

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2171814	(X3) Date Survey Completed 03/16/2023
Name of Provider or Supplier Grapevine Total Wellness, Pllc	Street Address, City, State 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	Laboratory representatives were present at the entrance conference. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas Health and Human Services Commission, Health Facility Compliance Arlington Group. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Southern Operations Branch-Dallas for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, direct observation, and confirmed in interview, the laboratory failed to follow its own written policy for labeling patient blood collection tubes for 2 of 2 patients in March 2023. The findings include: 1. Review of the laboratory's policy manual revealed: "TAB 5: Before Performing the Test (Pre-</p>

Analytic Processes) Pre-analytic Policies: Good lab practices include actions such as labeling patient specimens, recording the time and date of testing, having written (opposed to verbal) test orders from the ordering physician, and assigning each patient a unique patient identification number. Proper collection and handling is also an essential component of pre-analytic policies. It is the policy of this lab to adhere to the following procedures, which influence all activities from the time lab tests are ordered through the time that specimens are processed and received by the testing site... 6. Label collection tubes Label all vacuum tubes with at least the patient's^dob [sic] name and your initials as well as the time and date the specimen is drawn." 2. During a tour of the laboratory on 03/16/2023 at 11:33 a.m., the surveyor observed the following blood collection tubes in a rack beside the Qualigen FastPack IP analyzers labeled with only a patient name and no other patient identifiers: Patient 1: 1 lavender tube, 2 SST tubes, and 1 green top tube Patient 2: 1 lavender tube The laboratory failed to follow its own written policy for labeling patient blood collection tubes with patient dob, patient name, collector's initials, and time/date of draw. 3. During an interview on 03/16/2023 at 11:33 a.m., Testing Person 2 confirmed the above findings. KEY: Dob-date of birth SST-serum separator tube

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, laboratory procedures, laboratory records, and confirmed in interview the laboratory failed to perform calibration verification for 2 of 2 Qualigen FastPack IP immunoassay analyzers every 6 months as required in 2022. The findings include: 1. Review of the FastPack Test Method Verification Kit instructions for use revealed: "SUMMARY AND PRINCIPLE ... The verification of method performance should provide evidence that the accuracy, precision, and reportable range of the procedure are adequate to meet the customer's needs ...Calibration verification occurs through the testing of 3 or more levels of calibration materials that include a low, mid, and high value at least every 6 months ..." 2. Review of the laboratory procedure for calibration verification revealed: "Testo

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 specified by Qualigen, Inc." 3. Review of Qualigen FastPack IP calibration verification records revealed the following: Analyzer #1218 Date of Calibration Verification: 02/01/2022 Date of Calibration Verification: 10/11/2022 Elapsed time: 8 months Analyzer #1220 Date of Calibration Verification: 02/01/2022 Date of Calibration Verification: 10/11/2022 Elapsed time: 8 months The laboratory failed to perform calibration verification at least every 6 months in 2022. 4. During the exit interview on 03/16/2023 at 12:00 p.m., the Laboratory Director 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 laboratory policy, comparison studies, and confirmed in interview, the laboratory failed to have documentation of evaluating the relationship of test results between different instruments twice a year for 1 of 1 endocrine analyte (testosterone) in 2023, tested on two FastPack IP System Qualigen analyzers. **This is a repeat deficiency from a survey conducted on 08/25/2021.**
Findings Included: 1. During a tour of the facility on 03/16/2023 at 10:00 a.m. the surveyor observed two FastPack IP System Qualigen analyzers performing patient testing for testosterone. Qualigen Analyzer 1 Serial Number: 1218 Qualigen Analyzer 2 Serial Number: 1220 2. Review of laboratory policy, "Testosterone Method Comparison" revealed the following: "Policy: Verify that reportable results are comparable between analyzers that are in service. A random sample will be run on each analyzer that is in service every 6 months. Results must be within 10% of each other." 3. Review of laboratory FastPack IP System Qualigen analyzer comparison studies in 2022, revealed the following: a. Performed on: 03/08/2022 b. Performed on: 09/15/2022 The following comparison was due 03/15/2023, no study was provided. The laboratory failed to have documentation of evaluating the relationship of test results between different instruments twice a year for 1 of 1 endocrine analyte (testosterone) in 2023, tested on two FastPack IP System Qualigen analyzers. 4. During an interview on 03/16/2023 at 12:00 p.m. in the laboratory, the Laboratory Director confirmed the above findings.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures

each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of CMS 209 form, personnel records, and staff interview, the Laboratory Director failed to specify, in writing, the responsibilities and duties for 1 of 1 technical consultant (TC-1) engaged in technical oversight of moderate complexity testing. Findings Included: 1. Review of CMS 209 form listed TC-1 as a consultant of moderate complexity testing. 2. Review of laboratory personnel records revealed the Laboratory Director failed to specify TC-1 responsibilities and duties in writing for moderate complexity testing. 3. During an interview on 03/16/2023 at 12:00 p.m. in the laboratory, the Laboratory Director confirmed the above findings.