Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2017356	09/29/2020
Name of Provider or Supplier	**Street Address, City, State**	
Altus Baytown Hospital	1626 W Baker Road, 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 at the entrance and exit conferences. The facility representative was 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. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: A. Based on a random review of 22 patient records from November 2019 through January 2020 and staff interview, the laboratory failed to document reference ranges for I-Stat tests on patient final records for interpretation. The findings were: 1. Random review of 22 patient final reports from November 14, 2019 through January

	30, 2020 revealed, the laboratory failed to document reference ranges on the patient's final test report for interpretation for I-Stat tests. Date Patient ID Test Result 11/14 /2019 32896 PT/INR 13.5 sec/1.1 11/15/2019 32721 PT/INR 12.8 sec/1.1 11/21/2019 30518 BNP 804 pg/ml 11/26/2019 6464 PT/INR 13.5 sec/1.1 11/28/2019 33059 BNP 116 pg/ml 11/28/2019 33059 cTnl 0.00 ng/ml 11/28/2019 33059 PT/INR 16.9 sec/1.4 11/29/2019 23914 PT/INR 13.2 sec/1.1 01/02/2020 22579 PT/INR 11.3 sec/0.9 01/02 /2020 33195 PT/INR 12.9 sec/1.1 01/02/2020 343434 PT/INR 11.4 sec/1.0 01/04 /2020 33328 BNP 123 pg/ml 01/04/2020 27542 BNP 342 pg/ml 01/05/2020 33330 cTnl 0.07 ng/ml 01/05/2020 33330 BNP 475 pg/ml 01/05/2020 33330 PT/INR 27.3 sec/2.4 01/05/2020 33330 cTnl 1.17 ng/ml 01/06/2020 13617 PT/INR 11.5 sec/1.0 01 /08/2020 33361 PT/INR 11.0 sec/0.9 01/09/2020 12653 PT/INR 11.0 sec/1.0 01/15 /2020 33419 cTnl 0.00 ng/ml 01/16/2020 33442 BNP 171 pg/ml 01/16/2020 33442 cTnl 0.01 ng/ml 01/16/2020 33255 PT/INR 12.8 sec/1.1 01/30/2020 33458 PT/INR 12.2 sec/1.0 2. Interview with the technical consultant on 09/29/2020 at 1520 hours in the conference room confirmed the above findings after reviewing the patient results. She stated " When they reprint the results, the reference ranges do not print." Key: PT /INR - Prothrombin time and International Normalized Ratio BNP - Blood Urea Nitrogen cTnl - Cardiac troponin I B. Based on review of the laboratory final reports, 2014 establishment study for Troponin and interview with facility staff, the laboratory failed to document accurate and reliable test results for Troponin with the I-STAT Findings were: 1. A review of the 2014 laboratory's establishment studies for Troponin revealed the laboratory established the lower limit of the reportable range as 0.45 ng/ml. 2. Random review of patient final reports from 11/2019 to 01/2020 revealed 4 of 5 Troponin final reports were reported outside of the reportable range established. Date: Patient ID Test result 11/28/2019 33059 0.00 ng/ml 01/05/2019 33330 0.17 ng/ml 01/15/2019 33419 0.00 ng/ml 01/16/2020 33442 0.01 ng/ml 3. A review of the 2014 laboratory's establishment studies for Troponin revealed the laboratory established the lower limit of 0.45 ng/ml and failed to include this on the patient test reports. 4. An interview with the technical consultant on 09/29/2020 at 1530 hours in the conference confirmed the above findings. She stated that she was unaware that results were reported outside the reportable range. Key: sec seconds pg /ml picograms per milliliter ng/ml - nanograms per milliliter
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the patient final results and confirmed in interview, the laboratory quality assurance plan failed to identify and correct failures in the postanalytic systems. Findings were: 1. The laboratory failed to document reportable ranges on patient test reports for I-Stat tests when performed. (refer to D5805).