Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 01D0027697	**(X3) Date Survey Completed** 06/10/2021
Name of Provider or Supplier Auburn University Medical Clinic Laboratory	**Street Address, City, State** 400 Lem Morrison Drive, Auburn, AL	
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**
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of quality control records and an interview with the laboratory supervisor (also testing personnel #4) and testing personnel #5 and #1, the surveyor determined the laboratory failed to run a positive and negative control for the Healgen COVID IgG/IgM antibody test (qualitative testing) each day of patient testing. This affected the survey review period, July 30, 2020 (when testing began) until April 15, 2021 (when commercial controls, positive and negative, were acquired by the laboratory). The findings include: 1. During the tour, the laboratory staff stated the Healgen IgG and IgM antibody test system was used for COVID-19 testing. The testing began July 30, 2020. At the time testing began, there was no commercially prepared quality control, so the laboratory used a known positive patient for quality control. The laboratory did not use a known negative patient for control testing. Each day of patient testing, beginning on July 30, 2020, the laboratory ran and documented only a known positive patient for the control. Not until April 15, 2021, when commercially prepared quality control specimens became available, did the laboratory run and document a positive and negative control each day of patient testing. 2. During an interview on June 10, 2021 at 11:15 AM, the surveyor inquired about why only a positive control was documented for the Healgen COVID antibody testing. The laboratory supervisor and the testing personnel (#1 and #5) confirmed the laboratory only analyzed a known positive patient as quality control until commercial specimens became available. Although the surveyor and the testing personnel discussed the need

	for a qualitative procedure to have a positive and negative, no explanation was given for not running a negative, except the possibility of having a negative patient within a test run. .
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of installation and validation records for the Healgen IgG and IgM SARs-COV-2 antibody testing and the Sysmex XN-530 Hematology analyzer, the surveyor determined the Laboratory Director (also the Technical Consultant) failed to ensure the studies performed proved accuracy, precision and reportable range, when necessary, for the new procedures implemented in the laboratory on July 30, 2020 and August 24, 2020, respectively. This affected two of two new procedures/equipment installed in the laboratory, since the previous survey (11/19/2018). The finding include: 1. A review of the validation records for the Healgen IgG and IgM SARs-COV-2 antibody testing revealed the laboratory ran 2 negative and 2 positive patients and sent them to a local hospital for a comparison. (The surveyor reviewed a file folder with approximately 10 patient test results but was unable to determine with what these were compared to). The surveyor inquired of the laboratory supervisor how accuracy of testing was proven. This is when the laboratory supervisor reviewed the file and was able to find the 2 negative and 2 positive comparison study. There was no summary of accuracy and no laboratory director's signature to indicate he had reviewed and approved implementation of the testing. Patient testing began July 30, 2020. 2. A review of the installation and validation records for the Sysmex XN-530 revealed a carryover, precision and accuracy, and a reportable range study was done 8 /5/2020. There was no signature by the Laboratory Director (who is also the Technical Consultant) to indicate the data had been evaluated to ensure the performance specifications by the manufacturer had been proven. Patient testing began August 24, 2020.