Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0662289	03/15/2018
Name of Provider or Supplier	**Street Address, City, State**	
Dept Of Transfusion Medicine/Nih Clinical Center	10 Center Drive, Bethesda, MD	

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 a walk-thru of the HLA typing assay testing process, review of laboratory worksheets, the procedure manual and interview with staff, the laboratory failed to include and test, a positive and negative control material, when sanger sequencing methods were used in HLA Typing assays. The facility runs approximately 150 HLA Typing assays for sequencing per month. Findings inlcude: 1. During a walk-thru of the HLA typing assay testing process, the surveyor followed the path of one of one patient sample submitted for HLA Typing (Sample #2-171219-0046). 2. Review of the sanger sequencing assay worksheet named 'LT/SBT Primary Amplification_LS Layout' as Tray #SBT 010218 SF 1, tested on 1/2/2018 at 1:11pm, showed no well were designated for positive or negative control material(s). 3. Review of the HLA SOP #7421 (Version 1.7): titled 'Secore Sequencing Kit Testing' approved as current on March 13, 2018, there was no section titled, discussion of, or procedures for testing personnel to follow regarding the include of Postive and Negative control materials to be inlcuded with patient batch (assay) runs. 4. These findings were confirmed with the Technical and General HLA testing supervisors at approximately 3:15pm on the date

	of the survey. Both Technical and General supervisors interviewed admitted that they have never checked the accuracy of interpretative results by including Positive and Negative control materials on the runs.