

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0182116	(X3) Date Survey Completed 11/20/2025
Name of Provider or Supplier Cpg Urology	Street Address, City, State 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
D0000	A routine recertification survey was conducted by the Pennsylvania State Agency for CPG Urology on 11/20/2025. The laboratory was found out of compliance with the following conditions: 493.1230 Condition: General laboratory systems. 493.1250 Condition: Analytic systems.
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation, review of laboratory policy, and interview with the Laboratory Manager (LM), the laboratory failed to ensure Quality Control (QC) was performed as required per manufacturers (Siemens Multistix) and laboratory requirements when dipstick urinalysis examinations were performed for 2 of 2 years from 01/12/2024 to 11/20/2025. for the Siemens Multistix Reagent Strips from 01/12/2024 to 11/20/2025. Findings include: 1. The Siemens Multistix Reagent Strips packet insert document stated, "Test positive and negative quality control with new lot, new shipments of reagents, and when you open new bottle of reagent strips. Test reagents monthly that are stored for more than 30 days. Run QC tests to ensure reagent integrity; train new users; confirm test performance; and when patients' clinical conditions or symptoms do not match. Also run QC tests per your laboratory procedures." 2. The laboratory's procedure manual stated;" Urine Controls: Will be performed weekly every Thursday. Normal and abnormal urine tested. The lot number of the urine sticks is also recorded." 3. On the day of survey, 11/20/2025, the LM failed to provide documentation for QC performed for 2 of 2 years when dipstick urinalysis examinations were performed from 01/12/2024 to 11/20/2025. 4. The</p>

laboratory performed 7000 urine dipstick examinations in 2024 (CMS 116, estimated annual volume, dated 11/20/2025). 5. The LM confirmed the findings above on 11/20/2025 at 9:30 a.m.

D5200

GENERAL LABORATORY SYSTEMS
CFR(s): 493.1230

Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:
Based on lack of documentation, record review of the laboratory's procedure manual and interview with the Laboratory Manager, (LM), the laboratory failed to meet applicable general laboratory systems requirements in 493.1231 through 493.1236 for 2 of 2 years from 01/12/2024 to date of survey. Refer to D5217

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 Semen Analysis (PV), examinations performed 2 of 2 years from 01/12/2024 through the date of the survey. Findings include: 1. Review of the laboratory's Post Vasectomy Qualitative Semen Analysis Procedural Guidelines revealed "every six months a peer comparison semen analysis is done". 2. On the day of survey, 11/20/2024 at 08:45 am, the laboratory could not provide documentation of verification of accuracy for PV (presence or absence) examinations performed from 01/12/2024 through the date of the survey. 3. The laboratory performed 501 PV examinations in 2024 (CMS 116, estimated annual volume, dated 11/20/2025). 4. The LM confirmed the findings above on 11/20/2025 at 09:30 a.m. ** Repeat Deficiency**

D5400

ANALYTIC SYSTEMS
CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:
Based on lack of documentation, record review of laboratory procedure, and interview with Laboratory Manager (LM), the laboratory failed to meet applicable analytic systems requirements in 493.1251 through 493.1283 for 2 of 2 years from 01/12/2024 to date of survey. Refer to D5449

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on lack of documentation and interview with the Laboratory Manager (LM), the laboratory failed to monitor and document room humidity to ensure operating conditions were met for 1 of 1 Accu-Scope microscope used to perform Post Vasectomy Semen Analysis (PV) examinations from 01/12/2024 to 11/20/2025. Findings include: 1. The manufacturers operating environment specifications stated the following: -Accu-Scope microscope: maximum 80 % relative humidity 2. On the day of the survey, 11/20/2025, the laboratory failed to provide documentation for the monitoring of room humidity to ensure operating conditions were met for the following instruments used to perform PV examinations from 01/12/2024 to 11/20/2025: - 1 of 1 Accu-Scope microscope 3. The laboratory performed 501 PV examinations in 2024 (CMS 116, estimated annual volume, dated 11/20/2025). 4. The LM the above findings on 11/20/2025 at 09:30am.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(g)

(d)(3)(ii) Each qualitative procedure, include a negative and positive control material;

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 ensure a positive and negative control material was included each day patient specimens for post-vasectomy semen analysis (PV) were examined for 2 of 2 years from 01/12/2024 to 11/20/2025. Findings include: 1. The laboratory's Policy and Procedure for Post Vasectomy Semen Analysis stated, "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. On the day of survey, 11/20/2025 at 9:00 am, review of the laboratory's Semen Analysis Logs revealed a negative and positive visual control was not documented each day PV (presence or absence) testing was performed for 2 of 2 years from 01/12/2024 to 11/20/2025. 3. The laboratory reported a total volume of 501 PV examinations were performed annually (CMS 116, estimated annual

volume, dated 11/12/2025). 4. The LM confirmed the above findings on 11/20/2025 at 9:00 am. ** Repeat Deficiency**