Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2062209	11/19/2019
Name of Provider or Supplier	**Street Address, City, State**	
Altus Baytown Hospital Er	1404 W Baker Rd, Baytown, 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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on review of the laboratory test logs from 2018 and 2019 and confirmed in interview, the facility failed to document the time and date it received specimens. Findings were: 1. Review of 2018 and 2019 test logs revealed no documentation of the time the facility collects specimens for all nonwaived testing. Specimen time of collection/receipt into the laboratory is vital information in order to ensure specimens are tested within required storage time frames. 2. An interview with the technical consultant on 11/19/19 at 1135 hrs in the conference room confirmed that the facility does not log the time of specimen collection/receipt.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity.

	(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, review of the laboratory records, patient test records, and confirmed in interview, the laboratory failed to document the correct operating temperature for DDimer, CKMB and Troponin testing on the Quidel Triage Meter per manufacturer's instructions. Findings were: 1. Review of the manufacturer's instructions for the Quidel Triage DDimer test (PN: 26589en Rev. A 2018/04) under warnings and precautions "optimal results will be achieved by performing testing at temperatures between 20-24 C." 2. Review of the laboratory Policy and Procedure Alere Triage DDimer (Policy #15.0) under Reagents and Equipment "before using refrigerated test devices allow individual foil pouches to reach operating temperature (20 - 24 C or 68 - 75 F)...optimal results will be achieved by performing testing at temperatures between 20-24 C." 3. Review of the manufacturer's instructions for the Quidel Triage Cardiac Panel test (PN: 26584en Rev. A 2018/04) under warnings and precautions "optimal results will be achieved by performing testing at temperatures between 20-24 C." 4. Review of the laboratory Policy and Procedure Alere Triage Cardiac Panel (Policy #14.0) under Reagents and Equipment "before using refrigerated test devices allow individual foil pouches to reach operating temperature (20 - 24 C or 68 - 75 F)...optimal results will be achieved by performing testing at temperatures between 20-24 C." 5. Random review of August 2019 - October 2019 revealed 5 of 10 days with documentation of temperature outside of the acceptable range of 20-24 C. Date Temperature (F) 08/05/19 66 10/09/19 66 10 /10/19 66 10/16/19 66 10/26/19 65 6. Review of patient final reports of the above dates revealed Triage DDimer or Cardiac Panel patient testing were performed on the above dates. 8/5/19 Patient ID #16444 10/09/19 Patient ID #418 10/26/19 Patient ID #590 7. An interview with the technical consultant on 11/19/19 at 1135 hours in the conference room confirmed the above findings.
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 quality assessment reports and interview, the laboratory quality assessment policies and procedures failed to identify and correct problems identified in analytical systems. Refer to D5413