

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1010521	(X3) Date Survey Completed 12/18/2023
Name of Provider or Supplier Alpha Medical Center	Street Address, City, State 2505 West Beltline Road, Lancaster, 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	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493.
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation, manufacturer's instructions, laboratory policy, maintenance logs (May-November 2023), and confirmed in interview, the laboratory failed to document monthly maintenance on the Horiba Pentra C400 chemistry analyzer for 7 of 7 months reviewed in 2023. Findings included: 1. During a tour of the facility on 12/18/2023 at 2:00 p.m., the surveyor observed 1 Horiba Pentra C400 chemistry analyzer (Serial Number: 4367111) in the patient test area. 2. Review of manufacturer's instructions, "Pentra 400: User Manual" (Reference Number: 1300015907) revealed the following: "2.3. Monthly Procedures 2.3.1. To Clean the Reagent Needle (External Part): Clean the reagent needle (external part) on a monthly basis ... 2.3.2. To Clean Wash Towers: Clean wash towers with ABX Pentra Deproteinizer CP A11A01754 on a monthly basis ... 2.3.3. To Replace Syringe Plunger Tips: To ensure good pipetting precision, replace the syringe plunger tips on a monthly basis. ... 2.3.4. To Perform the T1 Test: Follow this procedure to check pipetting accuracy and precision on a monthly basis ... 2.3.5. To Clean the Cooling Unit Condenser: To maintain a good cooling capacity, clean the cooling unit condenser on a monthly basis." 3. Review of laboratory policy, "Operating and Testing of Clinical Chemistry by Horiba Pentra C400" (Approved by the Laboratory Director on: 12/22/22) revealed the following: " ...6. Testing Procedure 6.1.1. Ensure the analyzer is on. 6.1.2. Perform any required maintenance for the day, including</p>

weekly, monthly, 6-month, or as-needed." 4. Review of laboratory maintenance logs for the Horiba Pentra C400 chemistry analyzer in 2023 (May-November) revealed the following: a. May Monthly Wash towers cleaning: No documentation Cooling unit condenser cleaning: No documentation b. June Monthly Test T1: No documentation Cooling unit condenser cleaning: No documentation c. July Monthly Wash towers cleaning: No documentation Test T1: No documentation Cooling unit condenser cleaning: No documentation d. August Monthly Wash towers cleaning: No documentation Test T1: No documentation Cooling unit condenser cleaning: No documentation e. September Monthly Cooling unit condenser cleaning: No documentation f. October Monthly Wash towers cleaning: No documentation Test T1: No documentation Cooling unit condenser cleaning: No documentation g. November Monthly Wash towers cleaning: No documentation Cooling unit condenser cleaning: No documentation 5. During an interview on 12/18/2023 at 02:10 p.m., in the facility conference room, Technical Consultant 1 (TC-1) confirmed the laboratory failed to document monthly maintenance on the Horiba Pentra C400 chemistry analyzer for 7 of 7 months reviewed in 2023.