Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2080391	03/14/2019
Name of Provider or Supplier	**Street Address, City, State**	
Up Front Labs Llc	16812 Red Hill Ave 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
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 review of the laboratory temperature charts and devices, and interview with the technical supervisor, and laboratory personnel, it was determined that the laboratory failed to understand the digital thermometer features and failed to monitor and recorded the temperature properly. The findings included: a. The laboratory used refrigerators and freezers to store their laboratory reagents, supplies, and patient samples. b. The laboratory used digital thermometers to monitor the temperatures of the storage devices. c. The digital thermometer features "current", "Min", and "Max" temperature, including "Alarm" when the current temperature outside of the acceptable/optimal temperature ranges for storage matter established by the laboratory. d. The laboratory established acceptable/optimal temperature for its freezer is between -15 to -25 degree Celsius (oC) and refrigerators between 2 to 8 oC. e. At the time of survey (3/14/2019 @ 11 AM), a -28 oC observed a digital thermometer for its LC/MS/MS room, which is outside of its laboratory established acceptable storage temperature. f. Further interviewed and observed along with the testing personnel, the alarm was set at "Off" position for the digital thermometer while at the time of the survey (3/14/2019). g. Further review of a Temperature Records for Oct 2017 chart. Readings and records indicated that Refrigerator #1 and 2 were ranged between 2 - 8 oC but temperature were recorded as 36 the entire month, which

	were out of the set range for 2 - 8 oC. h. Further review of Freezer A thru C in the Oct 2017 temperature chart, where the range for acceptable temperature was between -15 to -25 oC. i. There were freezer temperatures out of -15 to -25 oC recorded as follows: F = freezer; D = date; T = temperature D T D T D T D T F #A 10/2 -27 10/4 -26 10 /23 -26 10/24 -26 F # B 10/2 -24 10/11 -11 10/12 -14 10/13-12 & more F # C 10/2 -13 10/5 -13 10/6 -12 10/13 -13 j. The laboratory failed to detect and monitor properly the temperature within the acceptable temperature range. k. The laboratory failed to take actions taken or documented to correct and maintain the storage temperature within the acceptable/optimal ranges.
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 review of the laboratory temperature charts and devices, and interview with the technical supervisor, and laboratory personnel, it was determined that the laboratory failed to document all corrective actions taken, when equipment or methodologies that perform outside of established operating parameters or performance specifications. The findings included: See D-5413
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the laboratory Patient Test Management - Chart Audit Record, and interview with the laboratory technical supervisor and personnel, it was determined that the laboratory failed to follow its written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems. The findings included: a. The laboratory established a mechanism to monitor, assess, and to ensure the accuracy of its patient test reports in house. b. The laboratory created "Patient Test Management- Chart Audit Record" (PTM audit) as well as in its Standard Operation Procedure (SOP) a "Laboratory Quality Assessment Plan" including Patient Test Management (PTM). c. Reviewed in house PTM audit records for a patient #171031051 with collected date of 10/30/2017, received date of 10/31 /2017 and final result report date of 11/03/2017. d. Follow its PTM audit flowchart, the laboratory used "check (V)" mark or "acceptable" and " N/A" to answer all the check statements under the column of "Criteria" d. With in the sub-criteria "Test

	Records" two questions were asked: Out of Control QC documented V Instrument print out V e. The laboratory did not identify what a "V" indicated ? The interpretation of "V" is unclear than "acceptable or N/A are clearly explained. f. There was no document of "Instrument print out" available in the QA file to verify the accuracy and reliability of the results sent from the point of data entry (instrument) to patient final report. g. The laboratory did not follow its established written policies and procedures to verify the accuracy and reliability of the patient final test report
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 review of the laboratory records, and interview with the laboratory technical supervisor and personnel, it was determined that the laboratory director failed to ensure that the quality control programs were maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The findings included: See D-5413, and D-5781
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 review of the laboratory Patient Test Management - Chart Audit Record, and interview with the laboratory technical supervisor and personnel, it was determined that the laboratory director failed to maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The findings included: See D-5891