Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0264233	07/21/2022
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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on July 21, 2022. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the general laboratory standard operating procedure manual (SOP) and staff interview, the laboratory failed to establish written instructions for sending specimens to an outside reference laboratory for testing The findings include: 1. The SOP did not include a written policy and procedure (to include collection, preservation, storage, transport, testing schedule times, or how to obtain additional assistance) for staff to follow when sending specimens to reference laboratory (Quest Diagnostics). 2. During an interview on July 21, 2022 at: 11:30 AM with the Office Manager, in an breakroom, in the back of the facility, confirmed that the laboratory did not have a written policy and procedure for staff to follow when sending specimens to reference laboratories.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)

	(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on Prostate Specific Antigen(PSA) Quality Control (QC) document review and staff interview, the laboratory failed to document corrective actions when QC failed or were out of normal range. The Findings include: 1. PSA QC document review revealed on 01/31/2022 the low control failed(0.85) normal range is 0.98-2.42. No corrective action was performed for the low control. 2. PSA QC document review revealed on 02/02/2022 the low control failed(0.89) normal range is 0.98-2.42. The low control was repeated, but failed again with a value of 0.87. No corrective action was performed for the low control. 3. PSA QC document review revealed on 02/024 /2022 the low control failed(0.88) normal range is 0.98-2.42. No corrective action was performed on the low control. 4. During an interview on July 21, 2022 with the Office Manager at approximately 12:30 PM, in the breakroom, confirmed that the controls were not in normal range, and no corrective action was performed to ensure that the control was in normal range.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on review of the Quality Control(QC) for Prostate Specific Antigen(PSA) document review and staff interview, the Laboratory Director(LD) failed to document corrective actions when QC failed. The Findings include: 1. QC for PSA document review revealed that the LD failed to review QC, and document corrective action for the laboratory. 2. During an interview with the Office Manager on July 21, 2022 at approximately 12:40 PM, confirmed that the LD failed to document corrective actions when the QC failed.