Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 01D2150656	**(X3) Date Survey Completed** 11/17/2020
Name of Provider or Supplier Park Place Healthcare, Llc	**Street Address, City, State** 3735 Corporate Woods Drive, Suite 105, Vestavia Hills, 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**
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 CMS CASPER reports, a review of the American Proficiency Institute (API) proficiency testing reports, and a telephone interview with the laboratory's testing personnel, the surveyor determined the laboratory failed to successfully participate in Routine Chemistry - Total Bilirubin testing for two of three consecutive events (Event #1 and #3 of 2020). These failures resulted in an initial unsuccessful participation for the laboratory. The findings include: 1. A review of the CASPER reports for proficiency testing revealed the laboratory scored zero percent (0 %) for Total Bilirubin (Chemistry) for Event #1 and Event #3, 2020. 2. A review of the API

	proficiency testing records revealed the laboratory failed to participate in testing, resulting in zero scores for the Total Bilirubin for Events #1 and #3 of 2020. 3. During a telephone interview on 11/17/2020 at 11:00 AM, the testing personnel stated the office manager (also a testing personnel) is responsible for submitting the proficiency testing results for grading, however she failed to submit the results to API by the submission deadline to ensure grading for both events. The testing personnel further stated the laboratory staff had performed self-evaluations for the testing.
D2093	ROUTINE CHEMISTRY CFR(s): 493.841(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on the CMS CASPER reports, a review of the American Proficiency Institute (API) proficiency testing reports, and a telephone interview with the laboratory's testing personnel, the surveyor determined the laboratory failed to submit proficiency testing results by the submission deadlines for Routine Chemistry (Total Bilirubin) testing for two of three consecutive events (Event #1 and #3 of 2020). The laboratory scored zero percent (0 %) for both events, due to the failure to timely submit the results (Failure to Participate). These failures resulted in an initial unsuccessful participation for the laboratory. The findings include: 1. A review of the CASPER reports for proficiency testing revealed the laboratory scored zero percent (0 %) for Total Bilirubin (Chemistry) for Event #1 and Event #3, 2020. 2. A review of the API proficiency testing records revealed the laboratory failed to participate in testing, resulting in zero scores for the Total Bilirubin for Events #1 and #3 of 2020. 3. During a telephone interview on 11/17/2020 at 11:00 AM, the testing personnel stated the office manager (also a testing personnel) is responsible for submitting the proficiency testing results for grading, however she failed to submit the results to API by the submission deadline to ensure grading for both events. The testing personnel further stated the laboratory staff had performed self-evaluations for the testing.
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on the CMS CASPER reports, a review of the American Proficiency Institute (API) proficiency testing reports, and a telephone interview with the laboratory's testing personnel, the surveyor determined the Laboratory Director failed to ensure test results were submitted to API for grading. This affected Routine Chemistry

	testing (Total Bilirubin) for two of three consecutive events (Event #1 and #3 of 2020). These failures resulted in an initial unsuccessful participation for the laboratory. The findings include: Refer to D2016.