Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	41D0083902	07/29/2022
Name of Provider or Supplier	**Street Address, City, State**	
Women & Infants Hospital	101 Dudley St, Providence, RI	

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
D0000	An onsite complaint survey was conducted at Women and Infants Transfusion Services for compliance with 42 CFR Part 493, Requirements for Laboratories.
D5026	IMMUNOHEMATOLOGY CFR(s): 493.1217 If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1271, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on surveyor review of Transfusion Services Laboratory records and procedures and staff interviews, the laboratory failed to include detailed step-by-step processes in their approved Transfusion Services standard operating procedures (SOP) (refer to D5403) and testing personnel (TP) failed to follow approved Transfusion Services SOP (refer to 5401). The cumulative effect of these systematic problems resulted in the laboratory's inability to ensure the accuracy and reliability of Immunohematology results.
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: A. Based on record review and staff interview on 07/29/2022, the laboratory staff

failed to follow the approved "Cord Blood Testing and Heel Specimens for ABO/RH & DAT, procedure # TRM.004.00.13 required for the review and release of blood products. Findings include: 1. Eight patient transfusion records with specific transfusion requirements were reviewed between January 2022 and July 2022. 2. Record review on 07/29/2022 of one of eight patient transfusion records (MRN: 008303744) in the PathNet BB Transfusion Patient Product Laboratory Information System (LIS) revealed the following in the "Blood Bank Comments" field: a. >>JUN /15122 09:00 00 cord tested 6/9 b. " JUN/11/22 14:-16:00 Heel type performed 06/11 /2022 14 46:25 EDT 3. Record review on 07/29/2022 of the Cord Blood Testing and Heel Specimens for ABO/RH & DAT, procedure # TRM 004.00.13 approved on 02/20 /2017 revealed the following under the section titled, "ABO/Rh Confirmation of Heel Specimens - for babies with orders for blood" a. "5. Place a comment under the comment section in Patient Product History giving the status of a retype and if O negative cells must be given." 4. Staff interview with the General Supervisor (GS#2) on 07/29/2022 at 11:03 AM confirmed that TP#1 failed to follow the procedure noted above for entering patient comments required for the review and release of blood products. The interview further revealed that the neonatal patient (MRN:008303744) received type O positive red cells on 06/15/2022. The GS#2 further revealed the patient's mom is O negative with positive screen due to Rhogam. For transfusion purposes, the patient should have received Rh negative red cells and platelets. 5. Staff interview with GS#2 on 07/29/2022 at 3:30 PM revealed that the laboratory performs an estimated total of 450 transfusions per year. A smaller portion of these includes specific transfusion requirements. B. Based on record review and staff interview on 07 /29/2022, the laboratory staff failed to follow the approved "Selection of Blood and Blood Products for Neonate" Procedure # TRM 006.18.12 before dispensing and releasing blood products. Findings include: 1. Eight patient transfusion records with specific transfusion requirements were reviewed between January and July 2022. 2. Record review on 07/29/2022 of patient record MRN:008303620 in the PathNet BB Transfusion Patient Product revealed the following comment under the "Blood Bank Comments" section: a. >>JUN.124/22 10:16: Infant must receive Rh Neg cellular products b. >> JUN/23122 12:29:00 Mom O neg pos screen Anti-D due to RHIG 06121/22 2x cord and heel on 06/23/22. 3. Record review on 07/29/2022 of "Selection of Blood and Blood Products for Neonate" Procedure # TRM 006.18.12, revealed "If the mother of a neonate demonstrates anti-D, provide the neonate with Rh negative platelets" under Section E Selection of Platelets for Transfusion. 4. Staff interview with General Supervisor (GS#2) on 07/29/2022 at 11:18 AM confirmed that the neonatal patient MRN:008303620 received B positive platelets on 06/24/2022. GS#2 stated platelets were issued by TP#3 at 1:00 AM and TP#2 prepared the syringe. TP#5 saw the platelets on the rotator at 10:00 AM on 06/25/2022 and discovered the patient received the wrong product. TP#5 reported this to the GS#2. The interview further revealed that testing personnel (TP#2 and TP#3) failed to follow the procedure noted above before reviewing and dispensing the blood products. GS#2 confirmed the patient's mother had a O negative blood type and a positive screen due to Rhogam, meaning for transfusion purposes, the infant should have received Rh negative products. C. Based on record review and staff interview on 07/29/2022, the laboratory staff failed to follow the approved "Dispense and Assign" Procedure # TRM.C013. 00.10 before dispensing and releasing blood products. Findings include: 1. Eight patient transfusion records with specific transfusion requirements were reviewed between January 2022 and July 2022. 2. Record review on 07/29/2022 of patient record MRN: 008090614 in PathNet BB Transfusion Patient Product Laboratory Information System (LIS) revealed the following comment under the "Blood Bank Comments" section: "TRANSFUSE O CELLS ONLY Patient is a subgroup A2 with an Anti-A1" 3. Record review on 07/29/2022 of "Dispense and Assign" procedure #

	TRM.C013.00.10 revealed "under section B Dispense, "6. Click on the yellow Comment icon (paperclip) and open the comments in the screen. Adjust the comment box so it is big enough for all the comments to be seen all at once." "Note: It is very important that the comments found in this area are followed. If the product being dispensed does not match these comments, do not release the product and select one that is more appropriate." 4. Staff interview with General Supervisor (GS#2) on 07/29 /2022 at 11:38 AM confirmed that the patient MRN: 008090614 received 3 units of A positive cells on 07/05/2022. The interview further revealed that testing personnel (TP#7 and TP#8) failed to follow the procedure noted above before reviewing and dispensing the blood products. The GS#2 also stated that the patient is A subgroup, and needed to receive O cells for transfusions.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and staff interview on 07/29/2022, the laboratory failed to include detailed step-by-step processes in their Cord Blood Testing and Heel Specimens for ABO/RH & DAT Procedure (TRM 004.00.13), approved on 02/20 /2017. Findings include: 1. Record review on 07/29/2022 of approved Cord Blood Testing and Heel Specimens for ABO/RH&DAT Procedure (TRM 004.00.13) approved 02/20/2017 revealed the following under the section titled "ABO/Rh Confirmation of Heel Specimens - for babies with orders for blood" a. "5. Place a comment under the comment section in Patient Product History giving the status of a retype and if O negative cells must be given." 2. The record review on 07/29/2022 revealed that the procedure did not include step-by-step process for entering patient comments during testing. 3. Staff interview with General Supervisor (GS#2) on 07/29 /2022 at 11:10 AM confirmed the findings above. The GS#2 further revealed that the "ABO/Rh Confirmation of Heel Specimens - for babies with orders for blood" Procedure (TRM 004.00.13) was recently updated and approved by the Laboratory Director on 07/14/2022.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)

	The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on record review and staff interview, the Technical Supervisor (TS) failed to perform the semi-annual competency of new testing personnel (TP) to assess the knowledge and skills necessary to perform high complexity laboratory testing in the specialty of Immunohematology. Findings include: 1. Record review on 7/29/2022 of the laboratory's CMS 209 form signed by the laboratory director (LD) on 7/29/2022 revealed, the Immunohematology laboratory had one TS and 2 General Supervisors (GS) listed. 2. Record review on 7/29/2022 of the credentials for the TS listed above revealed the TS is an M.D. with Board Certification as an Anatomic and Clinical Pathologist. 3. Record review on 7/29/2022 of the credentials for GS#1 revealed, GS#1 has a Bachelor's degree and does not qualify to be a TS in the specialty of Immunohematology. 4. Record review on 7/29/2022 of the credentials for GS#2 revealed, GS#2 has a Bachelor's degree and does not qualify to be a TS in the specialty of Immunohematology. 5. Immunohematology competency record review on 7/29/2022 for TP#8 hired on 6/20/2021 revealed: a. The semi-annual competency documentation was not signed by the TS as reviewed. b. The semi-annual competency documentation was signed by GS#1. 6. Staff Interview with the GS#2 on 7/29/2022 at 11:30 AM, confirmed the above findings. GS#2 stated, "I always do all of the competency for the Blood Bank techs." GS#2 further stated GS#1 was helping GS#2 with competency assessment.