Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2062209	12/13/2021
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.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, review of laboratory records from March 2021 to November 2021 and confirmed in interview, the laboratory failed to follow its policy for CBC patient analysis on the Medonic M hematology analyzer for three of ten patients reviewed. Findings included: 1. Review of the laboratory policy Complete Blood Count Using Medonic M-series under Handling of Abnormal and Flagged Results revealed "for WBC/WBC DIFF flags, repeat the testing after doing the following: Make sure the EDTA sample has been allowed to sit for 15-20 minutes before it is analyzed. This will allow for the anticoagulant and the blood to equilibrate. Always mix the sample well before analyzing. If WBC [or] WBC DIFF flags are not resolved, DO NOT REPORT PATIENT RESULTS. DE: Small particle interference; re-analyze OM: WBC DIFF - only one WBC population found, slide review advised. Blood sample may be too old or may be an abnormal pathological sample. Make sure the EDTA sample has been allowed to sit for 15-20 minutes before it is analyzed. This will allow for the anticoagulant and the blood to equilibrate. Always mix sample well

	before analyzing. Re-analyze the sample. If the flags are not resolved, do not report patient results. refer the sample to send out laboratory for testing. BD: WBC Diff; high interference between populations. Blood sample may be too old or may be an abnormal pathological sample. Make sure the EDTA sample has been allowed to sit for 15-20 minutes before it is analyzed. This will allow for the anticoagulant and the blood to equilibrate. Always mix sample well before analyzing. Re-analyze the sample. If the flags are not resolved, do not report patient results. refer the sample to send out laboratory for testing." 2. Random review of patient test records from March 2021 to November 2021 revealed three of ten patient test records with one of the above flags with no documentation of the corresponding corrective action. 8/28/21: Patient 3764 - OM 6/23/21: Patient 2445 - DE 6/16/21: Patient 2347 - BD 3. An interview with the technical consultant on 12/13/21 at 1135 hours in the conference room confirmed the above findings.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory quality control and patient test records from august 2020 to November 2021 and confirmed in interview, the laboratory failed to document corrective actions taken when quality control was outside of the acceptable range for four of twenty days reviewed for CBC testing on the Medonic M hematology analyzer. Findings were: 1. Random review of the CBC quality control records from August 2020 to November 2021 revealed four of twenty days with 1 or more quality control failures and no documentation of the corrective action. 8/25/20: Lot 2200602 8/11/20: lot 2200602 5/05/21: Lot 2210232 5/25/21: Lot 2210331 2. Random review of the laboratory records from the above dates revealed the laboratory performed eight CBC patient testing for the above dates. 8/25/20: Patient ID 3280, 448 8/11/20: Patient ID 3167, 1308 5/05/21: Patient ID 5160, 5159 5/25/21: Patient ID 5320, 5325 3. An interview with the technical consultant on 12/13/21 at 1135 hours in the conference room confirmed the above findings.