Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2150656	01/04/2019
Name of Provider or Supplier	**Street Address, City, State**	
Park Place Healthcare, Llc	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
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 a lack of validation documentation for the Reichert Unistat Bilirubinometer analyzer, and interviews with the Laboratory Director, the surveyor determined the laboratory failed to ensure the verification of the manufacturer's performance specifications was performed, approved, signed and dated by the Laboratory Director before the instrument was used by the testing personnel for patient testing. The findings include: 1. During the entrance tour of the laboratory on 1/4/2019 at approximately 9:20 AM, the Laboratory Director included on the test menu Neonatal Bilirubins performed on the Reichert Unistat Bilirubinometer. 2. A review of the "BILIRUBIN" binder revealed two levels of Pediatric Bilirubin quality controls (QC) were performed on 12/13/2018; there was no other documentation of validation or testing procedures. 3. As the survey continued on 1/4/2019 at 11:40 AM, the surveyor requested the validation records for the Bilirubinometer to review the laboratory's verification procedures of the manufacturer's performance specifications. The Laboratory Director stated the only "validation" performed was to run the Calibrator cuvette and run QC in December. The Director further explained the manufacturer's instructions "were very vague" on any other requirements. 4. As the interview continued on 1/4/2019 at approximately 11:50 AM, the surveyor explained the CLIA

	requirements for validation of precision, accuracy and reportable ranges of the tests as stated in the manufacturer's performance specifications, plus verification of the reference ranges for the laboratory's patient population. All validations must be reviewed and approved by the Laboratory Director before patient testing can begin. The surveyor then asked if the testing personnel had performed any patient bilirubins. The Director stated there was one patient tested on 12/13/2018, and two patients on 1/3 /2018; thus the above noted findings were confirmed. .
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 a review of the Reichert Unistat Bilirubinometer analyzer procedures and quality control (QC) records, and an interview with the Laboratory Director, the surveyor determined the laboratory failed to ensure at least two levels of QC were run and within acceptable limits prior to analyzing patient specimens and reporting the results on 1/3/2019. The findings include: 1. A review of the Bilirubin Policy and Procedure revealed, "Analysis of at least a normal and abnormal level of a commercial serum control assayed for total bilirubin will be used for quality control ... each day that patient samples are analyzed...". 2. A review of the "BILIRUBIN" binder revealed two levels of Pediatric Bilirubin QC were run on 12/13/2018; there was no other documentation of QC performed on any other days. 3. In an interview on 1/4/2019 at 11:58 AM, the surveyor asked about the dates of patient testing on the Bilirubinometer. The Laboratory Director stated QC and one patient Neonatal Bilirubin was performed on 12/13/2018, and two Bilirubins "were run yesterday" [1/3 /2019]. When asked for the QC for 1/3/2019, the Director checked with Testing Personnel #2 who had performed the patient testing. Testing Personnel #2 stated she had not run any QC on 1/3/2018, thus the above noted findings were confirmed. SURVEYOR ID #32558 Licensure and Certification Surveyor