Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2160654	(X3) Date Survey Completed 05/14/2021
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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on a review of API (American Proficiency Institute) proficiency testing (PT) records, and an interview with Testing Personnel #1, the surveyor determined the laboratory failed to ensure proficiency testing samples were rotated between all personnel who performed patient testing. This was noted on five out of six Hematology surveys, six out of six Microbiology surveys, and six out of six Chemistry surveys reviewed for 2019 (2nd and 3rd Event), 2020 (all three events), and 2021 (1st Event). The findings include: 1. A review of API attestation statements revealed Testing Personnel #1 had performed all the testing on five out of six Hematology surveys, six out of six Microbiology surveys, and six out of six Chemistry surveys reviewed. 2. During an interview on 05/14/2021 at 10:40 AM, Testing Personnel #1 confirmed the proficiency testing was not rotated to the other testing personnel (Testing Personnel #2) since 2nd Event 2019 Hematology.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action

	when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on the American Proficiency Institute (API) Proficiency Testing (PT) reports and an interview with the Technical Consultant, the surveyor determined the laboratory failed to successfully participate in Hematology - White Blood Cell Differential testing for two of three consecutive events (Event #2 of 2020 and Event #1 of 2021). The failures resulted in an initial unsuccessful participation for the laboratory. The findings include: 1. A review of the API Proficiency Testing reports revealed the laboratory scored sixty-seven percent (67%) for Event #2, 2020 and seventy-three percent (73%) for Event #1, 2021 for White Blood Cell Differential (Hematology). 2. During an interview on 05/14/2021 at 2:10 PM, the Technical Consultant confirmed the laboratory had unsuccessfully participated in Hematology - White Blood Cell Differential for two of three consecutive events.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on the American Proficiency Institute (API) Proficiency Testing (PT) reports and an interview with the Technical Consultant, the surveyor determined the laboratory failed to successfully participate in Hematology - White Blood Cell Differential testing for two of three consecutive events (Event #2 of 2020 and Event #1 of 2021). The failures resulted in an initial unsuccessful participation for the laboratory. The findings include: See D2016.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.

	This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to report SARS-CoV-2 (Severe Acute Respiratory Syndrome Coronovirus 2) test results for negative Coronovirus Disease 2019 (COVID-19) performed on the Sofia2 Flu + SARS Antigen FIA and Accessbio Carestart COVID-19 Antigen test from January 08, 2021 [the date State Surveyors received CMS guidance for surveying on this deficiency] to May 14, 2021. The laboratory failed to report negative results for SARS-CoV-2 for the COVID-19 antigen test results to the Alabama Department of Public Health and positive results were reported to the Report Card for Alabama Department of Public Health (which is not the mechanism to use to report a patient that has a reportable disease). Findings include: 1. A review of SARS-CoV-2 test results revealed patients were tested for SARS-CoV-2 using the Sofia2 Flu + SARS Antigen FIA and Accessbio Carestart COVID-19 Antigen test, starting November 20, 2020 through May 14, 2021. A total of 476 tests were performed (34 Positives and 442 Negatives) during this time period. 2. During an interview on May 14, 2021 at 09:45 AM, Testing Personnel #1 stated positive results were reported to the Novel Coronavirus (COVID-19) Report Card to the Alabama Department of Public Health. The Report Card has the following statement "If you are a Laboratorian, reporting on behalf of a laboratory, blood bank, or plasma center, the REPORT Card is not the mechanism you should use to report a patient that has a reportable disease or health condition." Testing Personnel #1 confirmed the laboratory had reported only positives (to the Report Card) but none of the negative SARS-CoV-2 patient test results were reported to the Alabama Department of Public Health due to sending negatives to a reference laboratory for confirmatory testing.