Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2244423	05/28/2024
Name of Provider or Supplier	**Street Address, City, State**	
Greater Houston Rheumatology	9614 Huffmeister Road, Houston, 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 survey of the laboratory was conducted on 05/28/2025. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories). STANDARD LEVEL DEFICIENCIES were cited.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (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 (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (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 manufacturer instructions for use, review of laboratory's policies /procedures, calibration records and staff interview, the laboratory failed to document 2 of 4 manufacturer required optical density reader's calibrations, the May 2023, and the April 2024 calibrations. Findings included: 1. Review of manufacturer instructions for use for the TheraTest Labs ELx800 optical density meter revealed the manufacturer required the Absorbance Plate Test to calibrate the optical density reader. There was no definition of frequency requirements for the Absorbance Plate Test. 2. Review of laboratory's policies/procedures revealed no definition of frequency requirements for Absorbance Plate Test for the TheraTest Labs ELx800 instrument. 3. In an interview on 05/28/2024 at 1137 hours in the laboratory the Testing Person number 1 (as indicated on submitted form CMS 209) stated that she thought the

	Absorbance Plate Test was performed annually but would like to confirm that with the manufacturer. 4. In a phone consultation with the manufacturer's representative on 05 /28/2024 at 1140 hours in the laboratory, the manufacturer's representative told laboratory's Testing Person number 1 that the Absorbance Plate Test was performed every 6 months with a standardized plate provided by the manufacturer. 5. Review of laboratory's Absorbance Plate Test calibration records for 2022, 2023 and 2024 revealed the laboratory performed Absorbance Plate Test on 11/02/2022 and 10/03 /2023. No Absorbance Plate Test calibration records could be located for May 2023 or April 2024. 6. In an interview on 05/28/2024 at 1140 hours in the laboratory the Testing Person number 1 confirmed the findings.