Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0659066	04/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
Vanderbilt University Medical Center	1301 Medical Center Dr-4605 Tvc, Nashville, TN	

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
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on interview with the Transplant Coordinator, interview with the Blood Bank Manager, review of Blood Bank Unit History print outs, it was determined that the Laboratory Director did not ensure that an effective Quality Assessment Program was in place when the Transplant Team received notification from the OPO (Organ Procurement Organization) concerning an ABO mismatch between Patient #2 and a transplanted liver and then failed to notify the Blood Bank of this issue prior to them issuing blood products. (Refer to D6094)
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 interview with the Transplant Quality Coordinator, interview with the Blood Bank Manager, and review of the Blood Bank Unit History print outs, it was determined that the Laboratory Director did not ensure that an effective Quality Assessment Program was established to ensure that the Blood Bank issued ABO compatible blood products to Patient #2 after receiving an ABO mismatched liver

	transplant. The findings included: 1. Interview with the Transplant Quality Coordinator on April 11, 2019 at 1:00pm verified that the Transplant Team received notification on 11/28/18(day after transplant) that the liver they received for Patient #2 was not type O but instead type A. 2. Interview with the Blood Bank Manager on April 11, 2019 at 11:00am verified that on 11/28/18 type O plasma was sent to the floor for Patient #2. The Floor Nurse refused the plasma units and returned them to the Blood Bank because of an ABO mismatch with a transplanted liver. The Blood Bank staff was not aware of the ABO issue with Patient #2 prior to the plasma being returned. The Floor Nurse then called the Blood Bank and told them of the ABO issue with the recently transplanted liver of Patient #2 after sending the type O plasma back to the Blood Bank. 3. Review of the Unit History print outs for Patient #2 indicated the following plasma units were issued on 11/28/18 at 13:13: Units refused by the floor and returned at 15:04 included: O pos W201918571147 O pos W204118444116 O pos W201918867812 O pos W201918567647 O pos W201918554446 O neg W201918572106 O neg W204118444104 O pos W201918572109 O pos W201918867507 O pos W204118443301 O pos W201918571167 O neg W201918572069 Units refused by the floor and returned at 15:04: O neg W204118444099 O pos W204118885295 O pos W204118888073 O pos W201918866255 O pos W204118885319 O pos W204118885159 O pos W201918866196 O pos W201918564276 O pos W201918867669 O pos W201918572073