

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D2083222	(X3) Date Survey Completed 03/15/2022
Name of Provider or Supplier Reddy Rheumatology Of Nwi	Street Address, City, State 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
D5313	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b)</p> <p>The laboratory must document the date and time it receives a specimen.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document the time it receives patient specimens for nine of 10 patients (PT#2-PT#10) reviewed. Findings include: 1. Review of patient records indicated that nine patients (PT#2-PT#10) did not have their specimen collection time recorded. PT#2 tested on 1/9/21 for 25 hydroxyvitamin D (25-OH Vitamin D) PT#3 tested on 3/1/21 for single-stranded deoxyribonucleic acid (ssDNA) PT#4 tested on 3/4/21 for cyclic citrullinated peptide (CCP) PT#5 tested on 4/22/21 for rheumatoid factor immunoglobulin M (RF IgM) PT#6 tested on 5/22/21 for tuberculosis (TB) PT#7 tested on 7/20/21 for CCP PT#8 tested on 10/2/21 for chromatin PT#9 tested on 1/29/22 for rheumatoid factor immunoglobulin G (RF IgG) PT#10 tested on 2/26/22 for 25-OH Vitamin D 2. On 3 /15/2022 at 4:21 pm, SP1 indicated that the patient specimen collection time was not being recorded for patient samples that are not sent to other laboratories. 3. The total annual testing volume sub-specialties of mycobacteriology, general immunology, and endocrinology is approximately 5450.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p>

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to provide equipment to allow personnel to follow the approved procedure for one of 15 tests performed (QuantiFERON TB Gold Plus). Findings include: 1. The procedure manual for "QuantiFERON - TB Gold Plus" (approved 10/12/2020) states that a "microplate shaker capable of speeds between 500 and 1000 rpm" is "required but not provided" and instructs the user to "cover [the] plate with a lid and mix thoroughly for 1 minute at 500 to 1000 rpm using a microplate shaker." 2. On 03/15/2022 at 2:34 pm, upon requesting the microplate shaker's location, SP1 acknowledged that the laboratory did not have a microplate shaker. SP1 indicated that they were swirling the plate on the countertop using their hand instead of using a microplate shaker. 3. The annual testing volume for QuantiFERON - TB Gold Plus is approximately 275.