Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2171814	08/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
Grapevine Total Wellness, Pllc	1000 W State Hwy 114, Grapevine, TX	

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	Based upon the onsite initial survey conducted 08/09/2021, this facility was found NOT to be compliance with CLIA regulations found at 42 CFR for the specialties /subspecialties in which it was surveyed. 493.1421 Condition: Laboratories Performing Moderate Complexity Testing; Testing Personnel The laboratory director was advised the laboratory was out of compliance and advised of conditions and deficiencies found during the survey. An opportunity for questions and comments was provided. Note: the last day of this survey was 08/28/2021 due to requested documentation provided on that date via electronic mail.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of QC records and in interview with the laboratory director, the laboratory failed to retain FastPak System Control Range cards (included Testosterone QC ranges) for 1 of 4 control kit lot numbers in 2021. Findings included: 1. Review of Testosterone QC records analyzed on FastPack IP System Qualigen from 2019 through 2021 revealed the laboratory had used a total of four (4) control kits. The laboratory did not retain FastPak System Control Range card (with QC ranges) provided by the manufacturer for the following QC set: Lot #2001037 (Control 1) and Lot #2001038 (Control 2) - used between 02/2021 and 06/2021 2. During an interview on 08/09/2021 at 3:15 pm, the laboratory director stated FastPak System Control Range cards should be retained. The QC ranges card was not provided for the above QC set.
D5439	CALIBRATION AND CALIBRATION VERIFICATION

	CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, calibration verification records, and in interview with the laboratory director, the laboratory failed to perform and document calibration verification for FastPack IP System Qualigen analyzers at least once every 6 months for 07/2020 and 01/2021. Findings included: 1 .Review of FastPack IP System Qualigen Testosterone manufacturer's instructions stated, "Every 6 months, verify calibration of the FastPack IP System using the FastPack Testo Method Verification Kit to verify that calibration is accurate to the limits of the reportable range specific by Qualigen, Inc." 2. Calibration verification records for FastPack IP System Qualigen analyzers, "Analyzer #1218" and "Analyzer #1220", revealed the last documented calibration verification was 01/2020. The laboratory had not performed and documented calibration verification every 6 months (07/2020 and 01 /2021) for the FastPack IP System Qualigen analyzers. 3. During an interview on 08 /09/2021 at 3:30 pm, the laboratory director confirmed the laboratory had not performed and documented calibration verification since 01/2020.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the Individualized Quality Control Program (IQCP), quality control (QC) records, patient records, and in interview with staff, the laboratory reported 33 patient Testosterone test results when QC did not meet criteria for acceptability on the FastPack IP System Qualigen for 3 of 13 days reviewed on 11 /2019, 01/2020, and 02/2020. Findings included: 1. Review of the laboratory's IQCP

	for the frequency of QC included analyzing two levels of QC material for Testosterone every 7 days. 2. Review of FastPack IP System Qualigen "Analyzer #1218" QC records from 11/2019 through 02/2020 revealed the following days Testosterone QC was not within the criteria for acceptability (QC range) and patient test results were reported: 11/05/2019 at 11:33 am- Control 2 (Lot #1809007) result was 448 ng/dL (manufacturer range: 460 - 1,060 ng/dL) and 9 patients were analyzed and reported between 11/06/2019 through 11/12/2019 (next acceptable QC run was on 11/13/2019). 01/29/2020 at 10:31 am - Control 2 (Lot #1809007) result was 1,064 ng /dL (manufacturer range: 460 - 1,060 ng/dL) and 24 patients were analyzed and reported between 01/29/2020 through 02/11/2020 (next acceptable QC run was on 02 /12/2020). 02/05/2020 at 9:17 am - Control 1 (Lot #1910047) result was 370 ng/dL (manufacturer range: 140 - 340 ng/dL) and 16 patients were analyzed and reported between 02/05/2020 through 02/11/2020 (next acceptable QC run was on 02/12 /2020). QC was not repeated and there was no documented corrective action (Refer to D5781). The laboratory failed to ensure QC was within acceptable criteria prior to analyzing and reporting patients for Testosterone. 3. During an interview on 08/09 /2021 at 3:15 pm, the laboratory director reviewed and confirmed the above findings.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on direct observation, review of the laboratory's records, and in interview with staff, the laboratory failed to have a system in place to evaluate and define the relationship between Testosterone test results using two FastPack IP System Qualigen analyzers twice a year (2020). Findings included: 1. During a tour of the laboratory on 08/09/2021 at 1:00 pm, two (2) FastPack IP System Qualigen analyzers, "Analyzer #1218" and "Analyzer #1220", were observed on the counter ready for use. During an interview on 08/09/2021 at 1:15 pm, TP #1 stated both analyzers were used for testing Testosterone. 2. Review of the FastPack IP System Qualigen analyzer verification studies revealed initial setup was 07/2019. Further review did not include a documented system in place to evaluate and define the relationship between Testosterone test results using two FastPack IP System Qualigen analyzers twice a year (2020). 3. During an interview on 08/09/2021 at 3:30 pm, the laboratory director could not provide documentation for evaluating and defining the relationship between Testosterone test results using two FastPack IP System Qualigen analyzers twice a year.
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 review of the Individualized Quality Control Program (IQCP), corrective action log procedure, quality control (QC) records, patient records, and in interview with staff, the laboratory failed to document corrective action when Testosterone QC did not meet criteria for acceptability on the FastPack IP System Qualigen for 4 of 17 days reviewed in 11/2019, 12/2019, 01/2020, and 02/05/2020. Findings included: 1. Review of the laboratory's IQCP for the frequency of QC included analyzing two levels of QC material for Testosterone every 7 days. Review of the corrective action log procedure stated, "This log is to be used to record any problems or abnormalities that occurred in your laboratory and to list the actions taken to correct them. Fill in the date the problem occurred. Describe the problem, the resolution and any corrective action that has taken pace to ensure the problem does not occur again ..." 2. Review of FastPack IP System Qualigen "Analyzer #1218" QC records from 11/2019 through 02 /2020 revealed the following days Testosterone QC was not within the criteria for acceptability (QC range) and corrective action was not documented: 11/05/2019 at 11: 33 am- Control 2 (Lot #1809007) result was 448 ng/dL (range: 460 - 1,060 ng/dL) 12 /18/2019 at 4:37 pm - Control 1 (Lot #1809006) result was 410 ng/dL (range: 130 - 330 ng/dL) 01/29/2020 at 10:31 am - Control 2 (Lot #1809007) result was 1,064 ng /dL (range: 460 - 1,060 ng/dL) 02/05/2020 at 9:17 am - Control 1 (Lot #1910047) result was 370 ng/dL (range: 140 - 340 ng/dL) A total of 33 patients were analyzed and reported when QC was not within the acceptable criteria. Refer to D5481. 3. During an interview on 08/09/2021 at 3:15 pm, the laboratory director was asked for corrective action related to the above four dates QC was not within range, he was unable to provide corrective action.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of the Individualized Quality Control Program (IQCP), corrective action log, quality control (QC) Testosterone records, patient records, and in interview with staff, the laboratory failed to evaluate and document all patient test results obtained in the unacceptable QC run and since the last acceptable QC run to determine if patient test results were affected for 73 of 73 patients in 11/2019, 12 /2019, 01/2020, and 02/05/2020. Findings included: 1. Review of the laboratory's IQCP for the frequency of QC included analyzing two levels of QC material for Testosterone every 7 days. Further review of the IQCP stated, "CONTROLS OUT OF RANGE: Describe what action would be taken if testing was mistakenly performed

	using product that had failed external QC (either Control 1 or Control 2 running out of range): Going back to time point of the previous passing external QC event, FastPack results would not be reported, and those patient samples would be sent out for retesting at outside lab. Patient testing would resume upon resolution of the external QC issue." 2. Review of FastPack IP System Qualigen "Analyzer #1218" QC records from 11/2019 through 02/2020 revealed the following days Testosterone QC was not within the criteria for acceptability (QC range) and no documentation of assessing patients obtained in the unacceptable QC run and since the last acceptable QC run to determine if patient test results were affected: 11/05/2019 at 11:33 am- Control 2 (Lot #1809007) result was 448 ng/dL (range: 460 - 1,060 ng/dL); 13 patients were analyzed and reported since the last acceptable QC run 10/30/219; and 9 patients were analyzed and reported between 11/06/2019 through 11/12/2019 (next acceptable QC run was on 11/13/2019). 12/18/2019 at 4:37 pm - Control 1 (Lot #1809006) result was 410 ng/dL (range: 130 - 330 ng/dL); 11 patients were analyzed and reported since the last acceptable QC run 12/11/2019 (next acceptable QC run was 12/19/2019 at 9:38 am). 01/29/2020 at 10:31 am - Control 2 (Lot #1809007) result was 1,064 ng/dL (range: 460 - 1,060 ng/dL); 16 patients were analyzed and reported since the last acceptable QC run 01/22/2020; and 24 patients were analyzed and reported between 01/29/2020 through 02/11/2020 (next acceptable QC run was on 02/12/2020). 02/05 /2020 at 9:17 am - Control 1 (Lot #1910047) result was 370 ng/dL (range: 140 - 340 ng/dL); 16 patients were analyzed and reported since the last acceptable QC run 01/22 /2020; and 24 patients were analyzed and reported between 01/29/2020 (unacceptable QC run) through 02/11/2020 (next acceptable QC run was on 02/12/2020). 3. During an interview on 08/09/2021 at 3:15 pm, the laboratory director was asked for documentation of assessing patients obtained in the unacceptable QC run and since the last acceptable QC run to determine if patient test results were affected for the above dates, none was provided. The laboratory did not take and document corrective action to ensure accurate and reliable test results.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the quality assessment (QA) procedure, monthly QA documentation, corrective action log, QC Testosterone records, patient records, and interview with the laboratory director, the laboratory failed to ensure their written policies monitored, assessed and corrected problems identified in the analytic systems for 2 of 12 months in 2019 and 2 of 12 months in 2020. Findings included: 1. Review of "Quality Assurance Assessment Program for FastPak IP System Testing" procedure stated, " ...Our laboratory assesses the QA plan monthly, using the QA Assessment, which (1) evaluates and monitors the overall quality of our testing; (2) helps evaluate how well our policies and procedures are working; and (3) minimizes the possibility of recurrent problems. If necessary, the policies and procedures contained in this QA Manual will be revised based on problems identified on the QA Assessment. Any revisions to policies and procedures will be communicated to the staff by having them read any changes to this manual and signing the QA Manual Approval Form ..." 2. Review of "Quality Assurance Assessment" documents for 11/25/2019, 12/30/2019,

	02/02/2020, and 03/02/2020 stated, "Write one of the following notations for each item: Y (Yes), N (No), or N/A (Not Applicable); Our QUALITY CONTROL POLICIES were performed as specified: Y - Each QC Event, two levels of quality control were tested and were within acceptable ranges before patients were tested. Y - Any necessary troubleshooting was performed and documented. Our QUALITY ASSURANCE PROGRAM is monitored for compliance: Y - The above information has been reviewed to determine whether errors that occurred this month could have been prevented by changing policies and/or procedures." 3. Review of the corrective action log, QC Testosterone records, and patient records for 11/2019, 12/2019, 01 /2020, and 02/2020 revealed the following problems identified were not monitored, assessed, and corrected by the laboratory: The laboratory reported 33 patient Testosterone test results when QC did not meet criteria for acceptability on the FastPack IP System Qualigen for 3 of 13 days reviewed on 11/2019, 01/2020, and 02 /2020. Refer to D5481 The laboratory failed to document corrective action when Testosterone QC did not meet criteria for acceptability on the FastPack IP System Qualigen for 4 of 17 days reviewed in 11/2019, 12/2019, 01/2020, and 02/05/2020. Refer to D5781 The laboratory failed to evaluate and document all patient test results obtained in the unacceptable QC run and since the last acceptable QC run to determine if patient test results were affected for 73 of 73 patients in 11/2019, 12 /2019, 01/2020, and 02/05/2020. Refer to D5783
D6052	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based on review of CMS-209 form, personnel files, and in interview with the laboratory director, the technical consultant failed to evaluate and document assessment of problem solving skills for 1 of 2 TPs (TP #1) competencies in 06/2020 and 12/2020. Findings included: 1. Review of the CMS-209 form included two TPs listed who perform Testosterone testing on FastPack IP System Qualigen. 2. Review of TP's #1 competency assessments completed 06/2020 and 12/2020 did not include assessment of problem solving skills, as required. 3. During an interview on 08/09 /2021 at 3:10 pm, the laboratory director/technical consultant reviewed and confirmed the above findings.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of CMS-209 form, personnel files, and in interview with Testing Person #2 (TP #2), the laboratory did not ensure individuals met the qualification requirements to perform testing. The laboratory failed to ensure 1 of 2 TPs (TP #2) was qualified to perform moderate complexity testing (Qualigen - Testosterone). Refer to D6065.

D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of CMS-209 form, personnel files, and in interview with TP #2, the laboratory failed to ensure 1 of 2 TPs (TP #2) was qualified to perform moderate complexity testing (Qualigen - Testosterone). Findings included: 1. Review of the CMS-209 form included two TPs listed who perform Testosterone testing on FastPack IP System Qualigen. 2. Review of the TP #2 personnel files did not include documentation of the minimum requirements to perform moderate complexity testing per CFR 493.1423(b)(4)(i). 3. During an interview on 08/09/2021 at 3:00 pm, TP #2 was unable to provide her high school diploma.