

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0678176	(X3) Date Survey Completed 07/30/2024
Name of Provider or Supplier Center For Women's Health	Street Address, City, State 4840 College Blvd, Overland Park, KS	
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
D6033	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on documentation of testing personnel (TP) competencies, and personnel qualifications, the laboratory failed to have a qualified person performing duties as a technical consultant. See D6035.</p>
D6035	<p>TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411</p> <p>(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's</p>

degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:
 Based on the review of the CMS 209 personnel report, documentation of testing personnel (TP) competencies, personnel qualifications, and interview, the laboratory failed to have a qualified person(s) performing duties as a technical consultant (TC). Findings: 1. Review of the CMS209 revealed one technical consultant and six TP for moderate complexity testing. Four of six TP had been employed for longer than six months. 2. Review of "Center for Women's Health Individual competency" forms revealed: a. Competencies in 2023 and 2024 for TP #2, #3, and #4 included direct observations that were performed by TP #1 who did not qualify as a TC. b. Competency in 2023 and 2024 for TP #1 included direct observations that were performed by a nurse practitioner who did not qualify as a TC. 3. Interview with the TP #1 on 7/30/24 at 9:30 a.m. confirmed, the laboratory failed to have a qualified person(s) performing duties as a technical consultant.

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:
 Based on review of the CMS 209 form, personnel records, and interview with the practice consultant, the laboratory failed to have educational credentials required to qualify one of six testing personnel (TP) to perform moderate complexity testing prior to reporting patient results (refer to 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 the CMS 209 form, personnel records, and interview with the practice consultant, the laboratory failed to have educational credentials required to qualify one of six TP to perform moderate complexity testing prior to reporting patient results. Findings: 1. Review of the CMS209 revealed six moderate complexity TP. 2. The surveyor requested credentials to qualify the TP. No educational credentials were made available to qualify TP #5 at the time of survey. TP #5 performed and reported 112 patient results from 12/5/22 to 4/20/23. 3. Interview with the practice consultant on 7/30/24 at 11:45 a.m. confirmed, the laboratory failed to have educational credentials required to qualify one of six TP to perform moderate complexity testing prior to reporting patient results.