Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D0535343	05/17/2024
Name of Provider or Supplier	**Street Address, City, State**	
Lovelace Women's Hospital	4701 Montgomery Boulevard Northeast, Albuquerque, NM	

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 unannounced onsite complaint investigation was conducted from 05/14/2024 through 05/17/2024. The allegations were substantiated and condition-level non-compliance was identified, as follows: D5026 CFR 493.1217 Condition: Immunohematology D6076 CFR 493.1441 Condition: Laboratory Director
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 review of policies and procedures, job aids, transfusion reaction forms, emergency release forms, laboratory information system (LIS) records, Centers for Medicare & Medicaid Services (CMS) -116 database, quality assessment forms, observation, electronic mail (email), and interview with the laboratory manager, the laboratory failed to meet the specialty of immunohematology condition as follows: 1. The laboratory failed to ensure an effective quality assessment with testing persons training when issuing incompatible plasma for one of one patient on 11/13/2023. Refer to D5293. 2. The laboratory failed to follow their own written policies and procedures when issuing plasma to one of one patient on 11/13/2023. Refer to D5401, I. 3. The laboratory failed to follow their own written procedure for ensuring documented pathology review for 6 of 11 blood product emergency releases in 2023 and 2024. Refer to D5401, II. 4. The laboratory failed to ensure the current laboratory director signed, dated, and approved the non-conforming event (NCE) policy and procedure. Refer to D5407. 5. The laboratory failed to follow their NCE policy and procedure for completing their investigation within their timeframes for one of one blood bank issue in 2023. Refer to D5791.

D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review transfusion records, policies and procedures, quality assessment records, and interview with staff, the laboratory failed to ensure an effective quality assessment with testing persons' training when issuing incompatible plasma for one of one patient on 11/13/2023. Findings included: 1. Review of transfusion records for patient 0010570794 included a problem identified by the laboratory. Two testing persons (TP-13 and 14) were involved in the preparation and issuance of incompatible plasma on 11/13/2023, refer to D5401, I. 2. Review of the BB 169 Training and Competency Assessment of Blood Bank Staff Procedure (version 6.0, effective 04/27 /203) included "Quality assurance forms" are filled out when "problems arise." The "Quality Assurance Forms" as stated in BB 169 procedure were provided by the laboratory manager regarding the incompatible plasma issued on 11/13/2023. A non-conforming event (NCE) form was provided and initiated on 11/17/2023, which was incomplete and not according to the required timeframes per the laboratory's written policy and procedure, refer to D5791. A root cause analysis, corrective action and preventative action, and effectiveness check had not been completed per the NCE policy and procedure. 3. During an interview on 05/15/2024 at 3:24 pm, the laboratory director and laboratory manager were asked for documentation of training or competency assessment of testing persons who perform procedures in immunohematology after the NCE on 11/13/2023. The laboratory manager stated a quiz about plasma compatibility (per the laboratory director's instruction) had been provided to 11 testing persons. 4. Review of the quiz documentation included four questions regarding plasma compatibility and 9 of 11 testing persons completed the quiz between 11/16/2023 and 12/03/2023. There was no documentation of the identity of the testing persons (who completed vs. who did not complete the quiz). During an interview on 05/15/2024 at 4:13 pm, the laboratory manager stated the identification of the testing persons could not be determined and the deadline was 12/07/2023 to complete the quiz.
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: I. Based on review of policies and procedures, job aids, transfusion reaction forms, emergency release forms, LIS records, and interview with the laboratory manager, the laboratory failed to follow their own written policies and procedures when issuing plasma to one of one patient on 11/13/2023. Findings included: 1. Review of BB 230

Massive Transfusion Protocol (MTP) Procedure (effective 06/22/2022) stated, "I ... 2. If the patient [sic] current type on file, compatible FFP may be assigned"; BB 413 Massive Transfusion (MTP) Flow Chart and Checklist Job Aid (effective 09/27/2022) stated, "Thaw 4 compatible FFP ..."; BB 776 Massive Transfusion Protocol Job Aid (effective 09/27/2023) stated, "4.) ...a ...iii. Type AB plasma given (Emergency issue)." Review of BB 225 Emergency Release of Blood Procedure (effective 11/15 /2022) stated, "A. When a request for Emergency Release Uncrossmatched RBCs is received: 1. Check if the patient has a current completed type and screen. a) If so, use the type and screen to allocate crossmatched units." (per the laboratory manager on 05 /14/2024 at 2:55 pm, this procedure was applicable to all blood products, plasma, platelets, red blood cells, cryoprecipitate). There was no written procedure specific to issuing plasma in an emergency, a job aid accompanied this procedure. Review of BB 411 Emergency Release Flowchart and Checklist Job Aid (effective 11/15/2022) stated, "Issue: Any AB FFP." 2. Review of patient 0010570794 ABO/Rh type and antibody screen in the laboratory's EPIC system (LIS) included a type/screen was performed on 11/12/2023 at 2:44 pm: B Pos and a negative antibody screen. According to the emergency release form for patient 0010570794, "B Pos" was documented on the form and four units of O pos plasma (incompatible) were issued and transfused on 11/13/2023 between 4:14 am and 4:57 am. The units were prepared by two testing persons (TP). The laboratory failed to follow their own written policies and procedures when issuing plasma. 3. Review of a "Suspected Transfusion Reaction Evaluation Form" for patient 0010570794 (blood type B pos) on 11/13/2023 under "Clerical check ...Patient and donor types" had a documented "X" under "Inaccurate" and stated, "Describe Discrepancy, if Inaccurate: ABO incompatible plasma given." According to the laboratory manager on 05/15/2024 at 10:00 am, the "Prohibiting Factor" pop-up window in SafeTrace (blood bank LIS) when issuing incompatible blood products was overridden by the testing person when the plasma was issued. It was unknown when this capability of overriding was dropped down to a tech level (testing person) versus a supervisory level of security. 4. Review of the four units of O pos of plasma that were issued in the SafeTrace system by TP-14 on 11/13/2023 for patient 0010570794 included the following: W035823075672C at 4:40 am W041223041008S at 4:32 am W041223041022W at 4:32 am W041223547968 at 4: 32 am In SafeTrace, the above plasma products included, "Activity: Factor Override ... Object ID Prod not compatible." 5. Further review of BB 230 Massive Transfusion Protocol (MTP) Procedure (effective 06/22/2022) stated, "V. Procedure Instructions A ...2. LWH, LWS, LRH - Call the pathologist on call if a MTP is activated" and "When Should I Call the Pathologist Job Aid" stated, "And if any of the following criteria are met: ...Massive Transfusion - LWS, LWH, and LRH is activated ...Site Specific Reasons to Call a Pathologist after Hours: Obstetric hemorrhage with > 2 RBCS or any obstetric hemorrhage requiring cryoprecipitate, plasma, or platelets as FYI after issuing products." Patient 0010570794 had a cesarean-section (obstetric procedure) performed prior to emergency release and was hemorrhaging. The laboratory manager was asked for documentation of the pathologist called when the MTP was initiated, no documentation was provided on 05/16/2024 at 2:30 pm. The laboratory failed to ensure patient 0010570794 was issued compatible plasma per their policies, procedures, and job aids. II. Based on review of laboratory procedures, a job aid, patient emergency release forms, and interview with the laboratory manager, the laboratory failed to follow their own written procedure for ensuring documented pathology review for 6 of 11 blood product emergency releases in 2023 and 2024. Findings included: 1. Review of BB 225 Emergency Release of Blood Procedures (versions 16.0 - effective 11/15/2022 until 11/22/2023 and version 17.0 - effective 11 /22/2023) stated on page 2, "B ...16. Inform the person picking up the blood that the BB 749 Emergency Uncrossmatched Form must be signed by the physician that is

	ordering the emergency release of Uncrossmatched blood, within 24 hours of issue. When returned, place copy into the Pathology review box." Review of BB 411 Emergency Release Flowchart and Checklist Job Aid (version 7.0 - effective 11/15 /2022 until 11/22/2023 and version 8.0 - effective 11/22/2023) stated, " ...6. Perform XM for RBCs and submit form(s) to pathologist for review and signature." 2. During an interview on 05/14/2024 at 2:55 pm, the laboratory manager confirmed the "Emergency Release of Blood Procedures" was applicable to all blood products (fresh frozen plasma, platelets, cryoprecipitate, and red blood cells). 3. Review of the following six (6) blood product emergency release forms for patients included Emergency Release Request for Red Blood Cells (Uncrossmatched) forms without a documented "Pathologist Review": 11/13/2023 - Patient 0010570794, two units of O Pos cryoprecipitate 11/13/2023 - Patient 0010570794, three units of O Pos packed red blood cells (PRBCs) 11/13/2023 - Patient 0010570794, three units of O Pos PRBCs 11 /13/2023 - Patient 0010570794, two units of O Pos PRBCs 12/25/2023 - Patient 0015247257, one unit of O Pos PRBCs 05/09/2024 - Patient 0016360840, one unit of O Pos PRBCs 4. During an interview on 05/15/2024 at 9:57 am, the laboratory manager stated the emergency release forms pathologist review is done during the monthly review or is sent to their main facility for review. He confirmed the above forms had not been documented for review. Word Key: BB - blood bank FFP - fresh frozen plasma P/pos - positive Rh type ID - identification Prod - product LWH - Lovelace Womens Hospital LWS - Lovelace Westside LRH - Lovelace Regional Hospital RBCs - red blood cells FYI - for your information XM - cross-match
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of policies and procedures and the CMS-116 database, the laboratory failed to ensure the current laboratory director signed, dated, and approved the non-conforming event (NCE) policy and procedure. Findings included: 1. Review of QUAL 51 Nonconforming Event (NCE) Management Procedure (version 6.0, effective 12/01/2023) and QUAL 28 Nonconforming Event (NCE) Management Policy (version 2.2, effective 11/29/2022) was used as part of the laboratory's quality assessment when an issue in blood bank was identified. The laboratory issued incompatible plasma to a patient 11/13/2023, refer to D5401, I and D5791. 2. Review of the first pages ("Approval and Periodic Review Signatures") of QUAL 51 and QUAL 28 procedure and policy did not include the current laboratory director signature and date of approval. 3. According to CMS-116 database, the current laboratory director has been the director since 06/21/2017.
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 review of policies and procedures, transfusion records, quality assessment forms, observation, email, and interview with the laboratory manager, the laboratory failed to follow their NCE policy and procedure for completing their investigation within their timeframes for one of one blood bank issue in 2023. Findings included: 1. Review of QUAL 51 Nonconforming Event (NCE) Management Procedure (version 6.0, effective 12/01/2023) stated, "III. Responsibility/Scope ...D. Owner of the event to complete the investigation in a timely manner and move the event through its lifecycle. 1. Phase 2 Responsible Department Investigation (RDI) must be completed within two (2) weeks from when it is received by the responsible department ... 2. Phase 3 Root Cause Analysis/CAPA must be completed within 60 days of initiation. 3. Effectiveness Check dates must not exceed six (6) months from completion of RCA /creation of CAPA plan." (CAPA - corrective action and preventative action) 2. Review of QUAL 28 Nonconforming Event (NCE) Management Policy (version 2.2, effective 11/29/2022) timeframes were consistent with QUAL 51 procedure and included, "5. Exceptions to stated TAT must be authorized by Laboratory Director /Director." (TAT - turnaround time) 3. Review of transfusion records for patient 0010570794 included a problem identified by the laboratory, refer to D5401, I. According to emergency release forms and EPIC/SafeTrace records, there were two testing persons involved in the preparation and issuance of the plasma (TPs- 13 and 14 as listed on the CMS-209 form). 4. Review of the BB 169 Training and Competency Assessment of Blood Bank Staff Procedure (version 6.0, effective 04/27/203) included "Quality assurance forms" are filled out when "problems arise." The "Quality Assurance Forms" as stated in BB 169 procedure were provided by the laboratory manager regarding the incompatible plasma issued on 11/13/2023, as follows: An NCE form was initiated on 11/17/2023 that stated, "Phase 1 ...Immediate Action Taken: Provider/floor/client notified; Brief Description of Event: Patient underwent a [sic] emergency release massive transfusion protocol. 4 Type O thawed plasma units were given type B Pos patient. Pathology was notified retroactively same day" and 13 weeks later (02/16/2024) "Phase 2 ...Event Investigation Notes: release of type-O plasma to a type-B patient. System override set at user level not supervisor. Build Your Problem Statement: Current State: Incompatible plasma given to patient with a [sic] LIS override; Desired State: What Should Be: compatible plasma given to patient without using a LIS override unless appropriate per policy." Phase two was not completed within the timeframe (completed >2 weeks on 2/16/2024) and phases three and four were incomplete. During an interview with the laboratory manager on 5/15 /2024 at 1:52 pm, he confirmed an authorization by the laboratory director was not given for an exception regarding the turnaround time for the NCE, per QUAL 28 policy. 5. The laboratory manager on 05/15/2024 at 10:40 am was able to provide evidence that an EPIC Beaker administrator increased the security level of overriding to supervisory approval and not "user" or testing person level on 11/20/2023 with a demonstration and emails. This was not documented in the NCE form. In addition, an RCA/CAPA and effectiveness check was not completed as required by their own written policy and procedure.
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 review of policies and procedures, job aids, transfusion reaction forms, emergency release forms, LIS records, CMS-116 database, quality assessment forms, observation, email, and interview with the laboratory manager, the laboratory director failed to provide overall management for immunohematology, as follows: 1. The laboratory director failed to ensure test procedures provided quality laboratory services in immunohematology. Refer to D6082. 2. The laboratory director failed to ensure quality assessment programs were maintained when failures were identified. Refer to D6094.
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 review of policies and procedures, job aids, transfusion reaction forms, emergency release forms, LIS records, CMS-116 database, and interview with the laboratory manager, the laboratory director failed to ensure test procedures provided quality laboratory services in immunohematology, as follows: 1. The laboratory failed to follow their own written policies and procedures when issuing plasma to one of one patient on 11/13/2023. Refer to D5401, I. 2. The laboratory failed to follow their own written procedure for ensuring documented pathology review for 6 of 11 blood product emergency releases in 2023 and 2024. Refer to D5401, II. 3. The laboratory failed to ensure the current laboratory director signed, dated, and approved the non-conforming event (NCE) policy and procedure. Refer to D5407.
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 review of policies and procedures, transfusion records, quality assessment forms, observation, email, and interview with the laboratory manager, the laboratory director failed to ensure quality assessment programs were maintained when failures were identified, as follows: 1. The laboratory failed to ensure an effective quality assessment with testing persons training when issuing incompatible plasma for one of one patient on 11/13/2023. Refer to D5293. 2. The laboratory failed to follow their NCE policy and procedure for completing their investigation within their timeframes for one of one blood bank issue in 2023. Refer to D5791.