Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D2083222	12/07/2020
Name of Provider or Supplier	**Street Address, City, State**	
Reddy Rheumatology Of Nwi	118 E 90th Drive, Merrillville, IN	

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
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory director failed to maintain the quality assessment program from December 2018 to December 7, 2020. Findings included: 1. Review of "General Quality Assessment Policy," version number "052113," signed by the laboratory director on 5-15-2018 indicated the following: a. The "Complaints and Corrective Actions File" was to be reviewed by the "laboratory director/supervisor" once a quarter. b. Quarterly meetings were required to "discuss all issues, including quality control." c. During the quarterly meetings, the laboratory director/supervisor was to review the "complaint forms," and "corrective action forms" and "all aspects of the quality assessment procedures instituted since the previous meeting." d. Meeting minutes of quarterly meetings were to be documented in writing. 2. In interview on 12-7-2020 at 11:04 AM, upon request for documentation of Quality Assessment reviews from 2018 to current, SP5, Technical Supervisor, indicated quarterly quality assessment meetings were not held and there was no documentation of quality assessment reviews. SP5 further indicated the "Complaints and Corrective Actions File" was not reviewed quarterly, as required by the "General Quality Assessment Policy." SP5 indicated it was unknown when the last quality assessment review was performed. 3. Review of "Clinical Laboratory Improvement Amendments (CLIA) Application For Certification" (CMS-116} form, signed by the laboratory director on 10-12-2020 indicated the laboratory performs 4,763 tests annually.