

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D1036087	(X3) Date Survey Completed 01/28/2019
Name of Provider or Supplier Regional Medical Laboratory, Inc	Street Address, City, State 1910 S Falcon Ave, Claremore, OK	
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
D0000	The recertification survey was performed on 01/28/19. The laboratory was found to be in compliance with standard-level deficiencies cited. The findings were reviewed with the technical consultant and the patient service centers director at the conclusion of the survey.
D6016	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p> <p>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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, and interview with the technical consultant and the patient service centers director, the laboratory director failed to ensure proficiency testing samples were tested as required under Subpart H. Findings include: (1) At the beginning of the survey, the surveyor reviewed the 2018 proficiency testing records. It was identified for 5 of the 9 events reviewed, the attestation statements had been signed approximately 3 weeks to 3 months after the samples had been tested (not within a time frame for the director to attest that, at the time of testing, the proficiency samples had been tested as required) as follows: (a) First Core Chemistry Event: The samples were tested on 01/25/18 and the attestation statement had not been signed by the laboratory director until 02/14/18; (b) Second Core Chemistry Event: The samples were tested on 05/30/18 and the attestation statement had not been signed by the laboratory director until 09/12/18; (c) Second Hematology/Coagulation Event: The samples were tested on 07/25/18 and the attestation statement had not been signed by the laboratory director until 09/12/18; (d) Second Immunology Event: The samples</p>

were tested on 08/09/18 and the attestation statement had not been signed by the designee until 09/12/18; (e) Third Hematology/Coagulation Event: The samples were tested on 11/20/18 and the attestation statement had not been signed by the laboratory director until 12/12/18. (2) The surveyor reviewed the findings with the technical consultant and the patient service centers director, and explained the attestation statement must be signed to definitively attest to the fact proficiency samples were tested in the same manner as patient specimens.