Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2132145	03/13/2018
Name of Provider or Supplier	**Street Address, City, State**	
General Physician Pc	45 Spindrift Drive, Suite 100, Buffalo, 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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on a surveyor's review of the manufacturer's packet inserts for the Accutest URS-10 Urine Reagent Strips and confirmed in an interview with laboratory and operation managers, the laboratory failed to follow the Accutest URS-10 manufacturer's requirements for performing external positive and negative controls with each new vial and failed to document the lot number and the expiration date of each vial of the Accutest URS-10 opened. FINDINGS: The laboratory and operation managers confirmed on March 13, 2018 at approximately 2:00 PM, the laboratory failed to document the lot number and the expiration date of each vial of the Accutest URS-10 opened and failed to perform and document the required external positive and negative quality controls. Approximately 5 urine patient specimens were tested from 10/19/2017 through survey date.
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 surveyor's review of the laboratory's policy and procedure manuals and

	confirmed in an interview with laboratory and operation managers, the laboratory failed to establish a comprehensive written policy and procedure that includes the six required components to assess testing personnel's competency. FINDINGS The laboratory and operations managers confirmed on March 13, 2018 at approximately 2: 10 PM, the laboratory failed to establish a written competency evaluation policy to monitor individual's competency based on the six criteria: 1. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; 2. Monitoring the recording and reporting of test results; 3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; 4. Direct observations of performance of instrument maintenance and function checks; 5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and 6. Assessment of problem solving skills.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on a surveyor's review of the laboratory's policy and procedure manuals and confirmed in an interview with laboratory and operation managers, the laboratory failed to establish a written QA policy to include a mechanism to monitor, assess and when indicated correct problems identified in the general laboratory system for hematology testing.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on a surveyor's review of the laboratory's policy and procedure manuals and confirmed in an interview with laboratory and operation managers, the laboratory failed to establish a written procedures to include: patient preparation, specimen collection, specimen labeling, including patient name or unique patient identifier, specimen storage and preservation and specimen acceptability and rejection. FINDINGS: The laboratory and operation managers confirmed on March 13, 2018 at approximately 2:30 PM, the laboratory failed to have written preanalytic procedures for patient preparation, specimen collection, specimen labeling, including patient name or unique patient identifier, specimen storage and preservation and specimen acceptability and rejection.

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 surveyor's review of the laboratory's temperature records, temperature policy, and confirmed in an interview with laboratory and operation managers, the laboratory failed to monitor the room temperature from 10/19/2017 through survey date. FINDINGS: 1. The laboratory and operation managers confirmed on March 13, 2018 at approximately 2:30 PM, the laboratory failed to follow the Accutest URS-10 Urine Reagent Strips and Sysmex XS 1000i hematology analyzer manufacturers requirements for room temperatures from 10/19/2017 through survey date. 2. There were no room temperature records available for review at survey.
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 a surveyor's review of the laboratory's policy and procedure manuals and confirmed in an interview with laboratory and operation managers, the laboratory director failed to specify, in writing, the duties and responsibilities for the testing personnel and laboratory manager involved in all phases of hematology testing. Refer to D5209