Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1105632	05/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Physicians Group Services Pa D/B/A	421 Kingsley Ave Ste 100, Orange Park, FL	

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
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on record review and laboratory staff interview, the laboratory did not test proficiency test samples the same number of times it tests patient samples for two of six chemistry events reviewed. (College of American Pathologists second event 2016 and first event 2017). The findings include: Review of the laboratory's College of American Pathologists (CAP) proficiency testing records showed the following for the third testing event of 2016: DAI-4, DAI-5, and DAI-6 were tested on 8/10/16 at 8:06am, 8/11/16 at 8:13am, 8/12/16 at 8:48am and 11:34am. The tests performed were: Creatinine quantitative and Specific Gravity quantitative. Review of the laboratory's CAP proficiency testing records showed the following for the first event of 2017: UDS-01, UDS-02, UDS-03, UDS-04, UDS-05 were tested on 3/15/17 at 9:05am and 14:54. The tests performed were: Ethanol and Methadone. Interview with the technical consultant on 5/30/18 at 9:23am confirmed that the laboratory does not routinely test patient samples more than once and proficiency testing samples for the events were tested multiple times.
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 record review and staff interview, the facility failed to have a program in place that evaluates the competency of its testing personnel, general supervisor, technical supervisor, and technical consultant for two of two years reviewed (2016-2018). The findings include: The facility was unable to provide documentation of a personnel competency program. The interview with the technical consultant on 5/30 /18 at 12:30 PM confirmed that the competency program in place did not meet the CLIA requirements of competency assessment.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of College of American Pathologists (CAP) proficiency testing results and staff interview, the laboratory failed to verify the accuracy of analytes that did not receive a grade for 7 testing events in 2016 and 4 events in 2017. The findings include: Review of CAP proficiency testing results showed the laboratory did not investigate the exception reason codes that appeared as scores for the evaluation of the results submitted for the following events: UDC-B 2016, UDC-C 2016, UDC-D 2016, DAI-B 2016, UDS-A 2016, UDS-B 2016, UDS-C 2016, DMPM-A 2017, UDS-A 2017, UDS-B 2017, and UDS-C 2017. The interview with the technical consultant on 5/30/18 at 10:00am confirmed the laboratory did not look into why CAP issued exception reason codes for the testing scores.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the procedure

	manual did not have hematology procedures for all of the required elements. The findings include: Review of the hematology procedure manual showed that the manual did not include instructions for storage and preservation, transportation, processing, referral, and criteria for acceptability and rejection. The procedure manual did not have corrective action when calibration or control results fail, reference ranges, the system for entering and reporting patient results, or the course of action to take if their test system becomes inoperable. The interview with the technical consultant on 5/30/18 at 11:30am confirmed the hematology procedure manual was missing all required elements.
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 observation, record review, and interview, the laboratory failed to store frozen Chemistry control material at the correct freezer temperatures for two of two years reviewed (2016-2018). The findings include: Observation of materials stored in the freezer in the laboratory on 5/30/18 at 2:20 PM showed the storage of Bio-Rad Level 1 and Level 3 Chemistry Control Materials. The manufacturer's labels on the control materials require a storage temperature of -20 to -70 degrees Celsius. Review of the temperature logs for the freezer showed that the temperatures ranged from -18 to -20 degrees Celsius from June 2016 - May 2018 and the temperature was not cold enough to reach the manufacturer's requirement for -20 to -70 degrees Celsius. The laboratory's acceptable range of -18 to -20 degrees Celsius on the freezer log, and temperatures recorded on the log, did not meet the manufacturer's storage requirement of -20 to -70 degrees Celsius. The interview on 5/30/18 at 2:20pm with the technical consultant confirmed that the manufacturer's requirements for storage temperatures were not met for the materials stored in freezer.
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 record review and interview with staff, the method verification of the ACT diff hematology instrument was incomplete. The findings include: The record review

	of the method verification of the ACT Diff hematology analyzer showed that the laboratory had not verified the accuracy of the instrument. The interview with the technical consultant on 5/30/18 at 11:15am confirmed the laboratory had not tested known samples to ensure expected results would be obtained.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based upon record review of patient reports and staff interview, the laboratory's patient test report failed to have the correct address of the testing laboratory for one of one patient report reviewed in May 2018. Findings included: Review of the patient test report dated 5/7/18 showed the location of the testing laboratory was not a correct address. The interview with the technical consultant on 5/30/18 at 11:00 am confirmed the patient test report did not have the correct address of the laboratory.