Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2152401	03/24/2026
Name of Provider or Supplier	**Street Address, City, State**	
Key T Wellness	1621 Fm 517 Rd E, Dickinson, 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	An announced Validation survey of the laboratory was conducted on 03/24/2026. The laboratory was found in substantial compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. STANDARD LEVEL DEFICIENCIES were cited.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) (a)Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of laboratory's Individualized Quality Control Plan (IQCP), Prostate-Specific Antigen (PSA) Qualigen FastPack IP System calibration records from June 2024 through June 2025, submitted patient test volumes and staff interview, the laboratory failed to document PSA calibration for one of one instance calibration was required as per laboratory's IQCP. Findings included: 1. Review of laboratory's IQCP for PSA (last reviewed and approved 12/03/2025) revealed: "Calibrations will be performed for PSA every 21 days ..." 2. Review of laboratory's PSA Qualigen FastPack IP System calibration records from June 2024 through June 2025 revealed laboratory failed to document calibration on 04/01/2025 as required by laboratory's

	IQCP. Last calibration documented: 03/11/2025 Next calibration documented: 04/22 /2025 Time elapsed: 42 days 3. Review of laboratory's submitted patient test volumes revealed the laboratory on average performed testing on approximately four to five patient samples per week. Thus, approximately twelve to fifteen patient samples were tested in the three-week period past the calibration due date. 4. In an interview on 03 /24/2026 at 1215 hours in the office, laboratory's Testing Person number one (as indicated on submitted Form CMS -209) confirmed the findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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 laboratory's calibration records, policies/procedures, calibration verification records, and staff interview, the laboratory failed to document calibration verification for one of four required Qualigen FastPack IP System calibration verification events from 2024 and 2025, for the two laboratory tested analytes, Testosterone and Prostate-Specific Antigen (PSA). Findings included: 1. Review of laboratory's calibration records from 2024 and 2025 revealed the laboratory routinely used two calibrators for Qualigen FastPack IP System calibration of Testosterone and PSA analytes, thus requiring calibration verification. 2. Review of laboratory's policies revealed the laboratory adopted the manufacturer's "PSA Calibration Verification Records" policy [document 65000161 Rev. 006 (06/15)] as its own. The policy stated: "PSA Every six months, verify calibration of the FastPack IP System using the FastPack Total PSA Method Verification Kit to verify that calibration is accurate to the limit of the reportable range specified by Qualigen, Inc." 3. Review of laboratory's policies revealed the laboratory adopted the manufacturer's "Testosterone Calibration Verification Records" policy [document 65000161 Rev. 006 (06/15)] as its own. The policy stated: "Testo (Testosterone) Every six months, verify calibration of the FastPack IP System using the FastPack Testo Method Verification Kit to verify that calibration is accurate to the limit of the reportable range specified by Qualigen, Inc." 4. Review of laboratory's FastPack IP System calibration verification records from 2024 through 2025 revealed there was no calibration verification documentation for either Testosterone or PSA for the first half of 2024, one of four required calibration verification events within the two-year period. Further investigation into the missing 2024 calibration verification event revealed calibration verification for the

	two analytes was last performed 08/08/2023 and then 11/12/2024, with a gap of 15 months between calibration verification events. 5. In an interview on 03/24/2026 at 1230 hours in the office, laboratory's Testing Person number one (as indicated on submitted Form CMS -209) confirmed the findings.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) (d)(3)(i) Each quantitative procedure, include two control materials of different concentrations; This STANDARD is not met as evidenced by: Based on review of laboratory's Individualized Quality Control Plan (IQCP), quality control (QC) records from June 2024 through June 2025, submitted patient test volumes and staff interview, the laboratory failed to document QC testing for four of four instances controls' testing was required for the two analytes tested by the facility, Qualigen FastPack IP System Testosterone and Prostate-Specific Antigen (PSA), as per laboratory's IQCP. Findings included: 1. Review of laboratory's IQCP (last reviewed and approved 12/03/2025) revealed: "QC Plan: ... Controls will be performed for Testosterone every seven days ..." And, "Controls will be performed for PSA every seven days ..." 2. Review of laboratory's Qualigen FastPack IP System QC records for Testosterone and PSA from June 2024 through June 2025 revealed both analytes had two levels of controls, Lower Level and Upper Level. Further review revealed the following four of four instances where controls' testing was not documented as required by laboratory's IQCP: a. For Testosterone: On 01/21/2025 - No lower or upper control results were documented. Last tested: 01/14/2025 Next tested: 01/28/2025 Elapsed time: 14 days. On 05/06/2025 - No lower or upper control results were documented. Last tested: 04/29/2025 Next tested: 01/28/2025 Elapsed time: 14 days. b. For PSA: On 01/21/2025 - No lower or upper control results were documented. Last tested: 01/14/2025 Next tested: 01/28/2025 Elapsed time: 14 days. On 05/06/2025 - No lower or upper control results were documented. Last tested: 04 /29/2025 Next tested: 01/28/2025 Elapsed time: 14 days. 3. Review of laboratory's submitted patient test volumes revealed the laboratory on average performed testing on approximately four to five patient samples per week. 4. In an interview on 03/24 /2026 at 1150 hours in the office, laboratory's Testing Person number one (as indicated on submitted Form CMS -209) confirmed the 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. This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures, instrument to instrument split sample comparison studies and staff interview, the laboratory failed to document one of three split sample comparison studies of its two Qualigen FastPack IP Systems used in 2024 and 2025, instruments numbers 0119 and 0081, employed in testing of Testosterone and Prostate-Specific Antigen (PSA). Findings included: 1. Review of

	laboratory's policies/procedures revealed the laboratory adopted the COLA "Split Sample Analysis" (Primer 9, 10/2021 COLA) as instructions for split sample analysis for comparing the accuracy of its two FastPack IP Systems. It stated: "Split specimen testing may be used - When a laboratory has multiple instruments and/or methods for testing the same analyte" However, this document did not specify the requirements for the frequency of split sample studies, and the laboratory did not have its own policy addressing instrument to instrument split sample comparison. 2. Review of laboratory's 2024/2025 FastPack IP Systems numbers 0081 and 0119 "Instrument to Instrument Events" split sample comparison studies revealed the laboratory did not have documentation of performing one of three comparison studies. The reviewed events were documented on 08/02/2024 and 08/01/2025. There was no documentation of instrument-to-instrument split sample comparison in February 2025. 3. In an interview on 03/24/2026 at 1245 hours in the office, laboratory's Testing Person number one (as indicated on submitted Form CMS -209) confirmed the findings.