Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2160654	(X3) Date Survey Completed 07/17/2019
Name of Provider or Supplier Park Place Healthcare, Llc	**Street Address, City, State** 3635 Market Street, Suite B, Hoover, AL	

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	Initial Certification Surveys were conducted simultaneously for CLIA identification numbers (#) 01D2160654 and 01D2159994 on 7/17/2019. The surveys were conducted by two State Agency surveyors, accompanied by two Regional Office representatives (Atlanta), who conducted FMS (Federal Monitoring Surveys) of the State Agency surveyors. The two laboratories occupy the same space and utilize the same equipment. However, based on observations, record reviews (including personnel and training, quality control, temperature /humidity, manufacturer's requirements, installation and validation records) and interviews, the surveyors determined the laboratories' hours of operation overlapped; and the laboratories failed to operate as two distinctly different entities. Both laboratories began patient testing on 2/11/2019. The State Agency surveyors reviewed the records simultaneously and observed the documentation, including installation and validations records for the Horiba ABx Micros 60 Hematology analyzer, environmental logs, and Hematology Quality Control records were photocopied and placed in binders for the individual laboratories. .
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 observations during the initial tour of the laboratory, a review of the temperature logs, a review of Hematology Quality Control (QC) storage requirements,

	and an interview with Testing Personnel #2, the surveyor determined the laboratory failed to establish acceptable refrigerator temperature ranges and ensure QC was stored as per manufacturer's requirements for 60 days in 2019. The laboratory further failed to ensure environmental parameters (room temperature, humidity, and refrigerator temperatures) were monitored and documented independently from a second laboratory which occupies the same address and space [CLIA # 01D2159994]. Duplicate (photocopied) environmental records were observed for each laboratory by the two surveyors conducting simultaneous reviews. The surveyors were unable to determine which laboratory should be credited with temperature and humidity monitoring from February thru July 2019. The findings include: 1. A review of the Horiba ABx Micros 60 Hematology analyzer's Operator Manual revealed QC should be stored at 4-8 degrees Centigrade (39-46 degrees F [Fahrenheit]). 2. A review of the 2019 environmental logs revealed the "acceptable range" for the refrigerator in which the QC was stored was 36-46 degrees F. The surveyor noted temperatures were less than 39 degrees F (colder than the storage requirements specified by the manufacturer) sixty days from February thru June 2019. 3. During an interview on 7 /17/2019 at approximately 2:15 PM, Testing Personnel #2 reviewed with the surveyor the environmental logs and manufacturer's QC storage requirements, and confirmed the above noted findings. .
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 observations during the initial tour, a review of the installation and validation records for the Horiba ABx Micros 60 Hematology analyzer, and an interview with the office manager, the surveyor determined the laboratory failed to ensure the manufacturer's performance specifications were verified independently for this laboratory. Two CLIA State Agency surveyors (with two CMS Regional Office surveyors also present) reviewed the records simultaneously for this laboratory and a second laboratory [CLIA ID # 01D2159994] which shares the same space and Hematology analyzer. Duplicate (photocopied) verifications studies performed on 2/11 /2019 were utilized by both laboratories. The surveyors were unable to determine which laboratory should be credited with the studies performed. The findings include: 1. During the initial tour of the laboratory on 7/17/19 at 9:30 AM, the surveyor observed only one Horiba ABx Micros 60 Hematology analyzer. 2. A review of the validation studies (accuracy, precision and reportable range), revealed the laboratory staff provided the same duplicate (photocopied) calibration and verifications studies performed on 2/11/2019 as the laboratory with CLIA #01D2159994. The two laboratories failed to perform the studies independently, and a comparison of records revealed the same precision studies performed on 2/11 at 9:37-9:54 AM. The surveyor further confirmed the raw data (instrument printouts) for the reportable range study (linearity and accuracy) had the same dates and times, 2/11/19 from 10:18 AM to 2:12 PM. 3. During the exit interview on 7/17/2019 at 2:43 - 3:00 PM, the State Agency

	CLIA Supervisor reviewed the above noted findings with the office manager who confirmed the documents for the validation studies had been copied, and not performed independently by each laboratory. .
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the Bacteriology Quality Control (QC) logs, and interviews with Testing Personnel (TP) #1 and #2, the laboratory failed to specify expected or acceptable quality control results for positive and negative Bacitracin ("A" disc) and media QC on the logs, and failed to document the actual results observed (reactivity) when performing the QC. The findings include: 1. A review of the Bacteriology records revealed the testing personnel documented the lot number, expiration date, and test performance date for the positive and negative QC for each new lot number of Strep Selective Agar (SSA) and Bacitracin ("A") discs. However, the Testing Personnel only documented "OK" for their QC results, and failed to document the reactivity of the QC. The QC logs further failed to specify the expected results for the positive and negative QC. 2. During interviews on 7/17/2019 at 1:25 PM, the surveyor asked TP #1 and #2 what they observed when their QC was "OK". TP #1 stated there was a "Halo" for the positive media and disc QC. When the surveyor asked what she meant by "Halo", TP #1 was unable to explain with any further details. When the surveyor asked about observations for the negative QC, TP #2 stated there was "no growth". The surveyor then asked what organisms were used for the positive and negative QC. 3. As the interview continued at 1:30 PM, TP #2 provided the surveyor with names of the QC organisms: "Strep agalactiae-group B" was the negative QC; [Strep] "pyogenes group A" was the positive QC. The surveyor then explained the importance of documenting the actual reactions observed and understanding the acceptable results expected. Both the positive and negative QC organisms should grow on the SSA, however the S. pyogenes should produce hemolysis (a "halo") with a "Zone of Inhibition" around the "A" disc; the S. agalactiae should have no hemolysis and "No Zone of Inhibition" around the "A" disc. .
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on reviews of the Hematology quality control (QC) records and the patient log, and an interview with Testing Personnel #2, the laboratory failed to ensure at least

	two levels of quality control were performed and acceptable, prior to analyzing patient specimens and reporting the results on one day in June 2019. The findings include: 1. A review of the QC records for the Horiba ABx Micros 60 Hematology analyzer revealed only the Low QC was within acceptable ranges on 6/25/2019; the Normal and High QC were not run until the late afternoon. 2. A review of the patient log revealed one patient CBCs (Complete Blood Counts) was performed at 9:08 AM on 6 /25/2019. 3. During an interview on 7/17/2019 at 1:55 PM, Testing Personnel #2 reviewed and confirmed the above noted findings. NOTE: Duplicate (photocopied) QC records were utilized for this laboratory and a second laboratory (CLIA # 01D2159994) which shares the same space and Hematology analyzer, and some of the same hours of operation (8:00 AM to 5:00 PM). The two laboratories had failed to maintain different hours of operation, and ensure QC was monitored and documented independently. .
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 reviews of quality assurance documentation and laboratory records, and interviews with Testing Personnel #1, #2 and the Office Manager, the surveyor determined the laboratory failed to implement effective quality assessment reviews to identify and correct problems identified in the analytical systems. The findings include: I. A review of quality assurance documentation revealed the laboratory routinely performed monthly quality assurance activities, however the reviews were inadequate to discover and correct problems in the following areas: A--BACTERIOLOGY A-1. A review of the Bacteriology QC logs revealed the laboratory failed to specify expected or acceptable quality control results for positive and negative Bacitracin ("A" disc) and media QC on the logs, and failed to document the actual results observed (reactivity) when performing the QC. Refer to D5471. A-2. A review of personnel records revealed the laboratory failed to ensure the testing personnel were trained to document the actual results observed (reactivity) when performing the positive and negative Bacitracin ("A" disc) and media QC, and further failed to ensure the testing personnel understood and were able to specify expected observations for acceptable Bacteriology quality control results. Refer to D6045. B--CHEMISTRY B-1. A review of Reichert Unistat Bilirubinometer QC records revealed the laboratory had retained the Quantimetrix Bilirubin Control manufacturer's assay sheet (Level 1 and 2) for lot number (#) 33441 and 33442 with acceptable ranges of 8.7-13.0 and 18.1-27.2 milligrams per deciliter (mg/dl) respectively. The QC log (where daily QC was recorded) included these values as the acceptable ranges. B-2. A review of contents in the laboratory refrigerator revealed bottles of Quantimetrix Bilirubin QC with lot #'s 33531 and 33532, the current and only lot #'s in use. B-3. During an interview with Testing Personnel #2 on 7/17/2019 at 11:20 AM, the surveyor asked for the manufacturer's assay sheet for Bilirubin QC lot #'s 33531 and 33532. Testing Personnel #2 obtained the assay sheet from the Bilirubin QC box. A review of the sheet revealed the acceptable ranges were 9.4-14.1 (Level 1) and 18.9-28.3 mg/dl (Level 2). TP #2 confirmed the laboratory had failed to ensure the correct acceptable ranges for the current QC lot number was utilized on the

	QC log. C--HEMATOLOGY C-1. A review of the installation and validation records for the Horiba ABx Micros 60 Hematology analyzer revealed the laboratory failed to ensure the manufacturer's performance specifications were verified independently for this laboratory. Refer to D5421. C-2. A review of the Hematology QC records and the patient log revealed the laboratory failed to ensure at least two levels of quality control were performed and acceptable, prior to analyzing patient specimens and reporting the results on one day in June 2019. Refer to D5481. C-3 A review of the temperature logs and Hematology Quality Control (QC) storage requirements revealed the laboratory failed to establish acceptable refrigerator temperature ranges and ensure Hematology QC was stored as per manufacturer's requirements for 60 days in 2019. The laboratory further failed to independently monitor and record environmental parameters. Refer to D5413. II. During the exit summation with Testing Personnel #1, #2 and the Office Manager on 7/17/2019 at 2:40 PM, these concerns were review and confirmed. .
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on reviews of laboratory records for this laboratory [CLIA # 01D2160654] and records for a second laboratory which occupies the same address and space [CLIA # 01D2159994], the Laboratory Director failed to ensure the two laboratories operated as two distinctly different entities with separate hours of operation, and laboratory records for each laboratory. Both laboratories began patient testing on 2/11/2019, and included operating hours with patient testing from 8:00 AM thru 5:00 PM. Two State Agency surveyors (with two CMS Regional Office surveyors also present) reviewed the records simultaneously and observed the documention for the Horiba ABx Micros 60 Hematology instrument validation (refer to D6013), Quality Assurance (refer to D6022), Environmental logs (refer to D6010), and Hematology Quality Control records (refer to D6021) were photocopied and placed in binders for the individual laboratories. Since both laboratories began operation on the same days and the records were duplicates, the surveyors were unable to determine which laboratory should receive credit for the records reviewed. The Laboratory Director should ensure the laboratories operated independently with different hours of operation, and separate records, processes and procedures. .
D6010	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2) 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)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed. This STANDARD is not met as evidenced by:

	Based on observations during the initial tour of the laboratory, a review of the temperature logs, a review of Hematology Quality Control (QC) storage requirements, and an interview with Testing Personnel #2, the surveyor determined the Laboratory Director failed to ensure: 1) the laboratory established acceptable refrigerator temperature ranges and ensured QC was stored as per manufacturer's requirements for 60 days in 2019. 2) the laboratory ensured environmental parameters (room temperature, humidity, and refrigerator temperatures) were monitored and documented independently from a second laboratory which occupies the same address and space [CLIA # 01D2159994]. Duplicate (photocopied) environmental records were observed for each laboratory by the two surveyors conducting simultaneous reviews. The surveyors were unable to determine which laboratory should be credited with temperature and humidity monitoring from February thru July 2019. The findings include: 1. Refer to D5413. .
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 a review of the installation and validation records for the Horiba ABx Micros 60 Hematology analyzer and an interview with the office manager, the surveyor determined the Laboratory Director failed to ensure the manufacturer's performance specifications were verified independently for this laboratory. Two State Agency surveyors (with two CMS Regional Office surveyors also present) reviewed the records simultaneously for this laboratory and a second laboratory [CLIA ID # 01D2159994] which shares the same space and Hematology analyzer. Duplicate (photocopied) verifications studies performed on 2/11/2019 were utilized by both laboratories. Surveyors were unable to determine which laboratory should be credited with the studies performed. The findings include: 1. Refer to D5421. .
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on reviews of the Bacteriology and Hematology Quality Control (QC) logs, and interviews with Testing Personnel (TP) #1 and #2, the Laboratory Director failed to: 1) ensure the laboratory specified expected or acceptable quality control results for

	positive and negative Bacitracin ("A" disc) and media QC on the logs, and ensure testing personnel documented the actual results observed (reactivity) when performing the QC; 2) ensure at least two levels of Hematology QC were performed and acceptable, prior to analyzing patient specimens and reporting the results on one day in June 2019; and 3) ensure the two laboratories sharing the same space and Hematology analyzer maintained different hours of operation; and monitored and documented QC independently. (Duplicate / photocopied QC records were utilized for this laboratory and the second laboratory (CLIA # 01D2159994). The findings include: 1. Refer to D5471 and D5481. .
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a reviews of quality assurance documentation and laboratory records, and interviews with Testing Personnel #1, #2 and the Office Manager, the surveyor determined the Laboratory Director failed to ensure the laboratory implemented effective quality assessment reviews to identify and correct problems identified in the analytical systems. The findings include: 1. A review of quality assurance documentation revealed the laboratory routinely performed monthly quality assurance activities, however the reviews were inadequate to discover and correct problems identified in the specialities of Bacteriology, Chemistry and Hematology. 2. Refer to D5791. .
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on observations during the initial tour, a review of the installation and validation records for the Horiba ABx Micros 60 Hematology analyzer, and an interview with the office manager, the surveyor determined the Technical Consultant failed to ensure the laboratory independently verified the manufacturer's performance specifications. Two CLIA State Agency surveyors (with two CMS Regional Office surveyors also present) reviewed the records simultaneously for this laboratory and a second laboratory [CLIA ID # 01D2159994] which shares the same space and Hematology analyzer. Duplicate (photocopied) verifications studies performed on 2/11 /2019 were utilized by both laboratories. The surveyors were unable to determine which laboratory should be credited with the studies performed. The findings include: 1. Refer to D5421. .

D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on reviews of personnel records, Bacteriology QC records, and interviews with Testing Personnel (TP) #1 and #2, the Technical Consultant failed to ensure the testing personnel were trained to document the actual results observed (reactivity) when performing the positive and negative Bacitracin ("A" disc) and media QC. The Technical Consultant further failed to ensure the testing personnel understood and were able to specify expected observations for acceptable Bacteriology quality control results. The findings include: 1. A review of personnel records revealed one generic training form for Hematology, Chemistry, and Bacteriology testing for TP #1 and #2. 2. A review of the Bacteriology records revealed the testing personnel documented the lot number, expiration date, and test performance date for the positive and negative QC for each new lot number of Strep Selective Agar (SSA) and Bacitracin ("A") discs. However, the Testing Personnel only documented "OK" for their QC results; the Technical Consultant had failed to ensure testing personnel were trained to document the reactivity of the QC results. 3. During interviews with TP #1 and #2 on 7 /17/2019 at 1:25 PM, the surveyor further determined the Technical Consultant failed to ensure testing personnel understood and were able to specify expected observations for acceptable Bacteriology QC results. 4. Refer to D5471. SURVEYOR ID #32558 Licensure and Certification Surveyor