Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2020794	12/27/2019
Name of Provider or Supplier	**Street Address, City, State**	
Global Discovery Biosciences	13885 Alton Pkwy Ste B, 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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observations and review of the laboratory temperature records, devices, and the laboratory facility, and interview with the laboratories. quality assurance (QA) and the testing personnel (TP). It was determined that the laboratory failed to follow the manufacturer's instructions and in a manner that provided the thermometer to perform and to ensure the storage conditions within the laboratory's stated performance specifications. The findings included: a. The laboratory used various types of refrigerators and freezers to store reagents, samples, and the laboratory supplies to ensure the stability and validity of the reagents, samples, and the laboratory supplies. b. The laboratory selected digital thermometers (DT) to monitor and maintain the storage devices in optimal/acceptable conditions. c. The DT features and provides the following information: 1) current temperature, 2) under Min/Max mode the temperature indicates the lowest and/or highest temperature conditions encountered in the past, but not know exact when, 3) under Lo/Hi mode the temperature indicates the acceptable/optimal temperature range set by the laboratory for the storage proper conditions, 4) Alarm with on/Off when the temperature reached outside of the acceptable range, the device should sound to alert the laboratory personnel to take actions. d. On 12/27/2019 @ 12:05 PM, touring the laboratory facility, the surveyor, QA and TP observed and noticed the digital thermometer used for F1 freezer showed a 10 oC for "Lo", 30 oC for "Hi" mode and Alarm was at Off position. d. The QA and TP indicated that the acceptable temperature range established by the laboratory for a freezer should be between -15 and -25 oC e. While the TP turned Alarm to "On"

	position, the digital thermometer sound off. to indicate sometime in the past, there was a temperature condition outside of the acceptable range for that F1 freezer. f. The TP pushed the "Mode" bottom and the digital thermometer showed "Min" and "Max" with a "Max" temperature of 6 oC, which was outside of -15 to -25 oC acceptable range, also outside of the 10 to 30 oC indicated when at first sight when began to tour the facility. g. While interview with the QA and TP for the use of the digital thermometer device, it appeared to the surveyor that the laboratory personnel were not familiar the exact functions of the *DT, and/or failed to follow the manufacturer's instructions in a manner that meet the laboratory's performance specifications.
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 observations and review of the laboratory temperature records, devices, and touring the laboratory facility, and interview with the laboratory's quality assurance (QA) and the testing personnel (TP). It was determined that the laboratory failed to define criteria for those conditions that were essential for proper storage of reagents and specimens and failed to monitor following the manufacturer's instructions for storage temperature conditions. The findings included: a. The laboratory used various types of refrigerators and freezers to store reagents, samples, and the laboratory supplies to ensure the stability and validity of the reagents, samples, and the laboratory supplies. b. The laboratory selected and used digital thermometers (DT) to monitor and maintain the storage devices in optimal/acceptable temperature conditions. c. On 12/27/2019 @ 12:05 PM, touring the laboratory facility, the surveyor, QA and TP observed and noticed the DT used for F1 freezer showed a 10 oC for "Lo", 30 oC for "Hi" mode. d. The QA and TP indicated that the acceptable /optimal temperature range established by the laboratory for a freezer should be between -15 and -25 oC and the refrigerator should be between 2 to 8 oC. e. The Lo /Hi at the time of survey (12/27/2019 @12:05 PM) for most of the DT indicated 10 to 30 oC for either refrigerators or freezers.
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 observations and review of the laboratory temperature records, devices, and the laboratory facility, and interview with the laboratories. quality assurance (QA) and the testing personnel (TP). It was determined that the laboratory failed to document all corrective actions taken, including actions taken when equipment, digital thermometer, that perform outside of established operating parameters or performance specifications. The findings included: a. The laboratory established its acceptable temperature ranges to store the laboratory reagents, samples, and the laboratory supplies for refrigerators and freezers. b. The laboratory elected to use the digital thermometer (DT), which is capable of monitoring and recording the lowest and highest temperatures continuously but does not indicate exact time if the temperature is outside of the acceptable range. c. Noticed (12/27/2019 @ 12:05 PM) that a F1 freezer had temperature of 6 oC Max recorded in the DT, which was outside of the laboratory established acceptable temperature range of -15 to -25 oC (see D-5411 and D-5413) d. The laboratory failed to take remedial actions and document the activities the laboratory took.
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 observations and review of the laboratory temperature records, devices, and the laboratory facility, and interview with the laboratory's quality assurance (QA) and the testing personnel (TP). 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 of following the manufacturer's instructions to use the digital thermometers. The findings included: a. The laboratory elected to use the digital thermometers (DT) to maintain and monitor the temperature conditions for laboratory storage devices. b. The laboratory personnel failed to be proficient in monitoring the devices and setting the acceptable temperature ranges properly for the DT (see D-5411 and D-5413) c. 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 of following the manufacturer's instructions to use the digital thermometers (see D-5781)