Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2161174	06/18/2019
Name of Provider or Supplier	**Street Address, City, State**	
Vitalant Transf Svcs - Jackson Park	7531 S Stony Island Ave, Chicago, IL	

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
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 review of policies and procedures manuals and laboratory records; surveyor observations; and interview with the General Supervisor (GS), blood distribution measures failed to 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). Findings include: 1. The Policy for Chicago does not include measures for monitoring the return of issued blood products. 2. Review of Emergency Released Red Blood Cells (RBCs)records show that on 04/26/19 at 1804, Four Units of O Pos RBCs (W287919000613, W286819020017, W28819000464, and W286819012817) were issued. The "Patient Snapshot Report" noted that the following; "4 RBCs issued-Only 2 Tx." 3. There was no documentation to show which units were returned to the lab, nor the condition, date, time, and /or disposition of those units. 4. At 2:30 PM on 06/18/19 the surveyor observed that there was no thermometer in the cooler staff used to transport blood throughout the hospital. There was no documentation to show that the temperature of the coolers was monitored. 5. At 3:00 PM on 06/18/19 the GS confirmed the surveyor's findings.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under

	appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (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 review of the laboratory's Application for Certification (FORM CMS 116); Laboratory Personnel Report (FORM CMS 209) and laboratory records and interview with the General Supervisor (GS), Blood and Blood products failed to be stored under appropriate conditions that include an audible alarm system that monitors proper blood and blood product storage temperature over 24-hour period. Findings include: 1. Review of FORM CMS 116 revealed that the laboratory is only open and functioning 8 hours per day, Monday through Friday from 7:00 AM to 3:00 PM. 2. Review of FORM CMS 209 revealed that there were 6 persons listed as laboratory staff for the laboratory which included the following: a. Laboratory Director who also functions as Clinical Consultant and Technical Supervisor. b. Total of 2 General Supervisors c. Total of 2 Testing Personnel 3. Review of laboratory records revealed that there is no documentation to show the monitoring of blood and blood products for 14 hours per day, Monday through Friday, and 24 hours per day on Saturday and Sunday. 4. At 3:00 PM on 06/18/19, the GS confirmed the surveyor's findings.
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (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 review of The Transfusion Agreement; patient records; laboratory records; and interview with the General Supervisor, the laboratory failed to investigate transfusion reactions that occurred in the facility for which it has investigational responsibility and make recommendations to medical staff regarding improvements in transfusion procedures. Findings include: 1. Review of The Transfusion Agreement with the Hospital, states, "Whereas ITxM provides blood and transfusion services, including blood acquisition and storage, distribution and testing activities..." 2. Review of patient records revealed that on 03/27/19 at 06:32 patient #4 was documented as having a possible transfusion reaction. 3. Review of laboratory records revealed that there was no documentation to show that the laboratory investigated the transfusion reaction of patient #4. 4. At 3:30 PM on 06/18/19, the GS confirmed the surveyor's findings.
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 record review and laboratory staff interviews, the laboratory director (LD) failed to provide overall management and direction in the specialty of Immunohematology. Findings Include: 1. The LD failed to ensure personnel performing tests in the laboratory are qualified and competent. See D6079. 2. The LD failed to ensure quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing are maintained after hours of operation. See D6082. 3. The LD failed to establish and maintain quality assessment (QA) perimeters to monitor Immunohematology testing performed after the laboratory's hours of operation. See D6094. 4. The LD failed to employ a sufficient number of laboratory personnel to provide 24 hour service at the Jackson Park hospital location as required in their Transfusion agreement. See D6101.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on record review, policies and procedures, the Laboratory Personnel Report (CMS 209), the lack of documentation, and an interview with the general supervisor (GS), the laboratory director (LD) failed to employ personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations in the specialty of Immunohematology. Findings include: 1. The ITxM laboratory's (Lab A) standard operating procedures (SOP), the Transfusion agreement with Jackson Park Hospital (Lab B), the CMS 209, the ITxM (Lab A) "User testing Performed" list were reviewed. 2. Lab A's CMS 209 lists 3 laboratory personnel performing immunohematology testing in the laboratory from 7a.m.-3p.m., Monday thru Friday. 3. Review of the Lab A's SOP and the Transfusion agreement between Lab A and Lab B revealed the following: *Lab A's "Emergency Issue of Blood Products" policy allows "Non Technical" personnel from Lab B to enter Lab A after the hours of operation to retrieve and test blood products without the presence of Lab A personnel. 4. Lab A's "User Testing Performed" list from 02/25/2019 to 06/18/2019 revealed the following: * Lab B is open 24 hours. * Out of the 12 testing personnel (TP) listed as having performed tests in Lab A, 9 TP were not included on the CMS 209. * These 9

	TP performed electronic crossmatching, Gel ABO/Rh Typing, and Gel Antibody Screening when Lab A was closed. * The TP of Lab B retrieved and issued 82 units of blood after Lab A's hours of operation and when Lab A personnel were not present. 5. The LD failed to ensure the credentials, training and competency of the 9 TP from Lab B met the criteria for personnel testing in the specialty of Immunohematology. 6. On an Initial survey conducted on 06/18/2019 at 3:00 PM, the GS confirmed the above findings and stated that some of the TP from Lab B were trained but was finding it difficult to coordinate.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on record review, policies and procedures, and an interview with the general supervisor (GS), the laboratory director (LD) failed to ensure that test systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing in the specialty of Immunohematology. Findings include: 1. The ITxM laboratory's (Lab A) standard operating procedures (SOP), the Transfusion agreement with Jackson Park Hospital (Lab B), Emergency Release policy and procedures for Lab B, and the ITxM (Lab A) "User testing Performed" list were reviewed. 2. Lab A is responsible for delivery and inventory management of all blood products necessary to meet Lab B's 24 hour transfusion needs. The LD failed to provide the laboratory with the qualified personnel needed to perform these 24 hour services. 3. The procedures manual and 'tests performed' lists revealed the following: * The LD failed to ensure that personnel from Lab A were present when blood products were removed and returned by Lab B. * Electronic Crossmatching, Gel ABO/Rh Typing, and Gel Antibody Screenings are performed after Lab A's hours of operation, by personnel from Lab B. 4. The review of 6 patients emergency release forms and the Emergency Release policy and procedures revealed the following: * A Pre-transfusion collection of blood is required for each emergency released blood order if not previously performed by the Lab A. * All 6 patients were issued units of blood. * Of the 6 patients, 5 patients had no record of pre-transfusion blood collection or testing by Lab A. * The Electronic Crossmatching was performed by Lab B for 5 out of 5 patients without the required blood type and screening results from Lab A. 5. The LD failed to ensure preanalytic, analytic, and postanalytic phases of testing were performed in accordance to established policies, procedures and applicable regulations when Lab B personnel requisitions, tests, retrieves, and return blood products when Lab A is not open for service. 6. On an Initial survey conducted on 06/18/2019 at 3:00 PM, the GS confirmed the above findings.
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 record review, policies and procedures, lack of documentation, and an interview with the general supervisor (GS), the laboratory director (LD) failed to establish and maintain quality assessment (QA) programs to assure the quality of laboratory services provided and to identify failures in quality as they occur in the specialty of Immunohematology. Findings include: 1. The ITxM laboratory's (Lab A) standard operating procedures (SOP) and transfusion records were reviewed. 2. The LD failed to establish QA perimeters to monitor the preanalytic, analytic, and postanalytic phases of testing when Lab B personnel requisitions, tests, retrieves, and return blood products from Lab A when it is not open for service. 3. The LD failed to ensure prompt review of transfusion reactions when Lab A is not opened for service. 4. On an Initial survey conducted on 06/18/2019 at 3:00 PM, the GS confirmed the above findings.
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart. This STANDARD is not met as evidenced by: Based on record review, policies and procedures, the CLIA application for certification (CMS 116), and an interview with the general supervisor (GS), the laboratory director (LD) failed to employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities in the specialty of Immunohematology. Findings include: 1. The Transfusion agreement with Jackson Park Hospital (Lab B), Emergency Release policy and procedures for Lab B, CMS 116, the ITxM (Lab A) "User testing Performed" list were reviewed. 2. The CMS 116 states the laboratory's hours of operation are 7a.m.-3p.m., Monday thru Friday. 3. Review of the Lab A's SOP and the Transfusion agreement between Lab A and Lab B revealed the following: * The Transfusion agreement between Lab A and Lab B states that Lab A is "responsible for delivery and inventory management of all blood products necessary to meet Lab B's transfusion needs". *Lab A's "Emergency Issue of Blood Products" policy allows "Non Technical" personnel from Lab B to enter Lab A after the hours of operation to retrieve blood products without the presence of Lab A personnel. 4. Lab A's "User Testing Performed" list from 02/25/2019 to 06/18/2019 revealed the following: * Lab B is open 24 hours. * TP from Lab B performed electronic crossmatching, Gel ABO/Rh Typing, and Gel Antibody Screening when there were no Lab A personnel present. *Lab B retrieved and issued 82 units of blood after Lab A's was closed and when Lab A personnel were not present. 5. The LD failed to ensure Lab A hired the required qualified personnel needed for 24 hours of laboratory coverage. 6. On an Initial survey conducted on 06/18/2019 at 3:00 PM, the GS confirmed the above findings.