

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0957436	(X3) Date Survey Completed 12/12/2019
Name of Provider or Supplier Michael Keith Wensley, Md Inc	Street Address, City, State 1382 Valencia Ave, Ste F, Tustin, 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 review of the laboratory's proficiency testing (PT) result reports and interview with the laboratory technical consultant (TC) and the testing personnel, it was determined that the laboratory failed, at least twice annually, to verify the accuracy of flow cytometry and HIV viral load it performed that are not included in subpart I of 42 CFR aprt 493. The findings included:L a. The laboratory performed flow cytometry using Bechman Coulter Epic XL flow cytometer to report CD19, CD3, CD4, CD 56 and CD8. b. The laboratory elected to enroll with American Proficiency Institute (API) PT program to verify the accuracy of the flow cytometer testing system. c. The laboratory attended a score of 50 % for CD4 in the 3rd 2018 API PT event which was unsatisfactory performance. d. The laboratory performed HIV viral load using Roto Gene 6000 Qiagen Real Time PCR. e. The laboratory elected to enroll with College of American Pathologists (CAP) PT program to verify the accuracy of the HIV viral load testing system. f. The laboratory attended a score of 40 % for HIV viral load in the HIV-A 2018 CAP PT event which was unsatisfactory performance. g. The laboratory performed CD4 and HIV viroal load in approximately 31 patient samples each testing monthly. h. The laboratory affirmed (12/12/2019 @ 12:15 PM) that the laboratory failed to verify at least twice annually for the accuracy of the testing systems, CD4 and HIV viral load.</p>
D6095	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6)</p> <p>The laboratory director must ensure the establishment and maintenance of acceptable</p>

levels of analytical performance for each test system.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's proficiency testing (PT) result reports, and interview with the laboratory technical consultant (TC) and the testing personnel (TP), it was determined that the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. The findings included; a. The laboratory performed CD4 and HIV viral load testings which are not listed in the subpart I of 42 CFR part 493. b. In order to verify the accuracy of the CD4 and HIV viral load testing systems, the laboratory elected to enroll with API and CAP PT programs, respectively. c. The laboratory failed to attain scores of 80 % for CD4 and HIV viral load in 2018 PT events, see D-5217