Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0473997	11/06/2018
Name of Provider or Supplier	**Street Address, City, State**	
Regional Medical Laboratory	1919 S Wheeling Ave, Suite 100, Tulsa, 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 11/06/18 The laboratory was found to be in compliance with standard-level deficiencies cited. The findings were reviewed with the general supervisor #1 at the conclusion of the survey.
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 a review of records, written policy, and interview with general supervisor #1, the laboratory failed to have a written clinical consultant and general supervisor competency policy based on the position responsibilities as listed in Subpart M. Findings include: (1) During the survey, surveyor #2 reviewed the competency assessment policy. It did not include guidance for assessing the competency of the clinical consultant and general supervisor; (2) The surveyors then reviewed personnel records for competency assessments performed during 2017 and 2018. There was no evidence clinical consultant and/or general supervisor competencies, based on their job responsibilities, had been performed; (3) The surveyors asked general supervisor #1 if a written policy to evaluate the clinical consultant and general supervisor based on job responsibilities was available. General supervisor #1 stated a policy to evaluate the clinical consultant and general supervisor based on job responsibilities had not been written or performed.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper

	storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of records and interview with general supervisor #1, the laboratory failed to monitor temperatures. Findings include: (1) At the beginning of the survey, general supervisor #1 stated to the surveyors the Quantimetrix Spinal Fluid Cell Count Control (level 1 and level 2) Quality Control material were stored in the laboratory refrigerator #1 (Frigidaire) within a range of 2 to 8 degrees C (Centigrade); (2) Later during the survey, surveyor #2 reviewed the temperature records from April 2017 through September 2018 and identified the following: (a) Temperatures not documented on the date of patient testing as follows: (i) 03/1/17 (ii) 06/16/17 (iii) 09 /01/17 (iv) 09/18/17 (3) The surveyors reviewed the findings with general supervisor #1 who stated the above temperatures had not been documented.
D5543	HEMATOLOGY CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of records and interview with general supervisor #1, the laboratory failed to test one control material each 8 hours of operation; and failed to test control specimens in duplicate when performing manual sperm counts using a hemacytometer. Findings include: (1) At the beginning of the survey, general supervisor #1 stated to the surveyors sperm counts were performed using a hemacytometer; (2) Later during the survey, surveyor #1 reviewed records for patient sperm counts performed in August 2017, February 2018, and October 2018. The following was identified: (a) There was no evidence a control material had been performed for 1 of 39 days of patient testing (testing performed on 02/20/18; (b) There was no evidence control materials had been tested in duplicate for 38 of 38 days of patient testing (the days of testing were 08/02,04,10,11,14,18,21,23,25,28,31/17; 02 /01,07,08,12,15,16,19,21,26,27,28/18; and 10/02, 04,05,08,09,10,15,16,22,23,24,25,26,29,30,31/18). (3) Surveyor #1 reviewed the records with general supervisor #1 who stated there was no evidence that a control had been tested on 02/20/18; and the controls had not been tested in duplicate as indicated above.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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; This STANDARD is not met as evidenced by: Based on a review of records and interview with general supervisor #2, the laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H. Findings include: (1) At the beginning of the survey, the surveyor reviewed 2017 and 2018 proficiency testing records. It was identified for 2 of 3 events, the attestation statements had been signed approximately 2 months after the samples had been tested (not within a timeframe for the director to attest that, at the time of testing, the proficiency samples had been tested as required) as follows: (a) First 2017 Hematology Event - The samples had been tested on 03/29/17 and the attestation statement had not been signed by the laboratory director until 05/24/17; (b) First 2018 Hematology Event - The samples had been tested on 03/27/18 and the attestation statement had not been signed by the laboratory director until 05/23/18. (2) The surveyor reviewed the findings with general supervisor #1 and explained that attestation statements must be signed within a timeframe to definitively attest to the fact that proficiency samples were tested in the same manner as patient specimens.