Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0659066	(X3) Date Survey Completed 12/05/2019
Name of Provider or Supplier Vanderbilt University Medical Center	**Street Address, City, State** 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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on surveyor record review the laboratory failed to ensure that staff perform second person check when issuing blood products. The findings include: 1. Review of the Vanderbilt University Medical Center Diagnostic Laboratories Issue of Blood Products procedure stated a second tech confirms orders and verifies labeling on all products that leave the Blood Bank. The second tech documents the verification by initialing the physician order. 2. Review of the laboratory records revealed that on 9/17 /2019 an order for Patient B was received and issued by TP4. The TP4 left the blood product on the counter and left the laboratory. The blood product was sent to the proper location where Patient B was located before a second check was completed.
D5553	IMMUNOHEMATOLOGY CFR(s): 493.1271(b)(f) (b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b). (f) 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 emergency release records and review of emergency release procedures, the laboratory failed to ensure Emergency Release Forms were signed by the requesting physician before or after blood was obtained. The findings include: 1. Review of the Vanderbilt University Medical Center Diagnostics Laboratories Emergency Release of Blood Products procedure stated that any unit emergency issued before any required testing, including ABO/RH compatibility testing or infectious disease testing is complete requires an Emergency Release Form to be signed by the patient's physician. 2. Review of 2018 Transfusion Service Request for Exceptional Release of Blood Components forms from January to December included 325 out of a total of 1,694 that were not complete with physician signature. 3. Review of 2019 Transfusion Service Request for Exceptional Release of Blood Components forms from January to August included 156 out of a total of 1,073 that were not complete with physician signature.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on surveyor record review and interview with laboratory personnel, the laboratory failed to correct problems identified in the Issuing of Blood Products procedures. The findings include: 1. The Vanderbilt University Medical Center Diagnostic Laboratories Issue of Blood Products procedure stated to record any special messages relevant to product order i.e. antibodies, notes to tech, and transfusion restrictions (Autologous, Directed Donors...) on requisition. 2. Review of the laboratory records indicated that on 10/9/2019 at 8:57 AM an order was received for Patient A. Patient A had special restrictions to only transfuse O negative blood. TP1 reviewed the order and the special restrictions in SoftBank. TP1 recorded the special restrictions onto the Physician Order Form incorrectly as O positive. TP2 performed a second check by verifying the information TP1 recorded on the Physician Order Form not the information in SoftBank. 3. Interview with TP3 the morning of 12 /4/2019 confirmed the special restrictions in SoftBank for Patient A were recorded by TP1 incorrectly onto the Physician Order Form which resulted in the wrong blood product being transfused. 4. Interview with QA1 on 12/4/2019 confirmed the special restrictions in SoftBank for Patient A were recorded incorrectly by TP1 resulting in the wrong blood products being issued, but no change to the Issue of Blood Products procedure was made when this error was discovered.