Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D2328241	03/03/2026
Name of Provider or Supplier	**Street Address, City, State**	
Join Parachute - Radcliff	23 S Wilson Road, Radcliff, KY	

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 on-site validation survey was conducted on March 03, 2026 with the following standard level deficiencies 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 direct observation, review of the laboratory's policies and procedures, and interview with the Center Quality Assurance Supervisor, the laboratory failed to include calibration and calibration verification procedures and defined reportable range in their written policies and procedures for one of one test (Total Protein).

	Findings Included: 1) During a laboratory tour on 3/03/2026 at 2:00PM, six Reichert Refractix DSP Digital Refractometers (Serial Numbers rf17910001, rf17910002, rf17910003, rf17910004, rf17910005, rf17910006) were observed in use. 2) Review of the laboratory's policies titled 'REFRACTOMETER EQUIP-008-014', 'CLIA REQUIREMENTS CLIA-001-08' and 'TOTAL PROTEIN DS-012-06' revealed the following not included: a) Total Protein Refractometer Calibration and Calibration verification procedures, including a minimum, mid-point and maximum value to verify reportable range at least every 6 months according to 493.1255 b) A defined reportable range for Total Protein as verified according to 493.1253(b)(1)(i)(C) The Policies EQUIP-008-014 and CLIA-001-08 stated the following: "Policy 6.1 An Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) are performed when a Refractometer is first placed into service and after repairs." The policies stated procedures on IQ, not OQ and PQ and did not contain information on calibration, calibration verification procedures and verified reportable range. 3) In an interview at 2:05PM, the Center Quality Assurance Supervisor confirmed the findings the laboratory policies did not state procedures on calibration, calibration verification nor verified reportable ranges.
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: I. Based on direct observation, review of manufacturer instructions, laboratory temperature/humidity records, policies, and interview with the Center Quality Assurance Supervisor, the laboratory failed to define, monitor and record humidity for the Reichert Refractix DSP Digital Refractomer in accordance with manufacturer instructions for 4 of 4 months (September to December 2025). Findings Included: 1) During a laboratory tour on 3/03/2026 at 2:00PM, six Reichert Refractix DSP Digital Refractometers (Serial Numbers rf17910001, rf17910002, rf17910003, rf17910004, rf17910005, rf17910006), were observed in use. 2) Review of the Reichert Ametek Refractix DSP Digital Refractometer manufacturer Instructions for Use (Version 13930000-101 Rev. C) revealed the following operational environment conditions on page 7: "Maximum Relative Humidity: 80% for temperatures to 31 degrees Celsius, decreasing linearly to 50% relative humidity at 40 degrees Celsius" 3) Review of the laboratory's PharmaWatch continuous monitoring temperature records revealed daily monitoring and recording of temperatures, but no monitoring or recording of humidity for any areas of the laboratory from September to December 2025. 4) Review of the laboratory's policy titled 'EQUIP-017-20 TEMPERATURE MONITORING SYSTEM' revealed no defined humidity ranges, monitoring or recording. 5) In an interview at 2:05PM, the Center Quality Assurance Supervisor confirmed the findings of humidity not defined, monitored and documented within the laboratory.
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 direct observation, review of laboratory's policies and procedures, instrument verification studies, donor deferral log, manufacturer's instructions, and interview with the Center Quality Assurance Supervisor, the laboratory failed to demonstrate reportable ranges and reference intervals (normal values) for Total Protein comparable to those established by the manufacturer and laboratory's patient population for six of six Reichert Refractix DSP Digital Refractometers. Findings Included: 1. During a laboratory tour on 3/03/2026 at 2:00PM, six Reichert Refractix DSP Digital Refractometers (Serial Numbers rf17910001, rf17910002, rf17910003, rf17910004, rf17910005, rf17910006), were observed in use. 2. Review of the laboratory's policies titled 'REFRACTOMETER EQUIP-008-014' and 'TOTAL PROTEIN DS-012-06' revealed no procedures for total protein calibration verification for minimum, mid-point and maximum value to verify the laboratory's reportable range and reference intervals to manufacturer's analytical claims and laboratory's patient population according to 493.1253. 3. Review of the laboratory's procedure Total Protein (DS-012-06) stated the following: "6.3 A donor is required to have TP that ranges between 6.0 g/100 mL - 9.0 g/100 mL" 4. Review of the laboratory's instrument verification studies 'Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ)', revealed a completion of a distilled water reading (0.0 g/mL), low control (6.0-6.4 g/mL) and high control (9.0-9.4 g/mL) performed three times on 6 Reichert Refractix DSP Digital Refractometers upon installation, but no further verification documentation of the reportable range and reference intervals established according to 493.1253(b)(1)(ii) with laboratory director signature of approval. 5. Review of the laboratory's donor deferral log revealed the following times a donor was deferred due to a Total Protein above the laboratory's criteria: Donor ID: 359973; Date: 12/29/2025; Serial Number: rf17910006; Total Protein: 10.4 Donor ID: 316750; Date: 12/18/2025; Serial Number: rf17910005; Total Protein: 10.1 Donor ID: 355959; Date: 12/17/2025; Serial Number: rf17910002; Total Protein: 10.0 Donor ID: 321054; Date: 12/17/2025; Serial Number: rf17910002; Total Protein: 9.8 Donor ID: 344938; Date: 12/17/2025; Serial Number: rf17910002; Total Protein: 9.8 Donor ID: 334449; Date: 12/3/2025; Serial Number: rf17910001; Total Protein: 9.7 Donor ID: 343116; Date: 11/26/2025; Serial Number: rf17910002; Total Protein: 10.8 Donor ID: 347221; Date: 11/26/2025; Serial Number: rf17910002; Total Protein: 9.5 Donor ID: 308242; Date: 11/21/2025; Serial Number: rf17910002; Total Protein: 10.0 Donor ID: 342293; Date: 11/20/2025; Serial Number: rf17910002; Total Protein: 10.2 Donor ID: 337166; Date: 11/19/2025; Serial Number: rf17910001; Total Protein: 10.2 Donor ID: 314463; Date: 11/17/2025; Serial Number: rf17910005; Total Protein: 10.0 Donor ID: 340873; Date: 11/17/2025; Serial Number: rf17910005; Total Protein: 10.5 Donor ID: 336309; Date: 11/7/2025; Serial Number: rf17910001; Total Protein: 9.6 Donor ID: 330019; Date: 11/3/2025; Serial Number: rf17910002; Total Protein: 9.8 Donor ID: 328019; Date: 10/17/2025; Serial Number: rf17910005; Total Protein: 10.6 Donor ID: 326356; Date: 10/17/2025; Serial Number:

	rf17910001; Total Protein: 9.5 Donor ID: 317155; Date: 10/9/2025; Serial Number: rf17910005; Total Protein: 9.4 Donor ID: 319413; Date: 10/2/2025; Serial Number: rf17910002; Total Protein: 9.6 6. Review of the Reichert Ametek Refractix DSP Digital Refractometer manufacturer Instructions for Use (Version 13930000-101 Rev. C) stated the following: "For easy evaluation, a Total Protein result of 6.0 to 9.0 g /100mL will be displayed in green. A result outside of that range will be displayed in red. The device measurement range is -1.0 to 11.0 g/100mL serum/plasma protein". 7. The laboratory was unable to provide documentation of verification that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population as required by 493.1253(b)(1)(ii). 8. In an interview at 2:05PM, the Center Quality Assurance Supervisor stated the laboratory directly used manufacturer's ranges, did not verify values beyond the range of 0 to 9.4 g/100mL, and did not verify if manufacturer reference intervals were appropriate to the laboratory's patient population.
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 the Center Quality Assurance Supervisor, the laboratory director failed to ensure verifications studies were complete, reviewed and approved for one of one test (Total Protein) performed on the Reichert Refractix DSP Digital Refractometers. Findings Included: 1. Review of the laboratory's policies titled 'REFRACTOMETER EQUIP-008-014' and 'TOTAL PROTEIN DS-012-06' revealed no procedures for total protein calibration verification for minimum, mid-point and maximum value to verify the laboratory's reportable range and reference intervals to manufacturer's analytical claims and laboratory's patient population according to 493.1253. 2. Review of the laboratory's instrument verification studies 'Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ)', revealed a completion of a distilled water reading (0.0 g/mL), low control (6.0-6.4 g/mL) and high control (9.0-9.4 g/mL) performed three times on 6 Reichert Refractix DSP Digital Refractometers upon installation, but no further verification documentation of the reportable range and reference intervals established according to 493.1253(b)(1)(ii) with laboratory director signature of approval. 3. In an interview at 2:05 PM, the Center Quality Assurance Supervisor confirmed the findings the laboratory directly used manufacturer's ranges, and the policy did not include complete procedures for calibration verification to verify the laboratory reportable range and reference intervals to manufacturer's analytical claims and laboratory's patient population with laboratory director signature of approval.