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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>08D0691598         | <b>(X3) Date Survey Completed</b><br><br>06/16/2022 |
| <b>Name of Provider or Supplier</b><br><br>Urology Associates Of Delaware, P A   | <b>Street Address, City, State</b><br><br>200 Banning Street, Suite 250, Dover, DE |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>  |
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| <b>D0000</b>              | A Recertification Survey was conducted on June 16, 2022 at approximately 10:15 am at Urology Associates of Delaware, PA. The laboratory was surveyed according to 42 CFR part 493 Clinical Laboratory Improvement Amendments (CLIA) requirements. Specific deficiencies are as follows:   |
| <b>D5413</b>              | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br/>CFR(s): 493.1252(b)</p> <p>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: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by:<br/>documentation and interview. The laboratory failed to document acceptable temperature ranges for the Heat Block and Incubator to ensure manufacturer's testing requirements are met. Findings include: 1. Temperature controlled spaces, equipment, and instruments must be monitored and results documented for acceptable temperature ranges. 2. At approximately 11:30 am on June 16, 2022 during document review, it was determined that the "Temperature Log", did not include acceptable ranges for the "Heat Block Temperature" or the "Incubator Temperature". 3. Upon review of the Quality Assurance Manual (QAM), there were no temperature ranges noted for either the heat block or the incubator. 4. At approximately 2:25 pm during interview, the Laboratory Director (LD) confirmed that the laboratory failed to include acceptable temperature ranges for the heat block and incubator in the QAM or on the Temperature Log.</p> |
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**D5415****TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**

CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:  
observation and interview. The laboratory failed to establish an expiration date for biology grade water used for testing upon opening. Findings include: 1. During a tour of the facility at approximately 1:00 pm on June 16, 2022, it was observed that IBI Water Lot#21DC0622A was labeled with a received date of "3/17/22" and an opened date of "5/5/22" handwritten on a laboratory-generated label. It did not, however have an expiration date as required. 2. During interview at approximately 2:20 pm, the LD confirmed the laboratory failed to establish or note an expiration date for the opened bottle of IBI Water.