

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0586412	(X3) Date Survey Completed 04/03/2019
Name of Provider or Supplier Rheumatology Services Medical Group	Street Address, City, State 8329 Brimhall Rd Ste 801, Bakersfield, CA	
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
D2075	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on reviews of the second quarter (Q2-2017), and first quarter (Q1-2018) of the College of the American Pathologists (CAP) proficiency testing records, random patient test results, and interview with the testing personnel, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event. The findings included: a. CAP reported 0% for RA /RF analyte. Analyte: Score: Event/Year: RA/RF 0% Q2-2017 RA/RF 60% Q1-2018 Abbreviations: RA=Rheumatoid Arthritis RF=Rheumatoid Factor b. For six (6) out of eight (8) random patient test results reviewed covering period from 3/15/2017 to 11/3 /2018, the laboratory analyzed and reported RA/RF analytes during the period of the laboratory received unsatisfactory proficiency testing scores. c. The testing personnel confirmed (4/3/2019, 1330) that the laboratory received the above unsatisfactory proficiency testing scores.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on reviews of the second quarter (Q2-2017), and first quarter 2018 (Q1-2018) of the College of the American Pathologists (CAP) proficiency testing records,</p>

random patient test results, and interview with the testing personnel, it was determined that the laboratory failed to at least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. The findings included: a. CAP reported the following unsatisfactory proficiency testing scores. Analyte: Score: Event/Year: Gran Abs 60% Q2-2017 MPV 20% Q2-2017 Gran Abs 40% Q1-2018 MCV 60% Q1-2018 Abbreviations: Gran Abs= Granulocyte Absolute MPV= Mean Platelet Volume MCV= Mean Corpuscular Volume b. For eight (8) out of eight (8) random patient test results reviewed covering period from 5/8/2018 to 2/15/2018 , the laboratory analyzed and reported Complete Blood Count (CBC) analytes which included the above analytes during the period of the laboratory received proficiency testing failures. c. The testing personnel confirmed (4/3/2019, 1330) that the laboratory received the above unsatisfactory proficiency testing scores.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iv)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:
Based on reviews of the second quarter (Q2-2017), first quarter (Q1-2018) of the College of the American Pathologists (CAP) proficiency testing records, random patient test results, and interview with the testing personnel, it was determined that the laboratory director failed to ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. See D 2078 and D 5217.