Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0264233	01/25/2021
Name of Provider or Supplier	**Street Address, City, State**	
Piedmont Physicians Urology Macon	330 Hosptial Drive, Bldg C, Cuite 315, Macon, GA	

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	A proficiency testing desk review was completed on January 25, 2021. At the time of the review, the laboratory was not in compliance with the Clinical Laboratory Improvement Amendments of 1988, 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
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 proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 153 and 155 and review of the laboratory's proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in two out of three events (Events 1 & 2 of 2020), resulting in the first

	unsuccessful occurrence for Routine Chemistry analyte #0245, Chloride (CL) analyte #0355, Creatine analyte #0405, Glucose (Non-Waived) analyte #0415, Potassium (K) analyte #0465, Sodium (NA) analyte #0475, BUN analyte #0505 the specialty of Routine Chemistry. The laboratory also failed to maintain satisfactory performance in two out of three events (Events 1 & 2 of 2020), resulting in the first unsuccessful occurrence for Hematology analyte #0760, Hematocrit (HCT) # 0785 and Hemoglobin (HGB) # 0795. Findings include: Refer to D2096 and D2130
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 153 and 155 and review of the laboratory's proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in two out of three events (Events 1 & 2 of 2020), resulting in the first unsuccessful occurrence for Routine Chemistry analyte #0245, Chloride (CL) analyte #0355, Creatine analyte #0405, Glucose (Non-Waived) analyte #0415, Potassium (K) analyte #0465, Sodium (NA) analyte #0475, BUN analyte #0505 the specialty of Routine Chemistry. 1. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed Routine Chemistry analyte #0245, Chloride (CL) analyte #0355, Creatine analyte #0405, Glucose (Non-Waived) analyte #0415, Potassium (K) analyte #0465, Sodium (NA) analyte #0475, BUN analyte #0505, on Events 1 & 2 of 2020 with a score of 0% for all listed analytes for both events. 2. The criteria for acceptable performance for the specialty of Routine Chemistry is 80%. 3. Desk review of the laboratory's proficiency testing reports from the American Association of Bioanalysts (AAB) confirmed the laboratory failed Routine Chemistry analyte #0245, Chloride (CL) analyte #0355, Creatine analyte #0405, Glucose (Non-Waived) analyte #0415, Potassium (K) analyte #0465, Sodium (NA) analyte #0475, BUN analyte #0505 the specialty of Routine Chemistry for Events 1 and 2 of 2020 resulting in the first unsuccessful performance.
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 proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's American Association of Bioanalysts (AAB) proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in two out of three events (Events 1 & 2 of 2020), resulting in the first unsuccessful occurrence for Hematology analyte #0760, Hematocrit (HCT) # 0785 and Hemoglobin (HGB) # 0795 the specialty of Hematology The findings include: 1. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed Hematology analyte #0760, Hematocrit (HCT)

	# 0785 and Hemoglobin (HGB) # 0795, on Events 1 & 2 of 2020 with a score of 0% for both events. 2. The criteria for acceptable performance for the specialty of Hematology is a score of 80%. 3. Desk review of the laboratory's proficiency testing reports from American Association of Bioanalysts (AAB) confirmed the laboratory Hematology analyte #0760, Hematocrit (HCT) # 0785 and Hemoglobin (HGB) # 0795 on Events 1 & 2 of 2020 resulting in the first unsuccessful performance.
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 proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's American Association of Bioanalysts (AAB) proficiency testing (PT) reports, the laboratory director failed to ensure the laboratory maintained satisfactory performance in two out of three consecutive events (Events 1 & 2 of 2020), resulting in the first unsuccessful occurrence for Routine Chemistry analyte #0245, Chloride (CL) analyte #0355, Creatine analyte #0405, Glucose (Non-Waived) analyte #0415, Potassium (K) analyte #0465, Sodium (NA) analyte #0475, BUN analyte #0505 the specialty of Routine Chemistry. The laboratory also failed to maintain satisfactory performance in two out of three events (Events 1 & 2 of 2020), resulting in the first unsuccessful occurrence for Hematology analyte #0760, Hematocrit (HCT) # 0785 and Hemoglobin (HGB) # 0795 the specialty of Hematology. The findings include: Refer to D6016
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's American Association of Bioanalysts (AAB) proficiency testing (PT) reports, the laboratory director failed to ensure the laboratory maintained satisfactory performance in two out of three consecutive events (Events 1 & 2 of 2020), resulting in the first unsuccessful occurrence for Routine Chemistry analyte #0245, Chloride (CL) analyte #0355, Creatine analyte #0405, Glucose (Non-Waived) analyte #0415, Potassium (K) analyte #0465, Sodium (NA) analyte #0475, BUN analyte #0505 in the specialty of Routine Chemistry. The laboratory also failed to maintain satisfactory performance in two out of three events (Events 1 & 2 of 2020), resulting in the first unsuccessful occurrence for Hematology analyte #0760, Hematocrit (HCT) # 0785 and

	Hemoglobin (HGB) # 0795 in the specialty of Hematology. The findings include: 1. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed Routine Chemistry analyte #0245, Chloride (CL) analyte #0355, Creatine analyte #0405, Glucose (Non-Waived) analyte #0415, Potassium (K) analyte #0465, Sodium (NA) analyte #0475, BUN analyte #0505, on Events 1 & 2 of 2020 with a score of 0% for all listed analytes for both events. 2. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed Hematology analyte #0760, Hematocrit (HCT) # 0785 and Hemoglobin (HGB) # 0795, on Events 1 & 2 of 2020 with a score of 0% for both events. 3. The criteria for acceptable performance for the specialties of Routine Chemistry and Hematology is 80%. 4. Desk review of the laboratory's proficiency testing reports from the American Association of Bioanalysts (AAB) confirmed the laboratory failed Routine Chemistry analyte #0245, Chloride (CL) analyte #0355, Creatine analyte #0405, Glucose (Non-Waived) analyte #0415, Potassium (K) analyte #0465, Sodium (NA) analyte #0475, BUN analyte #0505for Events 1 and 2 of 2020 resulting in the first unsuccessful performance. The laboratory also failed Hematology analyte #0760, Hematocrit (HCT) # 0785 and Hemoglobin (HGB) # 0795, on Events 1 & 2 of 2020 resulting in the first unsuccessful performance.