Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0506298	09/07/2022
Name of Provider or Supplier	**Street Address, City, State**	
Dimmit Regional Hospital	704 Hospital Drive, Carrizo Springs, 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
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of a sampling of patient test records from August 29, 2022 to September 6, 2022, and staff interview, it was revealed the laboratory's quality assessment program failed to identify when the time of collection was listed as occurring after the sample was received in the laboratory for 1 of 24 reports. The findings include: 1. A sampling of patient test records from August 29, 2022 to September 6, 2022 identified 1 of 24 reports where the collection time for the sample was listed as occurring after the samples were received in the laboratory. It was: Date: 09/04/2022 Patient ID: 10241937 Collection time: 0040 Receipt time: 0037 2. An interview with the compliance person on 09/06/2022 at 1500 hours in the break room - after his review of the records- confirmed the findings.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's RPR Quality Control Sheets from May 2022 to July 2022, review of the laboratory's RPR test records from May 2022 to July 2022, and staff interview, it was revealed the laboratory failed to have documentation of performing needle volume checks with each new ampule of antigen opened for 2 of 3 events. The findings include: 1. A review of the laboratory's RPR Quality Control Sheets from May 2022 to July 2022 revealed the laboratory defined the frequency of verifying the dispensing volume of the needle with each new antigen ampule. 2. A review of the laboratory's RPR test records from May 2022 to July 2022 revealed the laboratory documented changing the antigen ampule on the following days: May 27, 2022 July 1, 2022 July 29, 2022 3. Further review of the laboratory's RPR Quality Control Sheets from May 2022 to July 2022 revealed the laboratory failed to document verifying the needle volume on May 27, 2022 and July 29,2022. 4. A interview with the team lead tech on 09/06/2022 at 1600 hours in the laboratory - after his review of the records- confirmed the findings.