

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D0512030	(X3) Date Survey Completed 02/22/2018
Name of Provider or Supplier Women's Health Care Associates	Street Address, City, State 7720 S Broadway, Ste 440, Littleton, 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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on lack of a quality assessment (QA) plan for the general laboratory systems and staff interview, the laboratory failed to establish written policies and procedures for staff to follow in 2016 and 2017 for an ongoing mechanism to monitor, assess, and take corrective action as needed for the general laboratory systems to include confidentiality, specimen identification and integrity, complaint investigations, communications, personnel competency and evaluation of proficiency testing performance. Findings include: a. The staff was unable to provide a QA Plan for the general laboratory systems during the survey. b. The staff confirmed on 2/22/18 around 10 am that the laboratory had not written policies to evaluate general quality issues in the laboratory.</p>
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of competency assessment records and staff interview, the</p>

technical consultant failed in 2016 and 2017 to evaluate the competency of 7 of 7 laboratory personnel who performed moderate complexity testing where laboratory personnel were evaluated by a staff member who was not qualified to serve as a technical consultant and approximately 659 patient specimens are analyzed annually. Findings include: a. The laboratory performs automated vaginal wet preparation testing using the BD Affirm microbial identification system. b. Records showed that 7 of 7 testing personnel were evaluated for competency by a staff member who does not qualify as a technical consultant by not having earned, at minimum, a bachelor's degree in a natural or clinical laboratory science. d. Staff confirmed on 2/22/2018 around 10 am, the technical consultant did not in 2016 or 2017 assess the competency of testing personnel.

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:
The laboratory failed to ensure that 2 of 4 new testing personnel meet the minimum qualification requirements to perform the moderate complexity testing performed onsite (Ref D6065).

D6065

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:
Based on review of personnel records and staff confirmation, the laboratory failed to ensure that 2 of 7 testing personnel (#4 and 5 on Form CMS-209) was qualified to perform moderate complexity bacteriology testing using the BD Affirm in 2017 and 2018. The laboratory failed to maintain documentation that all testing personnel had earned at minimum a high school diploma or equivalent prior to testing patient specimens.