Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0643378	09/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
Orange County Public Health	1729 W 17th St, Bldg 40, Santa Ana, 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
D2056	VIROLOGY CFR(s): 493.831(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing result reports, and interview with the laboratory personnel, it was determined that the laboratory failed to attain an overall testing event score of at least 80 percent is unsatisfactory performance. The findings included: a. The laboratory performed viral antigen detection testing, in order to evaluate the proficiency testing performance for these testing systems, the laboratory enrolled with CAP (College of American Pathologists) PT VR 2016 Virology Ag Detect DFA. b. The laboratory attained an overall score of 67 % for the 2nd 2016 PT event, which was unsatisfactory performance. c. The laboratory performed viral load testing in approximately 500 patient samples each month. d. The laboratory confirmed that the laboratory attained an overall score of 67 % for the 2nd 2016 PT event, which was unsatisfactory performance.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing result reports, and interview with the laboratory personnel, it was determined that the laboratory director failed to

	ensure that the quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The findings included: See D- 2056