Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2137219	07/11/2019
Name of Provider or Supplier	**Street Address, City, State**	
Altus Houston Hospital Lp	6011 W Sam Houston Pkwy S, Houston, 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.
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) Chemistry proficiency testing records from 2018 and 2019, and confirmed in interview, the laboratory failed to attain a satisfactory score of at least 80% for the analyte pCO2, pH, and pO2 for 1 of 4 testing events. The findings were: 1. A review of the laboratory's API from 2018 and 2019 revealed the laboratory failed to attain a satisfactory score of at least 80% for the analytes pCO2, pH, and pO2 on 1 of 4 events: 2018 API Chemistry 2nd event pCO2 - 0% IB-06 - Lab result: 20; acceptable range: 21-32 IB-07 - Lab result: 127; acceptable range: 51-62 IB-08 - Lab result: 118; acceptable range: 60-71 IB-09 - Lab result: 133; acceptable range: 38-49 IB-10 - Lab result: 118; acceptable range: 28-39 pH - 0% IB-06 - Lab result: 7.74; acceptable range: 7.57 - 7.66 IB-07 - Lab result: 7.37; acceptable range: 7.1 - 7.18 IB-08 - Lab result: 7.20; acceptable range: 6.93 - 7.02 IB-09 - Lab result: 7.47; acceptable range: 7.21 - 7.30 IB-10 - Lab result: 7.68; acceptable range: 7.50 - 7.59 pO2 - 20% IB-06 - Lab result: 134; acceptable range: 101 - 132 IB-07 - Lab result: 127; acceptable range:

	51-93 IB-08 - Lab result: 118; acceptable range: 30 - 81 IB-09 - Lab result: 133; acceptable range: 62 - 99 2. An interview with the technical consultant on 7/11/19 at 1055 hours in the conference room confirmed the above findings.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory American Proficiency Institute (API) proficiency testing records, and confirmed in interview, the laboratory failed to document remedial action for PT failures for the analytes pCO2, pH, and pO2 for 1 of 4 testing events from 2018 and 2019. Findings were: 1. Review of the 2018 and 2019 API proficiency testing records revealed the laboratory failed to attain an 80% for the analyte pCO2, pH, and pO2 for 1 of 4 testing event for Chemistry. Cross refer to D2087 2. Review of the laboratory corrective actions for the above PT failures revealed no documentation of the patient remedial action. 3. An interview with the technical consultant on 7/11/19 at 1055 hours in the conference room confirmed the above findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's verification records and confirmed in interview, the laboratory failed to document complete verification studies for Abbott i-STAT and Triage Meter point of care analyzer. a) Abbott i-STAT b) Triage Meter The findings were: a) Abbott i-STAT 1. Review of laboratory records available for review revealed no documentation of the assessment for accuracy, precision, reportable range for pH, PCO2, PO2, HCO3, TCO2 sO2, and Lactate on the Abbott i-STAT analyzer using the Abbott i-STAT CG4 cartridges. 2. Review of the laboratory records revealed the laboratory performed pH, PCO2, PO2, HCO3, TCO2 sO2, and Lactate on the Abbott - iSTAT analyzer using the following reference ranges for venous and arterial specimens: Venous pH: 7.31 - 7.41 pCO2: 41 - 51 mmHg pO2: 80 - 105 mmHg O2 Sat (calc): 95 - 98% HCO3 (calc): 23 - 28 mmol/L TCO2: 24 - 29 mmol/L BE (calc): -2 - 3 Lactate: 0.36 - 1.25 mmol/L Arterial pH: 7.35 - 7.45 pCO2: 35 - 45 mmHg pO2:

	80 - 105 mmHg O2 Sat (calc): 95 - 98% HCO3 (calc): 22 - 26 mmol/L TCO2: 23 - 27 mmol/L BE (calc): -2 - 3 Lactate: 0.36 - 1.25 mmol/L 3. Review of laboratory records available for review revealed no documentation of the verification of the above normal ranges used for pH, PCO2, PO2, HCO3, TCO2 sO2, and Lactate on the Abbott i-STAT analyzer using the Abbott i-STAT CG4 cartridges. b) Triage Meter 4. Review of the laboratory records revealed the laboratory used the following normal range for CKMB, Troponin, and D-dimer on the Triage point of care analyzer: DDimer: 0 - 400 ng/mL CKMB: 0 - 4.3 ng/mL Trop: 0 - 0.40 ng/mL 4. Review of laboratory records available for review revealed no documentation of verification of the above normal ranges for CKMB, Troponin, and D-dimer on the Triage Meter point of care analyzer. 3. An interview with the technical consultant on 7/11/19 at 1130 hours in the conference room confirmed the above findings. Key: PCO2 - partial pressure or carbon dioxide PO2 - partial pressure of oxygen BEecf - base excess in the extracellular fluid compartment HCO3 - bicarbonate TCO2 - total carbon dioxide sO2 - oxygen saturation
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory policy, laboratory quality control records, patient test records, and confirmed in interview, the laboratory IQCP failed to have documentation of a complete quality control study to include external quality control material for each analyte and each day of the quality control plan prior to modifying the frequency of quality control testing for the Triage CKMB (Creatinine Kinase-MB), Troponin, DDimer and iSTAT Blood gas to every 30 days. a) Triage - CKMB, Troponin, D Dimer b) iSTAT - CG4 (pH, pCO2, pO2, TCO2) Findings were: a) Triage - CKMB, Troponin, DDimer 1. Review of the laboratory quality control study of the IQCP revealed no documentation of the quality control study that included at least two levels of external quality control material for the Triage CKMB, Troponin, and Ddimer for a minimum of 30 days. 2. An interview with the technical consultant on 7/11/19 at 1215 hours in the conference room confirmed the above findings. She stated that she is already working on a plan. b) iSTAT - CG4 (pH, pCO2, pO2, TCO2); 3. Review of the laboratory quality control study of the IQCP revealed no documentation of the quality control study that included at least two levels of external quality control material every 8 hours for the iSTAT pH, pCO2 (partial pressure of carbon dioxide), PO2 (partial pressure of oxygen) for 30 days. 4. Review of the laboratory CMS 116 records revealed the laboratory performed 54 chemistry testing annually. 5. An interview with the technical consultant on 7/11/19 at 1215 hours in the conference room confirmed the above findings. She stated that she is already working on a plan. key: IQCP - Individualized Quality Control Plan

D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on review of the laboratory verification records and confirmed in interview, the laboratory director failed to ensure the acceptability of the verification studies for the Cardiac (CKMB, Troponin) and DDimer testing on the Triage point of care analyzer. Findings were: 1. Review of the verification records for the Triage point of care analyzer for the CKMB, Troponin, and DDimer testing revealed no documentation of the laboratory director's signature of acceptability prior to patient testing. 2. An interview with the technical consultant on 7/11/19 at 1200 hours in the conference room confirmed the above findings.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the CMS form 209, personnel records for 2018 and verified by interview, the Technical Consultant failed to perform the semi- annual competency evaluations for 1 of 10 testing personnel (TP) in the year 2018. Findings were: 1. Review of the CMS form 209 revealed the laboratory had 10 testing personnel. 2. A review of the laboratory competency assessments for 2018 revealed the technical consultant failed to document the annual competencies for 1 of 10 testing personnel: TP #10. Testing person # 10, hired 1/29/18. initial competency performed on 2/1/18 and 2nd competency on 8/5/18 performed by TP #1, who does not qualify as a technical consultant. TP# 1 has a high school diploma. 3. An interview with the technical consultant on 7/11/19 at 0950 hours in the conference room confirmed the above findings. key: CMS - Centers for Medicaid and Medicare Services
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of the CMS form 209, personnel records for 2018 and 2019 and verified by interview, the Technical Consultant failed to perform the annual

	competency evaluations for 3 of 10 testing personnel (TP) in the year 2019. Findings were: 1. Review of the CMS form 209 revealed the laboratory had 10 testing personnel. 2. A review of the laboratory competency assessments for 2018 and 2019 revealed the technical consultant failed to document the annual competencies for 3 of 10 testing personnel: TP#6, TP#7, TP#8. Testing person # 6, hired 11/6/17. 2019 annual competencies performed on 5/1/19 performed by TP #1, who does not qualify as a technical consultant. TP# 1 has a high school diploma. Testing person # 7, hired 10/23/17. 2019 annual competencies performed on 5/1/19 performed by TP #1, who does not qualify as a technical consultant. TP# 1 has a high school diploma. Testing person # 8, hired 10/23/17. 2019 annual competencies performed on 5/1/19 performed by TP #1, who does not qualify as a technical consultant. TP# 1 has a high school diploma. 3. An interview with the technical consultant on 7/11/19 at 0950 hours in the conference room confirmed the above findings. key: CMS - Centers for Medicaid and Medicare Services