Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2143415	04/06/2018
Name of Provider or Supplier	**Street Address, City, State**	
D K Shah Md Pc	117 Mary'S Avenue - Ste 102, Kingston, NY	

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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on the surveyor's review of laboratory records and confirmed in an interview with the practice administrator and testing person on April 6, 2018 at approximately 11:15 AM, the laboratory was found to be testing without a valid CLIA certificate from September 8, 2017 until January 26, 2018. FINDINGS: 1. The laboratory brought the Beckman Coulter AcT diff 2 hematology analyzer to this facility from the practice's other location but failed to apply for a CLIA certificate for this location. Per section 493.43 of Subpart C of the CLIA Regulations, all laboratories performing nonwaived testing must file a separate application for each laboratory location. 2. Approximately 1700 patient CBCs were tested during the time the laboratory did not have a valid CLIA certificate.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's records and confirmed in an interview with the practice administrator and testing person, the laboratory failed to establish and verify the performance specifications for the Beckman Coulter AcT diff 2 hematology analyzer which was installed in September of 2017. Findings: 1. On April 6, 2018 at approximately 11:30 AM, the practice administrator and testing person confirmed that although there were records indicating that calibration, accuracy and precision were performed at the time of installation, there were no records of linearity (reportable range) and reference range determinations as part of a complete validation of the Beckman Coulter AcT diff 2 analyzer which was installed in September of 2017. 2. Approximately 2400 patient specimens were tested and reported for hematology when the above analyzer was used for patient testing from September 8, 2017 to April 6, 2018.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on the surveyor's review of validation documentation for the Beckman Coulter AcT Diff 2 hematology analyzer, the laboratory director failed to ensure that validation studies were complete. Refer to D5421.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on the surveyor's review of personnel records and confirmed in an interview with the practice administrator and testing person, the laboratory director failed to specify, in writing, the duties and responsibilities of the testing person involved in all phases of hematology testing.