

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D2083222	(X3) Date Survey Completed 06/28/2018
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on document review and interview, the laboratory failed to ensure the laboratory was enrolled in an HHS-approved proficiency testing (PT) program for Rheumatoid Factor (RF) testing during two of six testing events reviewed. Findings include: 1. Review of "General Quality Assessment Policy," approved by the Laboratory Director on 6-20-2018 read: "Reddy Rheumatology subscribes to the College of American Pathologists (CAP), which meets the criteria in Subpart I..." and "The CAP Surveys program is applied for every year at..." 2. Review of PT documentation indicated the laboratory did not enroll in PT for RF testing during Event 1, 2017 and Event 1, 2018. 3. Review of patient records indicated Patient #9 had an RF test performed on 4-15-2018, and Patient #10 had an RF test performed on 2-25-2018, when the laboratory had not enrolled in a PT program. 2. In interview on 6-28-2018 at 10:55 AM, SP#1 indicated PT testing for RF testing for 2018 was ordered on 5-24-2018, after Event 1 was due to the PT provider.</p>
D2003	<p>ENROLLMENT CFR(s): 493.801(a)(2)(ii)</p>

For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1)

This STANDARD is not met as evidenced by:

Based on document review and interview, the laboratory failed to maintain the accuracy of testing procedures for one of fourteen tests not included in subpart I during 2017, and in 2018, prior to the survey date. Findings include: 1. Review of "General Quality Assessment Policy," approved by the Laboratory Director on 6-20-2018, read: "For tests that are not offered by CAP or other accredited proficiency testing agencies, in order to establish and maintain the accuracy of its testing procedures...Reddy Rheumatology participates twice annually in a proficiency testing program available at: Thera Test Laboratories, Inc..." 2. Review of "Test Methodology and Annual Test Volume Log," (Enclosure I), signed by the Laboratory Director on 6-20-2018, indicated the laboratory performs Vitamin D (Vit D) testing. 3. Review of proficiency testing documentation indicated the laboratory did not perform a verification of the accuracy of its Vit D test during 2017, and in 2018, prior to survey date. 4. Review of patient testing indicated the laboratory performed Vit D testing on Patient #1 (6-17-2018); Patient #3 (5-26-2018); Patient #4 (6-17-2018); Patient #5 (6-17-2018); Patient #7 (6-17-2018); Patient #9 (4-15-2018); and Patient #10 (2-25-2018). 5. In interview on 6-28-2018 at 10:55 AM, SP#1 indicated the laboratory did not verify the accuracy of Vit D testing in 2017, nor had the laboratory verified the accuracy of Vit D testing in 2018 prior to the survey date.

D5311

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL
CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

REPEAT CITATION Based on document review and staff interview, the laboratory failed to follow written procedures for 3 of 3 testing procedures reviewed. Findings include: 1. Review of policy / procedure titled: "ANA Screen," approved by the Laboratory Director on 9-30-2016, read: "For separation of the serum, the sample is centrifuged for 10 minutes at ~2000 rpm (500 x g)." 2. Review of policy / procedure titled: "Rheumatoid Factor IgM and RF/3 (IgM, IgG, IgA)," approved by the Laboratory Director on 9-30-2016, read: "For separation of the serum, the sample is centrifuged for 10 minutes at ~2000 rpm (500 x g)." 3. Review of policy / procedure titled: "25-OH Vitamin D and other hydroxylated metabolites in serum or plasma," approved by the Laboratory Director on 9-30-2016, read: "For separation of the clot /cells and serum/plasma, the specimens are centrifuged for 10 minutes at ~2000 rpm (500 x g)." 4. Review of patient records indicated the following: a. Patient #1 had a Rheumatoid Factor (RF) test performed on 6-16-2018 and a Vitamin D (Vit D) test performed on 6-17-2018. b. Patient #3 had an RF test performed on 5-27-2018 and a Vit D test performed on 5-26-2018. c. Patient #4 had an RF test performed on 6-16-2018 and a Vit D test performed on 6-27-2018. d. Patient #5 had a Vit D test

performed on 6-17-2018. e. Patient #6 had an Antinuclear Antibody Screen (ANAcSr) performed on 6-16-2018. f. Patient #7 had an RF test performed on 6-16-2018 and a Vit D test performed on 6-17-2018. g. Patient #8 had an ANAcSr performed on 6-16-2018. h. Patient #9 had an RF and a Vit D test performed on 4-15-2018. i. Patient #10 had an RF and a Vit D test performed on 2-25-2018. 5. On 6-28-2018 at 11:35 AM, documentation of centrifuge timer and revolutions per minute (RPM) checks were requested from SP#1. The checks were not provided.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:
REPEAT CITATION Based on document review, observation, and staff interview, the laboratory failed to ensure testing was performed following the manufacturer's instructions for 3 of 4 test procedures reviewed (Vitamin D, Rheumatoid Factor, and Antinuclear Antibody Screen). Findings include: 1. Review of manufacturer's instructions for the Vitamin D (Vit D) test, titled "25-OH Vitamin D ELISA," version "07/08/2013," copyright unknown, read: "If the assay will not be completed within 48 hours, samples should be frozen at -20C or lower." 2. Review of manufacturer's instructions for the Rheumatoid Factor (RF) test, titled "EL-RF/3TM (IgM-IgG-IgA), copyright unknown, read: "For long-term storage freeze the specimens below -70C." 3. Review of manufacturer's instructions for the Antinuclear Antibody Screen (ANAcSr) test, titled "EL-ANAcSrTM), copyright unknown, read: "If testing cannot be completed within 14 days of collection, store the sera at -20C or below." 4. Patient records indicated: a. Patient #4 had blood drawn for an RF and Vit D test on 5-29-2018. The RF test was performed on 6-16-2018 and the Vit D test was performed on 6-17-2018. b. Patient #5 had blood drawn for Vit D on 5-22-2018. The Vit D test was performed on 6-17-2017. c. Patient #6 had blood drawn for and ANAcSr on 5-30-2018. The ANAcSr test was performed on 6-16-2018. d. Patient #7 had blood drawn for RF and Vit D on 6-1-2018. The RF test was performed on 6-16-2018 and the Vit D test was performed on 6-17-2018. e. Patient #9 had blood drawn for RF and Vit D on 3-26-2018. Both tests were performed on 4-15-2018. 5. Review of the freezer "Temperature Log" indicated freezer temperatures were as follows: Date Temperature in Degrees Celsius (C) _____ 3-26-2018 -20 3-27-2018 NR 3-28-2018 NR 3-29-2018 NR 3-30-2018 NR 4-1-2018 NR 4-2-2018 -20 4-3-2018 NR 4-4-2018 NR 4-5-2018 NR 4-6-2018 NR 4-7-2018 NR 4-8-2018 -20 4-9-2018 NR 4-10-2018 NR 4-11-2018 NR 4-12-2018 NR 4-13-2018 -20 4-14-2018 NR 4-15-2018 -20 5-23-2018 NR 5-24-2018 NR 5-28-2018 NR 5-29-2018 NR 5-30-2018 NR 5-31-2018 NR 6-1-2018 NR 6-2-2018 NR 6-3-2018 NR 6-4-2018 NR 6-5-2018 NR 6-6-2018 NR 6-7-2018 NR 6-8-2018 NR 6-9-2018 NR 6-10-2018 NR 6-11-2018 NR 6-12-2018 NR 6-13-2018 NR 6-14-2018 NR 6-15-2018 NR 6-16-2018 -19 6-17-2018 -20 NR = Not Recorded 6. On 6-28-2018 at 11:27 AM, the freezer temperature was observed to be 14.9 degrees Celsius (C) and at 12:42 PM on the same date, the freezer temperature was observed to be at -9.6C. 7. In interview on 6-28-2018 at 11:35 AM, SP#1 acknowledged temperatures were not within manufacturer's requirements on the above dates. SP#1 also acknowledged temperatures were not taken daily while patient specimens were in the freezer.

D6103**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory director failed to follow established policies and procedures to monitor the competency of one of two testing personnel at least semi annually during the first year the individual performed patient testing. Findings include: 1. Review of "Laboratory Personnel Report (CLIA)" form (CMS-209), signed by the laboratory director on 6-20-2018, indicated SP#2 was a testing personnel. 2. Review of policy / procedure titled: "General Quality Assessment Policy," approved by the laboratory director on 6-20-2018 read: "The Laboratory Director / Supervisor will complete a personnel evaluation at least twice a year for all newly hired personnel and at least once a year for all other employees involved with the testing and reporting of results." 3. Review of personnel records indicated SP#2, hire date 10-21-2016, did not have a competency assessment from date of hire to date of survey. 4. Review of patient records indicated SP#2 performed patient testing as follows: Patient # Date _____ 9 4-15-2018 10 2-25-2018 5. In interview on 6-28-2018 at 10:41 AM, SP#1 indicated SP#2 had not had a competency assessment performed.