Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0182116	01/12/2024
Name of Provider or Supplier	**Street Address, City, State**	
Cpg Urology	1111 Franklin Street Suite 410, Johnstown, PA	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on lack of documentation, review of the laboratory's procedure manual and interview with the Laboratory Manager (LM) ,the laboratory failed to verify twice annually the accuracy of Post-Vasectomy examinations performed from 01/11/2022 through the date of the survey. Findings include: 1. On the day of survey, 01/12/2024 at 08:29 am, the laboratory could not provide documentation of verification of accuracy for Post-Vasectomy examinations (semen analysis for presence or absence) performed from 01/11/2022 through the date of the survey. 2. According to the laboratory's Post-Vasectomy Qualitative Semen Analysis Procedural Guidelines, every six months a peer comparison semen analysis is done. 3. The laboratory reported a total of 500 semen analysis examinations were performed annually (CMS116). 4. The LM confirmed the findings above on 01/12/2024 at 09:45 a.m.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by:

	Based on review of the laboratory's policy and procedure for Post Vasectomy Semen Analysis, Semen Analysis Logs and interview with the Laboratory Manager (LM), the laboratory failed to document a positive and negative control each day patient specimens were examined for post-vasectomy semen analysis from 01/11/2022 to 01 /12/2024. Findings include: 1. The laboratory's Policy and Procedure for Post Vasectomy Semen Analysis states, "The physician will compare the slide with the QC visuals to determine the presence of sperm. The physician will complete and initial the Semen Analysis log as well as initial the QC portion of the log." 2. Semen Analysis Logs reviewed at the time of survey on 01/12/2024 at 08:12 am, revealed no documentation of a negative and positive visual control, each day patient testing (semen analysis for presence or absence) was performed from 01/11/2022 to 01/12 /2024. 3. The laboratory reported a total volume of 500 semen analysis examinations were performed annually (CMS116). 4. The LM confirmed the above findings on 01 /12/2024 at 9:45 am.