Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2195106	07/14/2022
Name of Provider or Supplier	**Street Address, City, State**	
Join Parachute Plasma Center	2605 Clarksville St, Paris, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. .
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 the review of the laboratory's records from December 2020 to June 2022, verification studies, and confirmed in an interview found the laboratory failed to have documentation of performed verification studies of accuracy, precision, reference ranges, and reportable ranges for two of six Reichert TS Meter D Refractometers for the test of total protein prior to patient testing. The findings were: 1. Review of the laboratory's records from December 2020 to June 2022 for Reichert TS Meter D Refractometers for the test of total protein revealed six Reichert TS Meter D Refractometers were in use. Instrument ID: rf92300001 SN: 14537-1020 Instrument ID: rf92300002 SN: 14532-1020 Instrument ID: rf92300003 SN: 14536-1020 Instrument ID: rf92300004 SN: 13167-0819 Instrument ID: rf92300005 SN: 15011-0621 Instrument ID: rf92300006 SN: 15255-0921 2. Further review of the laboratory's records from December 2020 to June 2022 revealed the following: Instrument ID: rf92300001 SN: 14537-1020 Put in use on 12/10/2020 Instrument ID: rf92300002

	SN: 14532-1020 Put in use on 12/10/2020 Instrument ID: rf92300003 SN: 14536-1020 Put in use on 12/10/2020 Instrument ID: rf92300004 SN: 13167-0819 Put in use on 12/7/2020 Instrument ID: rf92300005 SN: 15011-0621 Put in use on 12/7/2021 Instrument ID: rf92300006 SN: 15255-0921 Put in use on 12/3/2021 3. Review of the laboratory's verification studies for the above refractometers revealed no documentation of performed verification studies of accuracy, precision, reference ranges, and reportable ranges prior to patient testing for two of six Reichert TS Meter D Refractometers. Instrument ID: rf92300005 SN: 15011-0621 Instrument ID: rf92300006 SN: 15255-0921 4. An interview with the Director of Regulatory Affair and Quality Assistant Manager on 7/14/2022 at 12:05 pm in the conference room confirmed the above findings.