Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2150656	(X3) Date Survey Completed 02/10/2021
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 and a review of the American Proficiency Institute (API) proficiency testing reports, the surveyor determined the laboratory failed to successfully participate in Hematology testing for two of three consecutive events (Event #1 and Event #3 of 2020). The 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 Event #1 2020 and sixty percent (60%) for Event #3 2020 for both RBC and HCT (Non-Waived) (Hematology). 2. A review of the API proficiency testing records

	revealed the laboratory failed to participate in testing, resulting in zero scores for the RBC and HCT (Non-Waived) for Event #1 of 2020. Also, the review revealed the laboratory failed to successfully participate in testing, resulting in a score of sixty in Event #3 2020 for RBC and HCT (Non-Waived).
D2127	HEMATOLOGY CFR(s): 493.851(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 and a review of the American Proficiency Institute (API) proficiency testing reports, the surveyor determined the laboratory failed to submit proficiency testing results by the submission deadlines for Hematology (RBC and HCT(Non-Waived)) testing for Event #1 2020. The laboratory scored zero percent (0%) for this event, due to the failure to timely submit the results (Failure to Participate). The findings include: 1. A review of the CASPER reports for proficiency testing revealed the laboratory scored zero percent (0%) for Event #1 2020 for RBC and HCT (Non-Waived) (Hematology). 2. A review of the API proficiency testing records revealed the laboratory failed to participate in testing, resulting in zero scores for the RBC and HCT (Non-Waived) for Event #1 of 2020. This failure to participate in testing resulted from the laboratory's failure to timely submit the results to API.
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 CMS CASPER reports and a review of the American Proficiency Institute (API) proficiency testing reports, the surveyor determined the laboratory failed to successfully participate in Hematology testing for two of three consecutive events (Event #1 and Event #3 of 2020). The 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 Event #1 2020 and sixty percent (60%) for Event #3 2020 for both RBC and HCT (Non-Waived) (Hematology). 2. A review of the API proficiency testing records revealed the laboratory failed to participate in testing, resulting in zero scores for the RBC and HCT (Non-Waived) for Event #1 of 2020. Also, the review revealed the laboratory failed to successfully participate in testing, resulting in a score of sixty in Event #3 2020 for RBC and HCT (Non-Waived).
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 and a review of the American Proficiency Institute (API) proficiency testing reports, the surveyor determined the Laboratory Director failed to ensure test results were submitted to API for grading. This affected Hematology testing (RBC and HCT (Non-Waived)) for Event #1 2020. This failure along with D2121 resulted in an initial unsuccessful participation for the laboratory. The findings include: Refer to D2016. Refer to D2130. Refer to D2127.