Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	32D1065537	12/13/2019
Name of Provider or Supplier	**Street Address, City, State**	
Lovelace Regional Hospital - Roswell	117 East 19th St, Roswell, 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	During a complaint survey completed on 12/13/19 for 42 CFR part 493 Laboratory Requirements, the facility was found out of compliance with the following condition: 42 CFR Part 493.1441 Laboratory Director, High Complexity
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. This STANDARD is not met as evidenced by: Based on the review of transfusion records, nursing notes, electronic medical records, laboratory policy, nursing blood administration policy, and interviews with laboratory staff, the laboratory failed to ensure nursing staff reported all possible transfusion reactions to the laboratory for 1(BB #5) of 6(BB #1-BB#6) patient medical records reviewed from October and November 2019. This deficient practice could result in delayed identification and treatment of transfusion reactions. Findings are: A. Review of the medical record for BB (Blood Bank Patient) #5. had no documentation the laboratory was notified of a possible transfusion reaction 1. Consent signed 10/08/19 at 6:17 (am/pm not documented). 2. The Transfusion Record for PRBC(Packed Red Blood Cells) Unit W041519025216 indicated the transfusion started on 10/08/19 at 13: 17 pm. The transfusion was completed on 10/08/19 at 15:15 pm. The section, "Evidence of possible transfusion reaction?" was marked "No." 3. The Transfusion Record for PRBC Unit W041519020383 indicated the transfusion started on 10/08/19 at 15:45 pm. The transfusion was completed on 10/08/19 at 17:56 pm. The section, "Evidence of possible transfusion reaction?" was marked "No." 4. Nursing note dated 10/08/19 at 05:08 pm (2 hours and 23 minutes after 2nd transfusion started) indicated "Arrived into room, pt c/o feeling chills and pain in there (sic) right arm. Blood

product stopped. Temp checked to be 97.8. Dr [name of provider] on unit, reported incident to him, made aware of vital signs and pt complaint. Dr [name of provider] order to restart blood and offer hydralazine for anxiety. Blood resumed, pt refused hydralazine at this time. Upon further assessment, pt states she has been having chills off and on since early yesterday." B. Review of the Laboratory Blood Bank Policy, Crossmatch and Transfusion, dated 02/28/19, indicated: "All suspected adverse reactions to transfusions are to be investigated when the situation arises, whether or not the ordering physician requests it. THIS IS A STAT PROCEDURE. (see Transfusion. Reaction policy)" C. Review of the Laboratory Blood Bank Policy, Transfusion Reactions, dated 02/28/19 indicated the following: 1. "All personnel involved in the administration of blood products must be able to recognize a suspected reaction so that the transfusion can be stopped, diagnosis established, and appropriate therapy initiated promptly. All nursing personnel must have annual transfusion reaction, blood administration, and recipient identification training. All transfusion reactions, whether immediate or delayed, will be resulted the same and have medical director involvement in the type of reaction identified and treatment of the transfusion reaction. The physician ordering the transfusion will receive the transfusion reaction report. The pathologist will also give direction to the transfusion service whether more transfusions may take place or not." Procedure -"1. In the event a transfusion reaction is suspected, the transfusing nurse should immediately stop the transfusion and notify the physician. 2. Within 10 minutes of stopping the transfusion, the laboratory must be notified so that we may begin to investigate the cause of the reaction." 2. The laboratory Transfusion Reaction policy identified and defined 7 types of transfusion reactions; Hemolytic Transfusion Reaction, Febrile Nonhemolytic Transfusion Reaction, Allergic and Anaphylactic Reactions, Transfusion-Related Acute Lung Injury, Transfusion Associated Circulatory Overload, Transfusion-Associated Sepsis and Delayed Hemolytic Transfusion Reaction. 3. The laboratory Transfusion Reaction policy identified the following as signs and symptoms of transfusion reactions: Fever (increase of 1C or 2F) Chills Rigors (a sudden feeling of cold with shivering accompanied by a rise in temperature, often with copious sweating, especially at the onset or height of a fever) Headache Nausea or vomiting Pain at the infusion site or in chest, abdomen or flanks Dyspnea (difficult or labored breathing) Hypotension (low blood pressure) Hypertension (high blood pressure) Tachycardia (abnormally rapid heart rate.) Renal/Kidney Failure DIC (Disseminated Intravascular Coagulation - A condition where blood clots are excessively formed in the body's blood vessels) Urticaria (hives) Generalized flushing or rash Localized swelling or "angi-oedema" Bronchospasm (respiratory distress, wheezing) Anxiety Cyanosis (a bluish discoloration of the skin resulting from poor circulation or inadequate oxygenation of the blood) Orthopnea (sensation of breathlessness while lying down) Congestive heart failure (a weakness of the heart that leads to a buildup of fluid in the lungs and surrounding body tissues) D. Review of the Nursing Administration Policy, Blood Administration, dated 06/26/19, indicated: 1. Education on blood and blood products is provided in new employee orientation and annually thereafter. 2. [Hospital Laboratory] follows standards of the American Association of Blood Banks (AABB) and the Bureau of Biologics of the U.S. Food & Drug Administration (FDA) in procuring, maintaining, administering and monitoring blood and blood components. 3. Obtain the patient's vital signs including B/P (Blood Pressure), HR(Heart Rate), RR (Respiratory Rate) and temp (temperature) and record prior to initiation of blood component. 4. Monitoring for transfusion reaction a. Observe the patient closely for signs of transfusion reaction during the initial 15 minutes and throughout the transfusion. b. Should the patient demonstrate signs of transfusion reaction, see the table below for nursing/laboratory action(s): 3. Only 2 types of transfusion reactions were clearly identified in the table: Anaphylactic and Febrile. Other signs and

	symptoms were listed but the column containing the type of transfusion reaction was missing. 4. Nursing staff were instructed 3 times "Do not stop the transfusion" if the patient only had a temperature 2 degrees above baseline and/or chills in the Blood Administration Policy. There was no corresponding instruction in the laboratory policy. E. Review of AABB Technical Manual, 19th edition, indicated: "The transfusionist should be knowledgeable about signs and symptoms indicative of an adverse reaction and be able to act quickly...If a transfusion reaction is suspected, the transfusion should be stopped...As soon as possible, the transfusion service should be notified of a suspected transfusion reaction." F. During interview on 12/12/19 at 09:55 am, the Laboratory Supervisor stated: 1. The P-tag or transfusion record is not returned to the laboratory following a transfusion. It is scanned into the medical record. 2. There is no one dedicated to the Blood Bank and no one in the laboratory audits the transfusion records.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on the review of November 2019 Lactic Acid turn-around-time reports, patient medical records, manufacturer instructions, and interview with the Laboratory Manager, the laboratory failed to ensure that specimens were processed within the timeframe required by the manufacturer. 23 of 50 patient samples for lactate (or lactic acid) were received in the laboratory beyond the manufacturer's acceptable timeframe. Findings are: A. The laboratory performed lactate testing on patient samples that did not meet the manufacturer's requirements for specimen collection and handling. 1. Review of the Siemens Dimension Flex manufacturer's instructions for collection and handling of lactate samples indicated that samples must be chilled immediately and spun to separate cells from plasma within 15 minutes of collection. The manufacturer also indicated that the separated plasma may be stored for up to 24 hours if refrigerated or frozen for up to 1 month. B. Review of the patient medical records and turn-around-time report for 3(LA2, LA22, and LA24) of 23 patient samples tested 11 /01/19 to 11/30/19 confirmed that these samples were received by the laboratory more than 10 minutes after collection. There was no documentation that samples were spun and the plasma refrigerated or frozen within 15 minutes of collection. > 60 minutes LA2 - 128 Medical record indicated the sample was collected 11/02/19 at 6:47 pm and received by the laboraory at 08:55 pm. 46 - 60 minutes LA6 - 46 LA22 - 49 Medical record indicated the sample was collected 11/16/19 at 6:21 pm and received by the laboraory at 07:10 pm. 31 - 45 minutes LA26 - 37 16 - 30 minutes LA10 - 22 LA12 - 20 LA21 - 26 LA45 - 19 11 - 15 minutes LA7 - 13 LA8 - 13 LA11 - 11 LA14 - 13 LA24 - 15 Medical record indicated the sample was collected 11/26/19 at 11:50 am and received by the laboraory at 12:05 pm. LA25 - 15 LA29 - 12 LA32 - 14 LA33 - 11 LA44 - 12 LA36 - 11 LA40 - 15 LA41 - 12 LA42 - 14 LA46 - 12 C. During interview on the afternoon of 12/10/19, the Laboratory Manager confirmed this finding.

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 the review of transfusion records, nursing notes, electronic medical records, laboratory policy, and hospital policy, the laboratory failed to ensure the transfusion policies for both the laboratory and nursing staff had the same requirements for notification and clearly defined methods for identifying transfusion reactions. Findings are: A. Review of the Laboratory Blood Bank Policy, Transfusion Reactions, dated 02/28/19, indicated the following: 1. Procedure - "1. In the event a transfusion reaction is suspected, the transfusing nurse should immediately stop the transfusion and notify the physician. 2. Within 10 minutes of stopping the transfusion, the laboratory must be notified so that we may begin to investigate the cause of the reaction." a. Nursing staff failed to follow laboratory policy for notification of a transfusion reaction for BB #1 within 10 minutes. 11/09/19 19:30 pm 2 hours 45 minutes after transfusion started. Notified provider at 19:40 pm of a possible transfusion reaction. Dyspnea, chills, hypertension, tachycardia and fever documented on the transfusion record. Laboratory notification occurred at 20:10 pm on 11/09/19, 30 minutes later. 2. The laboratory policy identified and defined 7 types of transfusion reactions; Hemolytic Transfusion Reaction, Febrile Nonhemolytic Transfusion Reaction, Allergic and Anaphylactic Reactions, Transfusion-Related Acute Lung Injury, Transfusion Associated Circulatory Overload, Transfusion-Associated Sepsis and Delayed Hemolytic Transfusion Reaction. B. Review of the Nursing Administration Policy, Blood Administration, dated 06/26/19, indicated: 1. "Should the patient demonstrate signs of transfusion reaction, see the table below for nursing /laboratory action(s):" 2. Only 2 types of transfusion reactions were clearly identified in the table: Anaphylactic and Febrile. Other signs and symptoms were listed but the column containing the type of transfusion reaction was missing from the table. 3. Nursing staff were given the following instructions for Anaphylactic reactions - "1. Stop transfusion immediately. 2. Discontinue the blood unit and all involved blood tubing. 3. Attach a new bag of normal saline with IV tubing with a rate of TKO. 4. Notify provider. 5. Check all identifying names and numbers on the patient's wristband, unit and paperwork for discrepancies. 6. Record and monitor patient's vital signs. 7. Administer oxygen 2L/min/NC as indicated. 8. Begin a transfusion reaction investigation." 4. Nursing staff were instructed 3 times in the chart "Do not stop the transfusion" if the patient only had a temperature 2 degrees above baseline and/or chills in the Blood Administration Policy. There was no corresponding instruction in the laboratory policy. C. Review of transfusion records for 6 Blood Bank Patients (BB #1-BB #6) patients in October and November 2019 revealed no documentation the laboratory was notified of a possible transfusion reaction for BB #5. The patient initially reported chills and pain at the infusion site but later reported the chills had

	been ongoing. See D3025 D. Review of the Laboratory Blood Bank policies and the Nursing Blood Administration policy revealed no specific criteria for evaluating the following signs and symptoms associated with transfusion reactions that may already be present in the patient prior to transfusion: Chills Rigors (a sudden feeling of cold with shivering accompanied by a rise in temperature, often with copious sweating, especially at the onset or height of a fever) Headache Dyspnea (difficult or labored breathing) Hypotension (low blood pressure) Hypertension (high blood pressure) Tachycardia (abnormally rapid heart rate) Urticaria (hives) Generalized flushing or rash Bronchospasm (respiratory distress, wheezing) Anxiety 1. Review of transfusion records for 6 Blood Bank Patients (BB #1-BB #6) patients in October and November 2019 revealed 1 patient, BB #1, had signs of increased respiratory rate prior to transfusion of 2 units of PRBC on 11/09/19. 2. Unit W04151928752, transfusion started at 13:40 pm. The pre-transfusion RR (respiratory rate) at 13:35 pm was 22 breaths per minute, flagged as abnormal in the electronic medical record. At 15:00 pm, the patient's RR dropped to 19 and subsequent measurements ranged 20-24 until 19:40 pm when a possible transfusion reaction was identified during the transfusion of Unit W041519029352. The RR had increased to 37 breaths per minute by 19:30 pm.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic 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 analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on the review of transfusion records, nursing notes, electronic medical records, laboratory policy, hospital policy, and interviews with hospital and laboratory staff, the laboratory failed to have an effective quality assessment policy that ensured the accuracy of medical records for 3(BB #1, BB #2, and BB #4) of 6(BB #1 - BB#6) patients transfused in October and November 2019. Findings are: A. Review of the medical records, including nursing notes, flowsheets, and transfusion records revealed nursing staff failed to document information accurately in the medical record: BB (Blood Bank Patient) #1 1. The Transfusion Consent Form dated 11/09/19 at 10:10 am lacked the name of the ordering physician and the reason the patient's daughter signed instead of the patient. 2. The medical record had missing, incomplete, or data recorded differently on the transfusion record than on the Flowsheet. a. 11/09/19 vitals at 13:30 pm Heart rate 76 - Recorded as 78 on transfusion record Respiration rate 23 - Recorded as 22 on transfusion record b. 11/09/19 13:35 pm Unit W04151928752 issued by laboratory. c. 11/09/19 13:35 pm (transfusion record) W04151928752. Transfusion started 11/09/19 at 13:40 pm on Flowsheet. 11/09/19 14:00 pm Temperature not recorded on flowsheet but recorded as 98.1 on transfusion record. Heart rate 75 - Recorded as 77 on transfusion record. Respiration rate 23 - Recorded as 24 on transfusion record. d. 11/09/14:52 pm Temperature not documented on the Flowsheet - recorded as (") on transfusion record. e. 11/09/19 15:00 pm Temperature recorded as (") on transfusion record. f. 11/09/19 16:38 pm Unit W041519029352 issued by laboratory. g. 11/09/19 16:40 pm (same vitals data recorded on transfusion record for 16:45 pm) h. 11/09/19 16:45 pm, pre-transfusion data for Unit W041519029352; the transfusionist also recorded 16:45 pm as the start time of the transfusion. Respiration rate 22 - recorded as 24 on transfusion record. i. 11/09/19 18:

	00 pm 55 minutes after starting transfusion. All vital signs were recorded except for temperature. j. 11/09/19 18:15 pm 1 hour 20 minutes after starting transfusion (from transfusion record only) All vital signs were recorded except for temperature. k. 11/09/19 19:30 pm 2 hours 45 minutes after transfusion started. Notified provider at 19:40 pm of a possible transfusion reaction. Dyspnea, chills, hypertension, tachycardia and fever documented on the transfusion record. l. Transfusion stopped at 19:45 pm, 3 hours and 50 minutes after the start of the transfusion. m. Notified laboratory at 20:10 pm, 30 minutes after identification of the possible transfusion reaction. Unit W041519029352, nursing staff documented 2 different amounts of blood transfused, 250 mL under transfusion reaction section and 350 mL under total amount transfused on the transfusion record. BB #2 1. The medical record had missing, incomplete, or data recorded differently on the transfusion record than on the Flowsheet. a. 11/11/19 19:40 pm is recorded as both the start time of the transfusion and 15 - minute after starting vital sign check on the transfusion record for Unit W041219035976. b. 11/11/19 21:40 pm the transfusion is completed. The 15 - minute post-transfusion time was not recorded on the transfusion record. The Flowsheet indicated the next vitals (after 21:40 pm) were taken at 22:00 pm, 20 minutes later. BB #4 1. The Transfusion Consent Form dated 11/18/19 at 20:50 pm lacked the name of the ordering physician. B. During interview on 12/12/19 at 09:55 am, the Laboratory Supervisor stated: 1. There is no one dedicated to the Blood Bank and no one in the laboratory audits the transfusion records. 2. The P-tag or transfusion record is not returned to the laboratory following a transfusion. It is scanned into the medical record. C. During interview on 12/11/19 at 10:41 am, the Quality Director responsible for auditing transfusion records stated: 1. The hospital doesn't have an audit policy for transfusion records. A new policy from the transfusion committee has not been adopted yet. 2. "I don't look line-by-line," comparing the "P-tag" (Transfusion record) with the data recorded in the hospital's EMR (Electronic Medical Record). She checked the records for completion. She did a line-by-line comparison when the EMR was first implemented but doesn't do that anymore.
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 the review of transfusion records, nursing notes, electronic medical records, laboratory policy, nursing blood administration policy, and interviews with hospital and laboratory staff, the laboratory director failed to provide overall management of the laboratory's transfusion services. Findings are: The laboratory director failed to ensure the laboratory had an effective system to monitor compliance with Blood Administration policies. A. The laboratory failed to ensure nursing staff reported all possible transfusion reactions to the laboratory. B. The laboratory failed to have an effective quality assessment policy that ensured the accuracy of medical records. C. The laboratory failed to ensure the nursing policies for Blood Administration, including transfusion reaction identification and investigation, were complete and had the same requirements as the laboratory's policies. See 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 the review of transfusion records, nursing notes, electronic medical records, laboratory policy, nursing blood administration policy, and interviews with hospital and laboratory staff, the laboratory director failed to ensure the laboratory had an effective system to monitor compliance with Blood Administration policies. Findings are: A. The laboratory failed to ensure nursing staff reported all possible transfusion reactions to the laboratory for 1(BB #5) of 6(BB #1-BB#6) patient medical records reviewed from October and November 2019. This deficient practice could result in delayed identification and treatment of transfusion reactions. See D3025 B. The laboratory failed to have an effective quality assessment policy that ensured the accuracy of medical records for 3(BB #1, BB #2, and BB #4) of 6(BB #1 - BB#6) patients transfused in October and November 2019. See D5793 C. The laboratory failed to ensure the nursing policies for Blood Administration, including transfusion reaction identification and investigation, were complete and had the same requirements as the laboratory's policies. See D5559 D. During interview on 12/12/19 at 09:55 am, the Laboratory Supervisor stated: 1. There is no one dedicated to the Blood Bank and no one in the laboratory audits the transfusion records. 2. The P-tag or transfusion record is not returned to the laboratory following a transfusion. It is scanned into the medical record. E. During interview on 12/11/19 at 10:41 am, the Quality Director responsible for auditing transfusion records stated: 1. The hospital doesn't have an audit policy for how she reviews transfusion records. A new policy from the transfusion committee has not been adopted yet. 2. "I don't look line-by-line," comparing the "P-tag" (Transfusion record) with the data recorded in the hospital's EMR (Electronic Medical Record). She checked the records for completion. She did a line-by-line comparison when the EMR was first implemented but doesn't do that anymore.