

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0182116	(X3) Date Survey Completed 09/10/2019
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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and interview with the practice manager and a certified surgical technologist, the laboratory failed to establish a quality assessment (QA) policy for post vasectomy examinations analyzed from 12/20/2017 to the date of survey. Findings Include: 1. On the day of survey, 09/10/2019, the laboratory failed to provide a QA policy to assess the laboratory's pre-analytic, analytic and post-analytic systems from 12/20/2017 to 09/09/2019. 2. The practice manager and a certified surgical technologist confirmed the finding above from 09/10/2019 around 12:25 pm</p>
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory quality control (QC) records and interview with the practice manager and a certified surgical technologist, the laboratory failed to</p>

document QC procedures each day of patient testing on 81 of 96 post vasectomy examinations analyzed from 12/20/2017 to the date of survey. Findings Include: 1. On the day of survey, 09/10/2019, review of QC records revealed, the laboratory director did not document QC procedures each day of patient testing on 81 of 96 post vasectomy examination analyzed from 12/21/2017 to 09/10/2019. 2. In 2018, 72 post vasectomy examination were analyzed. 3. In 2019 (01/01/2019 to 09/10/2019) 9 post vasectomy examination were analyzed. 4. The practice manager and a certified surgical technologist confirmed the findings above from 09/10/2019 around 12:15 pm.

Repeat Deficiency