Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1086025	06/20/2019
Name of Provider or Supplier	**Street Address, City, State**	
Vitalant	10585 Armstrong Ave, Mather, 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
D5751	HISTOCOMPATIBILITY CFR(s): 493.1278(b)(6)(g) (b) HLA Typing. The laboratory must do the following: (b)(6) Check each HLA typing by testing, at a minimum the following: (b)(6)(i) A positive control material. (b)(6)(ii) A negative control material in which, if applicable to the technique performed, cell viability at the end of incubation is sufficient to permit accurate interpretation of results. In assays in which cell viability is not required, the negative control result must be sufficiently different from the positive control result to permit accurate interpretation of results. (b)(6)(iii) Positive control materials for specific cell types when applicable (that is, T cells, B cells, and monocytes). (g) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on Surveyor review of quality control and patient test records, policies and procedures, lack of an individualized quality control plan (IQCP), and interview with the laboratory Technical Supervisor and testing personnel, the laboratory failed to test a positive control material to check each HLA typing. The findings include: a. The laboratory does HLA typing using molecular methods, however does not test a positive control each day it tests the patient sample. The laboratory did not test any positive control on the day (02/10/2019) the patient sample # 3002269 was tested, which was found during review of the random patient sample testing records. The laboratory did not have any records showing that it had established an IQCP for HLA tying, either. b. The laboratory Technical and General Supervisors, on 6/20/2019 at 3: 40 pm, confirmed that the laboratory does not test positive control on the day of HLA typing. c. The laboratory's testing declaration form, signed by the laboratory Director on 6/17/2019, stated that the laboratory performs 17,295 tests, annually.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 Surveyor review of laboratory's policy & procedure, quality control test records for HLA testing, and interview with the Laboratory Technical Supervisor, it was determined that the laboratory director failed to ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The findings include: See D5751.