Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D2083222	04/03/2024
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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to follow policies for personnel competency assessment including performing direct observation and including results from American Proficiency Institute (API) in the assessment for one (SP-3) of one testing personnel. Finding include(s): 1. Review of American Proficiency Institute (API) "Attestation Statement", signed by the laboratory director on 10/26/23, indicated SP-3, (testing personnel, technical supervisor and general supervisor) performed proficiency testing for Event #2, 2023 for Rheumatoid Factor (RA/RF) on 8/19/23 that resulted in an "unacceptable" performance of 60%. 2. Review of the "General Quality Assessment Policy", signed by the laboratory director on 10/12/20, required the following for personnel competency: a) "The results from the API/CAP/TheraTest Laboratories, Inc surveys will be the measure of an employee's competence... which allows the supervisor/laboratory director to determine the quality of the laboratory technician's work." b) "The laboratory director will complete a personnel evaluation... at least once a year for all other employees involved with the testing and reporting of results." c) The "General Quality Assessment Policy" further explained competency assessment will contain "Direct observations of routine patient test performance, including specimen handling, processing and testing." 3. Review of the "Competency Assessment" for SP-3 completed on 3/25/24, indicated: a) The laboratory director signed off on competency, but the 60% failure for event 2, 2023 was not documented. b) The following (six) assessment categories were listed as being reviewed by the laboratory director: 1) Direct Observation of testing performance including specimen handling, processing,

	and testing 2) Monitoring of recording and reporting results 3) Review of Intermediate test results, worksheets, quality control (QC), Proficiency Testing (PT) 4) Direct Observation of performance of instrument maintenance and function checks 5) Assessment of performance using PT samples or previous analyzed specimens 6) Assessment of problem-solving skills. 4. On 4/03/24 at 11:10 am, Sp-3 confirmed that competency was completed remotely due to the SP-1 (laboratory director) living in another state. SP-3 acknowledged the competency document was completed by SP-3, then emailed to the laboratory director for a signature, the PT failure was not documented, and no direct observation occurred. 5. The following patients were tested by SP-3 from 8/01/23 through 1/16/24: Patients Date Analyte(s)_ PT# 1 08/01/23 RA /RF PT# 2 09/06/23 RA/RF PT# 3 10/17/23 RA/RF PT# 4 11/21/23 RA/RF PT# 5 12 /15/23 RA/RF PT# 10 01/16/24 RA/RF, Immunoglobulin M (IgM), Immunoglobulin G (IgG), Immunoglobulin A (IgA) 6. The annual test volume for Immunology was 4765.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to ensure a corrective action was performed as required per policy for one (2nd Event) of three events in 2023 for Rheumatoid Factor (RA/RF). The laboratory received an "unacceptable" performance of 60% using the test system: Thera Test LABS Advanced Immunoassays. Findings: 1. Review of "American Proficiency Institute Performance Summary", approved by the laboratory director on 10/26/23, for the 2nd Event of 2023 revealed a 60% score for Rheumatoid Factor (RA/RF). Samples RF-06 and RF-10 received an "unacceptable" performance for "negative" reported results. 2. Review of "Corrective and Preventive Action Form", signed by SP-1 (laboratory director) on 10/26/23 and recorded by SP-3 (testing personnel, technical supervisor and general supervisor) on 9/15/24, indicated that SP-1 and SP-3 acknowledged the Proficiency Test sample failure of the 2nd Event of Rheumatoid Factor (RA/RF). Under "Corrective and Preventative Action taken" a note stated, "the two samples that produced the failure could not be retested because the samples were disposed of." There was no mention of how samples should be processed in the future so corrective action can be performed per policy. 3. A review of the "General Quality Assessment Policy", signed by the laboratory director on 10/12/20, under "Personnel Competency Assessment policies", states, "When a technician fails a API/CAP/Thera Test Laboratories, Inc. test, he/she repeats the test under the supervision of the Laboratory Director/Supervisor." 4. On 4/03/24 at 11:10 am, during an interview with Sp-3 confirmed the remedial action was not completed per policy. 5. The following patients' samples were quantified using test system: Thera Test LABS Advanced Immunoassays after the proficiency failure: Patients Date Analyte(s)_ PT# 1 08/01/23 RA/RF PT# 2 09/06/23 RA/RF PT# 3 10/17/23 RA/RF PT# 4 11/21/23 RA/RF PT# 5 12/15/23 RA/RF PT# 10 01/16/24 RA/RF, Immunoglobulin M (IgM), Immunoglobulin G (IgG), Immunoglobulin A (IgA) 6. Annual Test volume for Immunology was 4765.