

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 32D2279120	(X3) Date Survey Completed 04/26/2024
Name of Provider or Supplier University Of New Mexico Cell Therapy Lab	Street Address, City, State 1 University Of New Mexico, 2325 Camino De Salud, 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 University of New Mexico Cell Therapy Lab on April 26, 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: 493.1409 Technical Consultant Moderate Complexity 493.1424 Testing Personnel Moderate Complexity
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 review of the CMS 209 form, personnel records, and staff interview, the laboratory failed to ensure all technical consultants met education requirements as evidenced by: 1. The laboratory failed to provide evidence technical consultant 2 met education requirements. Refer to 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</p>

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, personnel records, and staff interview, the laboratory failed to provide education records for 1 (TC 2) of 2 technical consultants (TC) for moderate complexity testing from July 2023 through April 2024. Findings included: 1. Review of the CMS 209 form revealed the laboratory designated 2 technical consultants (TC 1, TC 2) for moderate complexity testing. 3. A request was made for education records for TC 2. No documentation was provided. 4. During an interview on 04/26/2024 at 10:20 am, after review of the above records, the laboratory director confirmed the findings.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on review of CMS 209 form, CTL - 414 (Cell Therapy Lab) ADAM II (advance detection and accurate measurement) Fluorescence CD34 policy, and staff interview, the technical consultant failed to ensure a secondary or semi -annual evaluation was performed within the first year of training for 1 (TP 2) of 2 testing personnel (TP) in 2023. Findings included: 1. Review of the CMS 209 form revealed the laboratory designated 2 testing personnel (TP 1, TP 2) for moderate complexity testing. 2. Review of CTL - 414 ADAM II Fluorescence CD34 policy, under "Personnel Training, Competency and Proficiency" stated, "Annual competency

checks will be conducted for previously trained staff". No mention of a semi-annual evaluation being done within the first year after initial training. 3. The laboratory was asked to provide documentation of semi-annual evaluations being done. none were provided. 4. During an interview on 04/26/2024 at 10:00 am, after review of the above records, the laboratory director confirmed the findings.

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 staff interview, the laboratory failed to ensure all testing personnel met education requirements as evidenced by: 1. The laboratory failed to provide evidence test personnel 2 met the education requirements. 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 staff interview, the laboratory failed to provide education records for 1 (TP 2) of 2 testing personnel (TP) for moderate complexity testing from July 2023 through April 2024. Findings included: 1. Review of the CMS 209 form revealed the laboratory designated 2 testing personnel (TP 1, TP 2) for moderate complexity testing. 3. A request was made for education records for TP 2. No documentation was provided. 4. During an interview on 04/26/2024 at 10:20 am, after review of the above records, the laboratory director confirmed the findings.