

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0589655	(X3) Date Survey Completed 07/09/2019
Name of Provider or Supplier David R Taylor Md, Inc	Street Address, City, State 5640 N Fresno St Ste 110, Fresno, 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on review and the lack of documentation for room temperature where patients inoculated Dermatophyte Test Medium (DTM) are stored, and interview with the laboratory staff, it was determined that the laboratory failed to establish, monitor and document that is consistent with the manufacturer's instructions. The findings included. a. The laboratory has no documentation to show for the DTM room temperatures where the patient inoculated DTM vials are stored from years 2017, 2018, and up to the time of the survey (7/9/2019). b. For two (2) out of two (2) random patient test results reviewed covering period 3/16/2018 and 5/21/2019 the laboratory analyzed and reported DTM results in which there was no documentation of room temperatures. c. The laboratory staff affirmed (7/9/2019, 12N) that the laboratory has no documentation to show for the room temperatures.</p>