Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2154508	07/09/2019
Name of Provider or Supplier	**Street Address, City, State**	
Chi Arthritis And Rheumatology	6 Shackleford Drive, Little Rock, AR	

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
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: . Through a review of the validation studies for the Theratest DSX Immunoassay analyzer performed on November 29/2018, lack of documentation, and interview with staff, it was determined the laboratory failed to validate the method correlations for the DSX to verify that the manufacturer's reference intervals (normal ranges) are appropriate for the laboratory's patient population. As evidence by: A. The laboratory utilizes the Theratest DSX Immunoassay to process the following analytes: Single-Stranded Deoxyribonucleic Acid (ss-DNA), Double-Stranded Deoxyribonucleic Acid (dsDNA), Smith Antibody (SM), Ribonucleoprotein and Smith Antibodies (RNP/Sm), Sjogen-Syndrome Antigen A and B (SSA/SSB), Anti-topoisomerase 1 (ScL-70), Centromere, Anti-Cyclic Citrillinated Peptide (CCP ab), Rheumatoid factor (RF) Immunoglobin (Ig for A, G, and M), and Vitamin D (Vit D). B. A review of the validation studies for the Theratest DSX Immunoassay Analyzer performed on 11/29/2018 revealed no data was present (at time of survey) to verify that the manufacturer's reference intervals (normal ranges) are appropriate for the laboratory's patient population. C. Upon request, the laboratory was unable to provide method correlation data for the validation of the Theratest DSX Immunoassay analyzer. D. In

	an interview on 7/9/2019 at 11:00, the technical consultant (as listed on form CMS-209) confirmed that method correlation studies were not performed as part of the validation of the Theratest DSX Immunoassay analyzer.