Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2104354	09/10/2020
Name of Provider or Supplier	**Street Address, City, State**	
Atcg Laboratory	18 Technology Dr, Ste 107, Irvine, CA	

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
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 observation and touring the laboratory facility and storage devices for reagents or supplies on 09/10/2020 at approximately 10:10 am, review of the laboratory's temperature recorded charts, and interview with the testing personnel, and the testing consultant, it was determined that the laboratory failed to monitor the temperatures daily, and failed to document when out of the acceptable temperature ranges, for the storage freezers and refrigerators. The findings included: a. The laboratory has established the acceptable temperature range for its freezer storing reagents between -15 to -25 oC. b. On September 10, 2020 at approximately 10:10 AM, while touring the laboratory facility, noted that the laboratory using digital temperature thermometers to monitor the condition of all its freezer and/or refrigerators. c. The digital thermometer equip with many functions, including modes of "Min" and "Max" in addition to current temperature inside and outside of the storage. d. Modes of "Min" and "Max" indicate the temperature condition inside the storage whenever the lowest or highest temperature condition ever reached, but does indicate when it happened. e. Observed the digital temperature device for a freezer located in "Warehouse", "Brand/Model "Frigidaire" FFFU17M1QWB", Freezer serial# "WB612246959" acceptable range -15 to -30 oC. f. Noticed a -2.9 oC when pushed to mode of Max and Min was -29.2 oC, where acceptable range was set -15 to

	-25 oC g. Review of the "Freezer Temperature Log" for the year of 2020 from March thru September records, between May 12 thru June 17, no temperatures were recorded. h. Between June 18 and September 10, 2020, there were days other than Saturdays and Sundays, many days missed temperature records, as such on the dates, 06/30, 07/02, 07/03, 07/06, 07/07 etc.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation and touring the laboratory facility and storage devices for reagents or supplies on 09/10/2020 at approximately 10:10 am, review of the laboratory's temperature recorded charts, and interview with the testing personnel, and the testing consultant, it was determined that the laboratory failed to document all corrective actions taken, including actions taken when equipment/devices or methodologies that perform outside of established operating parameters or performance specifications; The findings included: a. The laboratory failed to document all corrective actions taken, including actions, when the storage equipment /devices used, the temperature was out of the acceptable temperature ranges. b. The laboratory used digital thermometers to monitor its storage devices to store reagents and laboratory supplies in order to ensure the validity and stability of the laboratory reagents and supplies. b. The laboratory personnel was not fully understood about its digital thermometer's build-in functions, see D-5413.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on observation and touring the laboratory facility and storage devices for reagents or supplies on 09/10/2020 at approximately 10:10 am, review of the laboratory's temperature recorded charts, and interview with the testing personnel, the testing consultant, and the laboratory director, it was determined that the laboratory director failed to ensure that the quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The findings included: a. The laboratory director failed to be responsible to ensure the quality assessment programs were established, and maintained and followed by the laboratory personnel to assure the quality of

	laboratory services provided and to identify failures in quality as they occur, see D-5413 and D-5781.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on observation and touring the laboratory facility and storage devices for reagents or supplies on 09/10/2020 at approximately 10:10 am, review of the laboratory's temperature recorded charts, and interview with the testing personnel, the testing consultant and the laboratory director, it was determined that the laboratory director failed to ensure that all necessary remedial actions were taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. The findings included: a. The laboratory director failed to ensure that all necessary remedial actions were taken and documented whenever significant deviations from the laboratory's established performance characteristics were identified, see D-5781.