

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0964598	(X3) Date Survey Completed 10/11/2018
Name of Provider or Supplier Urology Of Virginia, , Pllc	Street Address, City, State 225 Clearfield Avenue, Virginia Beach, 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	<p>An unannounced Clinical Laboratory Improvement Amendments (CLIA) complaint investigation (Complaint #VA00043659) was conducted at Urology of Virginia, PLLC on October 11, 2018 by a Medical Facilities Inspector from the Virginia Department of Health, Office of Licensure and Certification. The laboratory holds a Certificate of Compliance and operates under CLIA # 49D0964598. Based on the review of the documents and interview with the Laboratory Director, Clinical Operations Manager, Director of Facilities, and Clinical Manager of Urology Department, the inspector found one (1) of two (2) complainant's allegations to be substantiated. Related deficiency cited as follows:</p>
D5203	<p>SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: Based on a tour, review of the laboratory's policies and procedures, and interviews, the laboratory failed to follow their policy for labeling urine samples using two (2) patient identifiers (patient's full legal name and date of birth) and time of collection on forty-six (46) of 46 samples observed on October 11, 2018. Findings include: 1. During a facility tour with the laboratory director (LD), at approximately 10:30 AM, the inspector observed the following 46 patient urine samples in the five (5) laboratory specimen collection areas: POD A - Fourteen (14) urine samples with patient last name only, no time of collection, three (3) urine samples with patient last name only, date of birth, no time of collection; POD B - Seven (7) urine samples with patient first and last name, no date of birth, no time of collection; POD C - Fourteen (14) urine samples with patient first and last name, date of birth, no time of collection;</p>

POC D - Five (5) urine samples with patient first and last name, date of birth, no time of collection; POD E- Three (3) urine samples with patient first and last name, date of birth, no time of collection. The inspector asked the LD to describe the process of labeling patient urine samples. The LD stated: "our policy requests that the patient full legal name and date of birth be labeled on the urine cup. We now also ask the time of collection be added to the label. We have had to add the time of collection for accepting urine cytology and microbiology testing that may be added by a provider".

2. Review of the policies and procedure manual revealed a quality assurance (QA) procedure (Specimen Handling and Patient Identification, review date 9/9/16) that stated: "to ensure Urology of Virginia standing protocols are correctly performed by all clinical staff for quality results and specimen integrity, urine specimen cups will be labeled with patients' full legal name and date of birth." Review of the policies revealed a revision addendum issued for the Specimen Handling and Patient Identification procedure, dated 6/4/18, that stated: "as an additional part of the workflow, staff will be required to initial and write the time of collection on urine samples".

3. In an exit interview with the LD, Clinical Manager, Clinical Operations Manager, and the Director of Facilities, at approximately 1:30 PM, it was confirmed that the laboratory failed to ensure that their QA policy for labeling urine samples, using two (2) positive unique identifiers (patient full name and date of birth) with the time of collection, was followed for the 46 of 46 samples observed during the laboratory facility tour on 10/11/18.