Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0507433	06/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
Lamb Healthcare Center	1500 South Sunset, Littlefield, TX	

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
D3017	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(a) Arrangement for services. The facility must have a transfusion service agreement reviewed and approved by the responsible party(ies) that govern the procurement, transfer, and availability of blood and blood products. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, transfusion services agreements, and confirmed in interview, the laboratory failed to have a reviewed and approved arrangement for transfusion services agreement for Fresh frozen plasma and antibody identification services. The findings included: 1. Review of the laboratory's own procedure titled Fresh Frozen Plasma found a handwritten note on page 1 under PRINCIPLE - "Fax order for thawed plasma to 806-723-7225(Covenant) BC." Further review found on page 1 under PROCEDURE step 3. - "The patient is typed and Covenant Blood Bank (806)725-4256) is called to obtain the correct unit, ask that the plasma be sent thawed." 2. The transfusion services agreement for United Blood Services (UBS) and the Affiliation agreement (with Covenant Health System)were reviewed and found no agreement regarding the provision of thawed fresh frozen plasma. 3. Interview of the General Supervisor conducted on June 27, 2018 at 10:07 AM confirmed that the laboratory would obtain thawed fresh frozen plasma from Covenant Hospital if the need arose. She went on to confirm that the affiliation agreement did not define what transfusion services would be provided .
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

	This STANDARD is not met as evidenced by: Review of patient test records and interview of the general supervisor found that testing personnel failed to complete patient test records for waived and non-waived manual test kits. Findings Included: 1. Review of the Serology/ Manual Test logs (6 pages) for June and July of 2017 found that testing personnel failed to record lot numbers and expiration dates for 8 of 8 test kits used and 4 of 4 controls. In the two month period, testing personnel failed to document lot number of test kits and controls on logs as follows: ANA Kit - 5 of 6 pages had no documentation of lot used with expiration date. ESR Control - 6 of 6 pages had no documentation of lot used with expiration date. hCG Serum Control - 6 of 6 pages had no documentation of lot used with expiration date. Microalbumin - 5 of 6 pages had no documentation of lot used with expiration date. AmniSure kit - 6 of 6 pages had no documentation of lot used with expiration date. hCG kit - 6 of 6 pages had no documentation of lot used with expiration date. HIV kit - 5 of 6 pages had no documentation of lot used with expiration date. Mono kit - 6 of 6 pages had no documentation of lot used with expiration date. ESR Pipettes - 6 of 6 pages had no documentation of lot used with expiration date. hCG Urine Control - 6 of 6 pages had no documentation of lot used with expiration date. HIV Control - 6 of 6 pages had no documentation of lot used with expiration date. RF Kit - 5 of 6 pages had no documentation of lot used with expiration date. 2. Interview of the General Supervisor conducted on June 27, 2018 at 3:40 PM confirmed that testing personnel did not complete the test records to include the lot number and expiration dates as required.
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: Review of policies and procedures, contractual agreements and interview of facility personnel found that the laboratory director failed to ensure that the laboratory had an agreement to provide all transfusion services required by the laboratory. (see D 3017)