

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 32D2276159	(X3) Date Survey Completed 04/09/2024
Name of Provider or Supplier Whole Woman's Health Of New Mexico	Street Address, City, State 718 Lomas Blvd Nw, Albuquerque, NM	
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
D0000	An onsite initial survey conducted at Whole Woman's Health of New Mexico on 04/09/2024, found the laboratory to be out of compliance with the CLIA regulations found at 42 CFR, Part 493 Laboratory Requirements, with the following condition not met: D6033 - 493.1409 Technical Consultant (moderate complexity)
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of CMS 209 form, American Proficiency Institute (API) proficiency testing (PT) attestation form, and interview, the laboratory failed to ensure individual PT samples were not tested by more than one testing personnel for 3 of 4 PT events in 2023 through 2024. Findings included: 1. Review of CMS 209 listed 3 testing personnel (TP) performing moderate complexity testing. 2. Review of the API proficiency testing attestation forms from 2023 through 2024 revealed the following: 1. Event 2 of 2023: - TP 1 Tested samples "all" - TP 2: Tested samples "all" - TP 3: Tested samples "all" 2. Event 3 of 2023: - TP 1: Tested samples 11, 12, 13, 14, 15 - TP 2: Tested samples 11, 12, 13, 14, 15 3. Event 1 of 2024: - TP 1: Tested samples Rh01, Rh02, Rh03, Rh04, Rh05 - TP 2: Tested samples Rh01, Rh02, Rh03, Rh04, Rh05 3. Interview on 04/09/2024 at 10:00 am with Testing Personnel 2 stated, the facility's regular work routine is to have 1 testing personnel test a patient sample and it is not repeated or ran multiple times by other personnel, confirming the findings.</p>
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409

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.

This CONDITION is not met as evidenced by:

Based on review of the CMS 209 form, laboratory policy, personnel records, and staff interview, the laboratory failed to designate a qualified technical consultant as evidenced by: 1. The laboratory failed to designate a technical consultant that met the experience requirements. Refer to D6035.

D6035

TECHNICAL CONSULTANT QUALIFICATIONS

CFR(s): 493.1411

(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 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 review of the CMS 209 form, laboratory policy, personnel records, and staff interview, the laboratory failed to ensure experience requirements for 1 of 1 technical consultants (TC) for moderate complexity testing from March 2023 through March 2024. Findings included: 1. Review of the CMS 209 form revealed the laboratory designated 1 technical consultant (TC 1) for moderate complexity testing. 2. Review

of the laboratory policy titled "Technical Consultant Qualifications and Responsibilities" stated the following experience requirements: "2. M.D or D.O. with a current medical license in the state of the laboratory's location and 1 year laboratory training in the designated specialty ..." 3. A request was made for the designated technical consultant's 1 year laboratory training or experience in the designated specialty. No documentation was provided. 4. During an interview on 04/09/2024 at 10:20 am, after review of the above records, Testing Personnel 2 confirmed the findings.

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 CMS 209 form, competency assessment records, and interview, a qualified technical consultant (TC) failed to assess the competency for 1 of 3 testing personnel (TP) (TP 1 - TP 3) performing Rhesus factor (Rh) testing in 2024. Findings included: 1. Review of the CMS 209 form listed three (3) testing persons for performing Rh testing. 2. Review of the laboratory's "Annual Laboratory Testing Personnel Assessment" records revealed TP 1's annual competency was evaluated by TP 2 on 03/14/2024. A qualified technical consultant failed to conduct the competency assessment for testing personnel. 3. During an interview on 04/09/2024 at 10:20 am, after review of the competency records, TP 2 confirmed the findings.