system. b. No documentation existed to show that the laboratory had enrolled in an approved PT program for 2018 and 2019 in the specialty of bacteriology for the molecular CT/NG testing. c. Staff stated they were unaware that participating in a PT program was required for these analytes. d. Staff confirmed the laboratory hadn't enrolled in a PT program for the CT/NG molecular testing for 2018 and 2019 as required by subpart I of the federal CLIA regulations.
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: Based on a review of the laboratory's quality control (QC) plan, QC records, and staff interview, the laboratory failed to follow their written policy to test twice each month external positive and negative control materials for both Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG) using the Cepheid GeneXpert CT/NG analyzer, and 117 patient specimens were tested since testing began in September 2018. Findings include: a. The laboratory tests patient specimens for Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG) using the Cepheid GeneXpert CT/NG analyzer. b. The laboratory's QC plan states that external QC (positive and negative) is tested twice each month and with each new lot and shipment of CT/NG cartridges. c. On 1-28-19 at around 11:30 a.m., staff stated that external controls are tested twice each month, normally every other Monday. d. Records showed that from 8/27/18 through 9/9/18, 6 patient specimens were tested but only postive and no negative control material had been tested. e. Records showed that from 9/10/18 through 9/23/18, 13 patient specimens were tested but neither positive nor negative control materials had been tested. f. Records showed that from 9/24/18 through 10/7/18, 12 patient specimens were tested but neither positive nor negative control materials had been tested. g. Records showed that from 10/22/18 through 11/4/18, 13 patient specimens were tested but neither positive nor negative control materials had been tested. h. Records showed that from 11/5/18 through 11/18/18, 19 patient specimens were tested but neither positive nor negative control materials had been tested. i. Records showed that from 11/19/18 through 12/2/18, 15 patient specimens were tested but neither positive nor negative control materials had been tested. j. Records showed that from 12/3/18 through 12/16/18, 15 patient specimens were tested but neither positive nor negative control materials had been tested. k. Records showed that from 12/17/18 through 12/30/18, 26 patient specimens were tested but neither positive nor negative control materials had been tested. l. Records showed that from 12/31/18 through 1/2/18, 4 patient specimens were tested but neither positive nor negative control materials had been tested. m. On 1-28-19 at about 1:30 p.m., staff stated that they couldn't find all of the Cepheid CT/NG QC records. n. On 1-28-19 at about 1:30 p.m., staff confirmed they had no documentation that positive and negative QC materials had been tested every two weeks as required by their laboratory's QC plan.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of the procedure manual and staff confirmation, the laboratory director failed to review, sign and date her approval of the Cepheid Chlamydia trachomatis (CT)/Neisseria gonorrhoeae (NG) procedure since testing began in September 2018.
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 a review of laboratory policy, competency assessment records and staff interview, the technical consultant failed in 2018 to evaluate the competency of 6 of 6 testing personnel who performed non-waived testing and approximately 115 patient specimens have been analyzed since testing began in September 2018. Findings include: a. The laboratory tests patient specimens for Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG) using the Cepheid GeneXpert CT/NG analyzer. b. Laboratory policy states that competency of testing personnel must be assessed with initial training and annually thereafter. c. Competency records showed that testing personnel were evaluated for competency in 2018 by a staff member who is not qualified to serve as a technical consultant. d. Staff stated that they were unaware of the regulatory requirements of a technical consultant and confirmed none of the testing personnel were assessed by the technical consultant in 2018 as required by the federal CLIA regulation.