Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0656687	11/07/2018
Name of Provider or Supplier	**Street Address, City, State**	
Diagnostic Laboratory Of Oklahoma	1145 S Utica Ave, Suite G-162, 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	Recertification survey was performed on 11/06/18 and 11/07/18. The findings were reviewed with the laboratory manager, quality assessment specialist, technical supervisor and lab manager during an exit conference performed at the conclusion of the survey. The laboratory was found to be in compliance with standard-level deficiencies cited.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of records and interview with the lead technologist and quality assessment specialist, the laboratory failed to verify the accuracy of testing when the proficiency testing program did not evaluate submitted results. Findings include: (1) On the first day of the survey, surveyor #2 reviewed 2017, and 2018 proficiency testing records and identified the following had not been evaluated by the proficiency testing program: (a) General Chemistry/Therapeutic Drugs (i) C-A 2017 event (aa) Sodium - CHM-01 (2) Surveyor #2 further reviewed the records and could not locate documentation verifying the laboratory had performed a self-evaluation of the non-graded results; (3) Surveyor #2 asked the lead technologist and quality assessment specialisit if the results had been documented as evaluated. They both reviewed the records and stated the non-graded results had not been documented as reviewed.
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: Based on a review of records, manufacturer's instructions, and interview with the QA specialist and lead technologist, the laboratory failed to follow the manufacturer's instructions for implementing reagents. Findings include: (1) On the first day of the survey, the lead technologist stated to surveyor #1 PT/INR (Protime/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing were performed on the Sysmex CA-620 analyzer (note: the INR value was calculated using the normal patient PT geometric mean determined by the laboratory). The lead technologist also stated the following lot numbers had been put into use on 07/01/18: (a) PT reagent - Dade Innovin lot #549715A (b) PTT reagent - Dade Actin FSL lot #556926 (c) Dade CiTrol control level 1 lot #548074 (d) Dade CiTrol control level 3 lot #556501 (2) On the second day of the survey, surveyor #1 reviewed the manufacturer's implementation instructions for new reagent lot numbers (the surveyor had a copy of the manufacturer's implementation instructions obtained from another laboratory). For the method correlation and quality control sections, the instructions stated: (a) Section II titled "Method Correlation" stated: (i) "40 samples: 20 normal, 20 abnormal *Normal samples (Section I) may be used for the Method Correlation and Verification of Reference Range" *Abnormal Samples should span the Reportable Range of assay" (ii) "Assay samples of current and new lot number reagents simultaneously or within 1 hour of each other" (iii) "Calculate Linear Regression statistics" (b) Section III titled "Quality Control" stated: (i) "Assay new lot number of QC material with the new lot of reagent in PTN and APTTN protocols" (ii) "Collect a minimum of 30 data points over multiple days and stability limits of control" (iii) "Calculate the mean, 2 SD and 3 SD range" (3) Surveyor #1 reviewed the implementation records for the reagent lot changes. The following was identified: (a) For the method correlation, the laboratory had not used 20 normal and 20 abnormal samples as follows: (i) PT - The laboratory had used 9 normal and 31 abnormal samples; (ii) PTT - The laboratory had used 19 normal and 21 abnormal samples. (b) For the quality control, the laboratory had not used a minimum of 30 data points as follows: (i) Level 1 PT and PTT - The laboratory had used 25 data points: (ii) Level 3 PT and PTT - The laboratory had used 25 data points. (4) Surveyor #1 reviewed the findings with the QA specialist and lead technologist. Both stated the laboratory had not followed the manufacturer's instructions as indicated above.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical supervisor, laboratory manager, QA specialist, and lead technologist, the laboratory failed to have a policy

	for monitoring the effectiveness of their IQCP. Findings include: (1) On the first day of the survey, the lead technologist stated the following to surveyor #1: (a) The laboratory performed Serum Qualitative Pregnancy testing using the Fisher Healthcare Sure-Vue Serum/Urine hCG test kit; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test. (2) Surveyor #1 reviewed the IQCP (dated as approved on 12/11/15) and identified the following: (a) Although a QA (Quality Assessment) review had been performed on 01/25/18 (as a review for 2017), only the front page of the two-sided form had been completed, therefore, surveyor #1 determined the review was incomplete; (b) The QA portion of the IQCP did not address how the laboratory will monitor the QCP (Quality Control Plan) and did not specify the frequency for evaluating the QCP to ensure it continued to provide accurate and reliable results. (3) Surveyor #1 reviewed the records with the technical supervisor, laboratory manager, QA specialist, and lead technologist, and asked if there was a policy to address how the laboratory will monitor the QCP, including the frequency of the reviews and if there was additional documentation to show a complete QA review had been performed on 01/25/18. All of the persons stated that QA reviews were to be performed annually, but the laboratory did not have a policy that specified how the QCP will be monitored and the frequency. In addition, they stated that the QA review performed on 01/25/18 was not complete.