Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D2271384	**(X3) Date Survey Completed** 08/04/2025
Name of Provider or Supplier Join Parachute - Brownwood	**Street Address, City, State** 1019 N Fisk Ave, Brownwood, 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	A validation survey was conducted on 08/04/2025 and standard level deficiencies were cited.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, quality control (QC) records, and interview with the Center Quality Supervisor, the laboratory failed to include calibration verification, corrective actions for QC failures, and a defined reportable range in their written procedures for one of one test (total protein). Findings included:

	1. Review of the laboratory's procedures Refractometer (EQUIP-008-014) and Total Protein (DS-012-06) did not include the following: a) total protein refractometer calibration verification including a minimum, a mid-point, and a maximum value to verify the reportable range, at least every 6 months according to 493.1255 (Refer to D5439); b) a defined total protein reportable range as verified according to 493.1253 (b)(1)(i)(C) (Refer to D5421); and c) corrective actions to take and document when total protein low and/or high quality control (QC) levels were out of the acceptable range criteria. 2. Review of total protein QC from 2024 and 2025 included 7 of 9 days (random sampling) when QC was out of the acceptable range criteria and there was no documentation of the corrective action taken. Refer to D5781. 3. During an interview on 08/04/2025 at 12:49 PM, the Center Quality Supervisor stated that when QC was out of the acceptable range criteria, the testing person opens a new vial. If the QC fails a second time, then the refractometer is removed from service. The written procedures did not include these steps to take.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 direct observation, review of manufacturer's instructions, temperature records, and interview with staff, the laboratory failed to ensure their temperature range was according to Vacuette tubes manufacturer's storage requirements for 4 of 4 months reviewed. Findings included: 1. During a tour of the Supply Room on 08/04 /2025 at 1:20 PM, the following Vacuette tubes were observed stored on shelves (random sampling): a) purple top tubes, lot number B250235T, expiration date 02/01 /2026 (50 tubes) b) blue top tubes, lot number B2410339, expiration date 10/01/2025 (50 tubes) c) white top tubes, lot number B241233R, expiration date 04/02/2026 (50 tubes) 2. Review of Vacuette tubes manufacturer's storage requirements stated, "Store tubes at 4-25C (40-77F)." 3. Review of the laboratory's electronic temperature system "Chekit" for "Supply Room 1" from 09/2024, 10/2025, 03/2025, and 04/2025 included a defined temperature range of "15-30C." The upper range was beyond Vacuette tubes manufacturer's storage requirements upper range (25C). 4. During an interview on 08/04/2025 at 1:34 PM, the Quality Assurance Supervisor and the Center Quality Supervisor confirmed the Supply Room temperature range was not according to the Vacuette tubes manufacturer's storage requirements.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)

	(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, verification studies, and interview with staff, the laboratory failed to verify the total protein reportable range and reference intervals (normal values) for one of one method (TS Meter-DSP refractometers). Findings included: 1. Review of the laboratory's procedures Refractometer (EQUIP-008-014) and Total Protein (DS-012-06) did not include total protein calibration verification procedures, to include a minimal, mid-point, and a maximum value to verify the laboratory's reportable range. The procedures did not include a defined total protein reportable range. Refer to D5403. 2. Review of the laboratory's procedure Total Protein (DS-012-06) stated, "6.3 A donor is required to have TP that ranges between 6.0 g/100 mL - 9.0 g/100 mL" (reference interval). 3. The laboratory provided verification studies of the refractometer's performance specifications from 12/08/2022. Two levels of QC were performed three times on 6 refractometers upon installation. 4. The laboratory was unable to provide reportable range and reference interval verification documentation, and the laboratory director signature of approval, as required. 5. During an interview on 08/04/2025 at 2:45 PM, the Quality Assurance Supervisor and the Center Quality Supervisor were unable to provide documentation verifying total protein reportable range, reference intervals, and the laboratory director's signature of approval. Word Key: TS Meter - total solids DSP - digital signal processor TP - total protein
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 procedures, interview with the Center Quality Supervisor, review of verification studies, and review of annual test volume, the laboratory failed to perform calibration verification for 4 of 4 in-service total protein refractometers at least every 6 months in 2023 and 2024. Findings included: 1. Review of the laboratory's procedures Refractometer (EQUIP-008-014) and Total

	Protein (DS-012-06) did not include total protein calibration verification procedures, to include a minimal, mid-point, and a maximum value to verify the laboratory's reportable range. 2. During an interview on 08/04/2025 at 12:21 PM, the Center Quality Supervisor confirmed calibration verification was not performed on the 4 in-service refractometers (rf16270003, rf16270004, rf16270005, rf16270006) in 2023 and 2024. 3. Further review of the laboratory's procedures did not include a defined reportable range. The laboratory provided verification studies of the refractometer's performance specifications from 12/08/2022, a reportable range had not been verified. Refer to D5403 and D5421. 4. Review of the laboratory's annual test volume included 17,328 total protein tests.
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 laboratory's procedures, QC records, and in interview with the Center Quality Supervisor, the laboratory failed to document corrective actions taken when total protein low and/or high quality control (QC) levels were out of the acceptable range criteria for 7 of 9 days. Findings included: 1. Review of the laboratory's procedures Refractometer (EQUIP-008-014) did not include actions to take and document when total protein low and/or high quality control (QC) levels were out of the acceptable range criteria. 2. Review of total protein QC from 2024 and 2025 included the following days (random sampling), QC was out of the acceptable range criteria and there was no documentation of corrective actions taken: 04/11/2024 at 2:14 PM - QC High Control (lot number K305932) value was 9.5 (range: 8.6 - 9.4), it was repeated at 2:25 PM, the value was 9.3. 06/24/2024 at 11:25 AM - QC High Control (lot number K306711) value was 9.5 (range: 8.6 - 9.4), it was repeated at 11: 34 AM, the value was 9.2. 09/09/2024 at 6:54 AM - QC High Control (lot number K306711) value was 10.0 (range: 8.6 - 9.4), it was repeated at 7:26 AM, the value was 9.0. 02/03/2025 at 12:56 PM - QC High Control (lot number K306711) value was 9.5 (range: 8.6 - 9.4), it was repeated at 1:05 PM, the value was 9.0. 03/04/2025 at 12:38 PM - QC Low Control (lot number K306518) value was 6.5 (range: 5.6 - 6.4), it was repeated at 12:47 PM, the value was 6.2. 03/11/2025 at 11:52 AM - QC Low Control (lot number K306518) value was 6.6 (range: 5.6 - 6.4), it was repeated at 12:02 PM, the value was 6.1. 04/07/2025 at 11:43 AM - QC High Control (lot number K306765) value was 9.5 (range: 8.6 - 9.4), it was repeated at 11:55 AM, the value was 9.2. 3. During an interview on 08/04/2025 at 12:49 PM, the Center Quality Supervisor stated that when QC was out of the acceptable range criteria, the testing person opens a new vial. If the QC fails a second time, then the refractometer is removed from service. The Center Quality Supervisor confirmed the 7 of 9 days reviewed did not include documented corrective actions taken when QC did not meet their criteria.

D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, verification studies, and interview with staff, the laboratory director failed to ensure verification studies were complete, reviewed and approved for one of one test (total protein) performed on refractometers. Findings included: 1. The laboratory provided verification studies of the refractometers' performance specifications from 12/08/2022. Two levels of quality control (QC) were performed three times on 6 refractometers upon installation. The accuracy and precision data of the refractometers was not reviewed and signed by the laboratory director. 2. In addition, the laboratory was unable to provide reportable range and reference interval verification documentation. 3. During an interview on 08 /04/2025 at 2:45 PM, the Quality Assurance Supervisor and the Center Quality Supervisor were unable to provide documentation verifying total protein reportable range, reference intervals, and the laboratory director's signature of approval.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Based on review of competency assessments, laboratory's procedures, and interview with the Center Quality Supervisor, the technical consultant failed to include required components for competency assessments for 5 of 10 testing persons (random sampling). Findings included: 1. Review of "PERFORMANCE OBSERVATION FORM TRN-0050A-02" (competency assessment) included the testing person's name, date of observation by the technical consultant (TC), "Task Observed: Donor Screening/Moderate Complexity", "Equipment ID" (refractometer), and "SOP(s) Utilized: SOP-DS-012." (SOP - standard operating procedure) 2. Review of "TOTAL PROTEIN SOP-DS-012" did not include the following competency assessment requirements, as outlined under 493.1413(b)(8)(iii) through (b)(8)(v): a) review of intermediate test results or worksheets, quality control records, proficiency testing results and preventive maintenance records; b) direct observation of performance of instrument maintenance and function checks; c) assessment of test performance through testing previously analyzed specimens, internal blind testing samples of external proficiency testing samples; and d) assessment of problem solving skills. 3. Review of TP-6 (11/21/2024 - date assessed), TP-7 (12/24/24), TP-8 (07/04/2025), TP-9 (05/22/2025), TP-10 (07/17/2025) competency assessments did not include the four requirements, 493.1413(b)(8)(iii) through (b)(8)(v). 4. During an interview on 08 /04/2025 at 11:00 AM, the Center Quality Supervisor reviewed and confirmed the above findings.