Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1094068	(X3) Date Survey Completed 07/08/2020
Name of Provider or Supplier American Clinical Solutions Llc	**Street Address, City, State** 721 Cortaro Dr, Sun City Center, FL	
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	An announced CLIA recertification survey was conducted at American Clinical Solutions LLC on 07/08/20. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process. This STANDARD is not met as evidenced by: Based on observations, record review, and interview with the Technical Supervisor the laboratory failed to install their Beckman Coulter Olympus AU 640 Chemistry analyzer with the space requirements for 2 (2018-2020) out of 2 years. Findings Included: Observations of the Olympus AU 640 on 07/08/20 at 7:00 PM revealed that the Chemistry Analyzer was 12 inches away from the back wall. Review of the manufacturer's instruction (MI) of the Beckman Coulter Olympus AU 640 Chemistry analyzer revealed, "Installation Space Requirements: As shown in the figure below, this system requires space around it for safe installation." A review of the figure revealed a minimum distance of 20 inches was required from the back of the machine. Interview on 07/08/20 at 7:00 PM with the Technical Supervisor confirmed that the Chemistry analyzer was not installed per the manufacturer's instructions. Photographic evidence was obtained.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and

	test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on record review and interview with the Technical Supervisor the laboratory did not follow manufacturer's instructions (MI) and keep the Beckman Coulter Olympus AU 640 Chemistry analyzer in the required humidity range for 21 (November 2018) out of 22 (October 2018-July 2020) months reviewed. Findings Included: Review of MI for the Beckman Coulter Olympus AU 640 Chemistry analyzer revealed that the "humidity must be between 40 and 80% RH with no condensation." The MI also stated that "Temperature and humidity fluctuations must be within the specified range(s), otherwise the system cannot produce reliable data." Review of the Humidity record revealed humidity was not in the 40-80% range on the following days: July 2020 - 5/5 out of range, June 2020 - 22/22 out of range, May 2020 - 20/20 out of range, April 2020 - 22/22 out of range, March 2020 - 22/22 out of range, February 2020 - 22/22 out of range, January 2020 - 22/22 out of range, December 2019 - 21/21 out of range, November 2019 - 20/20 out of range, October 2019 - 18/23 out of range, September 2019 - 10/20 out of range, August 2019 - 1/22 out of range, July 2019 - 2/22 out of range, June 2019 - 3/20 out of range, May 2019 - 13/22 out of range, April 2019 - 16/22 out of range, March 2019 - 14/21 out of range, February 2019 - 3/20 out of range, January 2019 - 17/22 out of range, December 2018 - 9/20 out of range, November 2018 - 0/21 out of range, and October 2018 - 1/23 out of range. Interview on 07/08/20 at 7:00 PM with the Technical Supervisor confirmed that the aforementioned dates were not in the 40-80% humidity range.