Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0495521	07/13/2022
Name of Provider or Supplier	**Street Address, City, State**	
El Campo Memorial Hospital	303 Sandy Corner Road, El Campo, 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
D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f) (a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: An unannounced revisit was performed on 7/12/2022 to 7/13/2022. NEW DEFICIENCY Based on review of the laboratory policy, laboratory and patient test records from May and June 2022, and confirmed in interview, the laboratory failed to follow its policy to investigate incompatible blood components for one of one patient reviewed in May 2022. Findings included: 1. Review of the laboratory policy Compatibility Testing (revised 4/28/22) revealed "any agglutination/hemolysis is considered incompatible -- will be sent out to South Texas Blood and Tissue Center (STBTC) for further consultation and evaluation. Technologist will: a. notify the laboratory manager or director b. if an emergency exists, notify the physician of the delay in providing compatible blood. c. Obtain 4 EDTA (purple) or 3 EDTA (pink) tubes from the patient. Always save an extra tube for Blood bank Department as back up and send the rest of the tubes. Copy the work up and send it to the courier. Technologist will follow up for the updates. d. order out units only appropriate for the patient, negative for the antigen corresponding to the antibody detected and compatibility testing must be performed in house." 2. Review of the laboratory blood

	bank records from May and June 2022 revealed on 5/27/2022 Unit W140922027088 was incompatible with Patient 233218 with a notation of "emergency release". Laboratory records revealed a "1+" for the AHG phase for the compatibility testing. 3. Review of the laboratory records revealed no notification to the laboratory manager or director for the above incompatible blood nor the consultation and evaluation from STBCTC per the laboratory policy. 4. An interview with the testing personnel #3 on 7 /12/2022 at 1420 hours in the laboratory confirmed the above findings. She stated that the above unit of blood was not transfused and that STBCTC rejected the specimen because the tube was missing the date of collection and truncated patient name"; therefore, no evaluation was performed. Key: SSTBCTC - South Texas Blood & Tissue Center AHG - AHG phase occurs when anti-human globulin is added to red cells to detect binding of either antibody or complement (or both) to those cells
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: A second revisit was conducted 07/12-13/2022 ****NEW DEFICIENCY**** A review of the laboratory's daily maintenance records for the Dimension EXL chemistry system from June 1, 2022 to July 12, 2022, and staff interview, it was revealed the laboratory failed to have documentation of performing corrective actions when cuvette temperatures were recorded as outside the manufacturer's specifications. The findings include: 1. A review of the laboratory's daily maintenance records for the Dimension EXL chemistry system from June 1, 2022 to July 12, 2022 revealed the manufacturer required cuvette temperatures to be within a temperature range of 36.8 - 37.2 C. 2. Further review of the records identified the laboratory documented cuvette temperatures outside the manufacturer's required range on 33 of 42 days (78.6%) reviewed. The days and temperature were: Date Temperature 06/02 36.7C 06/05 36.7 C 06/06 36.7C 06/07 36.7C 06/08 36.7C 06/09 36.7C 06/10 36.7C 06/11 36.7C 06/14 36.7C 06/15 36.7C 06/16 36.6C 06/17 36.6C 06/18 36.6C 06/19 36.6C 06/21 36.7C 06 /22 36.7C 06/24 36.7C 06/25 36.6C 06/26 36.7C 06/27 36.7C 06/28 36.7C 06/29 36.5 C 06/30 36.6C 07/01 36.7C 07/02 36.7C 07/03 36.6C 07/04 36.6C 07/05 36.6C 07/06 36.6C 07/07 36.7C 07/08 36.6C 07/09 36.7C 07/12 36.6C 3. The laboratory was asked to provide documentation of performing corrective actions for the identified temperatures. No documentation was provided. 4. An interview with the chemistry tech on 07/13/2022 at 0905 hours in the laboratory revealed the facility did not know corrective actions needed to be performed. She stated that she contacted the manufacturer who told her the cuvette thermometer required recalibration. This confirmed the findings.