Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2118296	(X3) Date Survey Completed 07/06/2022
Name of Provider or Supplier Altus Waxahachie, Lp	**Street Address, City, State** 1791 North Hwy 77, Waxahachie, 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	Laboratory representatives were present at the entrance conference. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas Health and Human Services Commission, Health Facility Compliance Arlington Group. 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 Southern Operations Branch-Dallas 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.
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 verification studies for the Piccolo Xpress (MetLac 12 Panel) chemistry analyzer, laboratory records, and confirmed in interview, the laboratory failed to ensure the reportable range for 12 of 12 chemistry analytes were verified by

the laboratory's studies in 2022 (March). Findings included: 1. According to verification studies, the laboratory added two Piccolo Xpress (MetLac 12 Panel) chemistry analyzers (Serial numbers P22358 and P22329) to their test menu on 03 /2022. 2. A review of verification studies for the Piccolo Xpress (MetLac 12 Panel) chemistry analyzers revealed the laboratory's established reportable range was based on the manufacturer's reportable range and did not coincide with the reportable range obtained in the verification studies for chemistry analytes as required by 493.1253 as follows: Serial number P22358 Reportable range from verification study: ALB: 2.2 -5.8 g/dL Manufacturer's reportable range: ALB: 1.0-6.5 g/dL Reportable range from verification study BUN: 5.0-106 mg/dL Manufacturer's reportable range: BUN: 2.0-180 mg/dL Reportable range from verification study CA: 4.3-14.5 mg/dL Manufacturer's reportable range: CA: 4.0-16.0 mg/dL Reportable range from verification study CL: 83.0-124.0 mmol/L Manufacturer's reportable range: CL: 80.0-135.0 mmol/L Reportable range from verification study CRE: 0.4-15.1 mg/dL Manufacturer's reportable range: CRE: 0.2-20 mg/dL Reportable range from verification study GLU: 31.0-639.0 mg/dL Manufacturer's reportable range: GLU: 10.0-700.0 mg/dL Reportable range from verification study K: 2.3-7.7 mmol/L Manufacturer's reportable range: K: 1.5-8.5 mmol/L Reportable range from verification study LAC: 0.61-9.10 mmol/L Manufacturer's reportable range: LAC: 0.30-9.99 mmol/L Reportable range from verification study MG: 0.5-6.6 mg/dL Manufacturer's reportable range: MG: 0.1-8.0 mg/dL Reportable range from verification study NA: 116.0-164.0 mmol/L Manufacturer's reportable range: NA: 110-170 mmol/L Reportable range from verification study PHOS: 1.6-16.0 mg/dL Manufacturer's reportable range: PHOS: 0.2-20.0 mg/dL Reportable range from verification study CO2: 11.0-35.0 mmol/L Manufacturer's reportable range: CO2: 5.0-40.0 mmol/L The laboratory's established reportable range did not coincide with the reportable range obtained in the verification studies for all the above analytes. Serial number P22329 Reportable range from verification study: ALB: 2.2 -5.8 g/dL Manufacturer's reportable range: ALB: 1.0-6.5 g/dL Reportable range from verification study BUN: 5.0-106 mg/dL Manufacturer's reportable range: BUN: 2.0-180 mg/dL Reportable range from verification study CA: 4.3-14.5 mg/dL Manufacturer's reportable range: CA: 4.0-16.0 mg/dL Reportable range from verification study CL: 83.0-124.0 mmol/L Manufacturer's reportable range: CL: 80.0-135.0 mmol/L Reportable range from verification study CRE: 0.4-15.1 mg/dL Manufacturer's reportable range: CRE: 0.2-20 mg/dL Reportable range from verification study GLU: 31.0-639.0 mg/dL Manufacturer's reportable range: GLU: 10.0-700.0 mg/dL Reportable range from verification study K: 2.3-7.8 mmol/L Manufacturer's reportable range: K: 1.5-8.5 mmol/L Reportable range from verification study LAC: 0.61-9.10 mmol/L Manufacturer's reportable range: LAC: 0.30-9.99 mmol/L Reportable range from verification study MG: 0.5-6.6 mg/dL Manufacturer's reportable range: MG: 0.1-8.0 mg/dL Reportable range from verification study NA: 116.0-164.0 mmol/L Manufacturer's reportable range: NA: 110-170 mmol/L Reportable range from verification study PHOS: 1.6-16.0 mg/dL Manufacturer's reportable range: PHOS: 0.2-20.0 mg/dL Reportable range from verification study CO2: 11.0-35.0 mmol/L Manufacturer's reportable range: CO2: 5.0-40.0 mmol/L The laboratory's established reportable range did not coincide with the reportable range obtained in the verification studies for all the above analytes. 3. Review of laboratory records revealed the following annual laboratory test volumes: 12 ALB tests 12 BUN tests 12 CA tests 12 CL tests 12 CRE tests 12 GLU tests 12 K tests 12 LAC tests 12 MG tests 12 NA tests 12 PHOS tests 12 CO2 tests 4. During an interview on 07/06/2022 at 12:03 pm, the Laboratory Director confirmed the above findings. Word Key: ALB: albumin BUN: blood urea nitrogen CA: calcium CL: chloride CRE: creatinine GLU: glucose K: potassium LAC: lactate MG: magnesium

	NA: sodium PHOS: phosphorus CO2: carbon dioxide
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 laboratory's Individualized Quality Control Plan (IQCP), manufacturer's instructions, quality control (QC) logs, patient testing logs, and confirmed in interview, the laboratory's IQCP failed to support its reduction in frequency to every 30 days for the Metlac 12 cartridge on the Piccolo Xpress chemistry analyzer. Findings included: 1. Review of the laboratory's "Quality Control Plan- Abaxis Piccolo Metlac 12 Panel" revealed: "Two levels of external controls (low and high) will be run for every new lot number of reagent disc, every new shipment of reagent disc and every 30 days. The QC results are reviewed for acceptability before reporting patient result, If [sic] QC results are not in range, corrective action is taken and QC rerun and acceptable prior to running patient samples." The laboratory's IQCP failed to support its reduction in frequency to every 30 days. 2. Review of the Piccolo Metlac 12 Panel assay sheet revealed: "Quality Control ...Abaxis recommends control testing to follow federal, state, and local guidelines." 3. Review of QC records from October 2021 through November 2021 revealed the laboratory performed quality control on the following dates on the Piccolo Xpress chemistry analyzer Metlac 12 cartridge (random sampling): QC level 1 lot #2011042-1, expiration date 04/30/22 QC level 2 lot #2011042-2, expiration date 04/30/22 QC level 1 and 2 was performed on 10/13/2021 through 10/24/2021 (12 days) QC level 1 and 2 was performed on 10/26/2021 through 11/13/2021 (19 days) 4. Review of patient records revealed the laboratory failed to perform QC every day of patient testing. Refer to D5447. 5. During an interview on 07/06/2022 at 12:29 pm, the Laboratory Director confirmed the laboratory's IQCP failed to support its reduction in frequency to every 30 days for the Metlac 12 chemistry cartridge.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory policies, quality control (QC) records, patient records, and confirmed interview, the laboratory failed to

	perform two levels of control each day of patient testing on the Piccolo Xpress analyzer for the Metlac 12 cartridge for 1 of 1 day in 2022 (03/2022). Findings included: 1. Review of the Piccolo Metlac 12 Panel assay sheet revealed: "Quality Control ...Abaxis recommends control testing to follow federal, state, and local guidelines." 2. Review of laboratory policies revealed the laboratory developed an Individualized Quality Control Plan (IQCP) to modify the quality control frequency for each day of patient testing to implement monthly quality control. The IQCP failed to support its reduction in frequency to every 30 days for the Metlac 12 cartridge on the Piccolo Xpress analyzer. Refer to D5445. 3. A random sampling of QC and patient records from March 2022 through May 2022, revealed the following dates QC was not performed and patients were tested on the Piccolo Xpress analyzer for the Metlac 12 cartridge: 03/10/2022- Patient ID: 1223 QC last performed on 02/18/2022 Note: The Metlac 12 cartridge tested for the following chemistry analytes: glucose, blood urea nitrogen (BUN), creatinine, sodium, potassium, chloride, carbon dioxide, calcium, phosphorus, magnesium, albumin, and lactate. 4. During an interview on 03 /09/2021 at 1:15 pm, the Laboratory Director confirmed the laboratory failed to perform QC every day of patient testing.
D6055	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 whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual, the submitted Centers for Medicaid and Medicare Services (CMS)-209 form, personnel records, laboratory records, patient test records, and confirmed in staff interview, it was revealed the technical consultant (TC) failed to have documentation of performing competency assessments for 17 of 17 testing persons (TP) prior to performing patient testing for the Metlac 12 panel on the Abaxis Piccolo chemistry analyzer in 2022. The findings include: 1. Review of the laboratory's policy and procedure manual titled "Quality Control Program" revealed, "Competency Assessment Program ...2. Changes in instrumentation or methodology will require re-evaluation of all employees to include the new instrumentation or methodology. Documentation of training on new instrumentation or methodology will be in the form of a checklist which will be completed and signed by each employee prior to resulting patient specimens." 2. Review of the laboratory's submitted CMS-209 revealed 17 testing personnel listed to perform moderate complexity testing. 3. Review of the laboratory's personnel records revealed no documentation of competency assessments for 17 of 17 testing personnel prior to performing patient testing of the Metlac 12 panel. 4. Review of laboratory records submitted on the day of the survey revealed the laboratory implemented the Metlac 12 panel for testing on Abaxis Piccolo chemistry analyzer in March 2022. 5. Review of patient test records revealed 12 patients were tested and reported on the Metlac 12 panel from March 2022 through July 2022. 6. During an interview on 07/06 /2022 at 10:00 hours, the laboratory director and testing person 1 confirmed the above findings.