

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0222574	(X3) Date Survey Completed 09/15/2022
Name of Provider or Supplier The Urology Group	Street Address, City, State 1860 Town Center Drive - Suite 150, Reston, VA	
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	An announced CLIA recertification survey was conducted at The Urology Group on September 15, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies are as follows:
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the laboratory's policy and procedure manual, lack of documentation, and interview, the laboratory did not have a policy/procedure for performing competency assessments on testing personnel (providers) performing post-vasectomy examinations on the date of the survey on September 15, 2022. Findings include: 1. Review of the laboratory's policy and procedure manual revealed a lack of documentation of a policy for performing competency assessments on testing personnel (providers) performing post-vasectomy specimen examinations. The inspector requested to review the laboratory's policy for performing competency assessments on testing personnel (providers) performing post-vasectomy specimen examinations. The laboratory provided no policy for review. 2. In an exit interview with the office manager, primary testing personnel, laboratory director and reference laboratory director on September 15, 2022 at approximately 12:00 PM, the above finding was confirmed.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p>

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 a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS 209), accuracy verification records, lack of documentation, and interviews, the laboratory failed to verify the accuracy of post-vasectomy specimen examinations twice annually in calendar year 2021. (Review time-frame January 2021 until date of survey, September 15, 2022.) Findings include: 1. Review of the laboratory's CMS 209 personnel form revealed five (5) testing personnel (TP B, C, D, E and F) were identified by the laboratory director (LD) as responsible for performing patient post-vasectomy specimen examinations during the review timeframe of January 2021 to September 15, 2022. (See Testing Personnel Code Sheet.) 2. Review of the laboratory's twice annual accuracy verification documentation for calendar years 2021 and 2022, revealed a post-vasectomy specimen accuracy verification performed on July 14, 2021 for TP B, C, D, E and F. The surveyor requested to review the second post vasectomy accuracy verification for calendar year 2021. The laboratory provided no documentation for review. On September 15, 2022 at approximately 10:30 AM, the office manager stated, "We didn't realize we needed two accuracy verifications per year." 3. In an exit interview with the office manager, primary testing personnel, laboratory director and reference laboratory director on September 15, 2022 at approximately 12:00 PM, the above finding was confirmed.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS 209), testing personnel (TP) records, and an interview, the laboratory director (LD) failed to document the review/approval of the initial training and competency assessment for TP F in calendar year 2022. (See Personnel Code Sheet.) Findings include: 1. Review of the CMS 209 form revealed that the LD identified one new testing personnel, TP F, responsible for moderate complexity post-vasectomy specimen examinations since January 2022. 2. Review of TP records revealed a lack of documentation of the LD's review/approval of the training and competency assessment for TP F. The inspector requested to review TP F's training and initial competency. The laboratory provided no documentation to review. 3. In an exit interview with the office manager, primary testing personnel, laboratory director and reference laboratory director on September 15, 2022 at approximately 12:00 PM, the above finding was confirmed.