

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1053414	(X3) Date Survey Completed 03/20/2024
Name of Provider or Supplier Unique Medi Tech Llc	Street Address, City, State 20505 Crescent Bay Dr, Lake Forest, CA	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of test accuracy records, lack of test verification records, and interview with the laboratory staff on 3/20/2024 at 12:00 PM, laboratory failed to have a system for verifying the accuracy of the fiber density measurement test at least twice annually. The finding includes: 1. The laboratory performed microscopic measurement of the nerve fiber density test based on the PGP9.5 immunohistochemical stain. The laboratory did not verify the accuracy of the fiber density measurement test. Therefore, the accuracy of the laboratory's test results cannot be assured and may have potential to harm patients. 2. On 3/20/2024 at 12:00 PM, the laboratory staff confirmed the laboratory did not perform accuracy verification for the fiber density measurement test. 3. The laboratory's testing declaration form, signed by the laboratory director on 03/20/2024 stated that the laboratory performed approximately 500 tests in histopathology, annually.</p>
D6079	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and</p>

493.1487 respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratories test accuracy records and interview with the laboratory staff on 3/20/2024 at 12:00 PM, the laboratory director failed to assure compliance with the applicable regulations and potentially may have harmed patients. The finding include: See D5217