Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0954933	09/08/2022
Name of Provider or Supplier	**Street Address, City, State**	
Springfield Urology Llc Dba Urology Specialists	1164 East Home Road, Suite J, Springfield, OH	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record reviews and interviews with the Laboratory Director (LD) and the Testing Personnel (TP), the LD and TP failed to attest to the routine integration of microbiology proficiency testing (PT) samples into the patient workload using the laboratory's methods for two out of two PT events in 2022. This deficient practice had the potential to affect 2800 patients tested under the subspecialties of bacteriology and mycology from 02/18/2022 to 06/21/2022. Findings Include: 1. Review of the laboratory's policy and procedures titled "Urology Specialists of Ohio, Standard Operating Procedures, #24 and #31" provided for the inspection, did not find any procedures for the attestation of the routine integration of PT samples into the patient workload. 2. Review of the 2022 American Proficiency Institute (API), microbiology 1st and 2nd event attestation statement pages failed to find the signature of the LD and TP. 3. The inspector requested the 2022 API microbiology 1st and 2nd event attestation statement pages which contained the LD and TP signatures from the TP. The TP confirmed no signatures were completed on the attestation pages and was unable to provide the requested documents. The interview occurred 09/08/2022 at 12: 15 PM.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on record reviews and interviews with the Laboratory Director (LD) and the Practice Administrator (PA), the laboratory failed to establish and follow written policies and procedures to assess the competency of the Technical Supervisor (TS) based on the responsibilities of the position, as specified in the personnel requirements in subpart M. This deficient practice had the potential to affect 2800 patients tested under the subspecialties of bacteriology and mycology from 11/15/2021 to 09/08 /2022. Findings Include: 1. Review of the laboratory's "Urology Specialists of Ohio Standard Operating Procedures", provided for the inspection, did not find any policy or procedure for personnel competency assessment. 2. Review of the laboratory's Form CMS-209, approved, signed and dated by the LD on 08/12/2022, showed one individual qualified by the Laboratory Director to function in the assigned position of TS. 3. Review of the laboratory's 2021 and 2022 competency assessment documentation provided for the inspection, did not find any documentation for the TS based on the responsibilities of their assigned positions. 4. The Inspector requested the laboratory's competency assessment documentation for the TS based on the responsibilities of the position from the LD and the PA. The LD and the PA confirmed the laboratory did not establish a policy and procedure for the assessment of the TS, did not assess the competency of the TS based on the responsibilities of the assigned position, and were unable to provide the requested documentation on the date of the inspection. The interview occurred 09/08/2022 at 11:00 AM.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Director (LD), the laboratory failed to ensure test requisitions included the time of specimen collection, when appropriate. This deficient practice had the potential to affect 2800 patients tested under the subspecialties of bacteriology and mycology from 10/01/2020 to 09 /08/2022. Findings Include: 1. Review of the laboratory's "Urology Specialists of Ohio, Standard Operating Procedures, #24" provided for the inspection, found the following statement: "Urine can be stored for up to 48 hours at room temperature following collection into Vacuette containers with CCM preservative, or at 4C for up to 3 days and at -5 to -30 degrees Celsius to up to 7 days." 2. Review of the

	laboratory's "Urology Specialists of Ohio, Standard Operating Procedures #28" provided for the inspection, found the following statement: "1. For patient samples: If at room temperature it can be stored for 48 hours. If in fridge at 2 to 8 can be stored up to 3 days. If in Freezer at -15 to -25 can be stored up to 7 days." 3. Review of one out of one patient test reports found the following: "Collection Date/Time: 09/06/2022 00:00 Received Date/Time: 09/06/2022 00:00" 4. The inspector requested documentation of collection and receipt times from the LD. The LD confirmed sample collection and receipt times was not documented and was unable to provide the requested information. The interview occurred 09/08/2022 at 12:55 PM.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the manufacturer's operating instructions and an interview with the sole Testing Personnel (TP), the laboratory failed to perform the Traceable brand thermometer maintenance as defined by the manufacturer. Findings Include: 1. Direct observation of laboratory operations revealed a Traceable brand thermometer, model VWR-AD, serial number 200443451, with an expiration date of 07/28/2022 utilized to monitor patient samples and reagent storage at 2 to 8C. 2. Further direct observation of laboratory operations revealed another Traceable brand thermometer, model VWR-AD, serial number 200443455, with an expiration date of 07/28/2022 utilized to monitor patient samples and reagent storage at -15 to -25C. 3. The TP confirmed the laboratory did not perform instrument maintenance as required by the manufacturer and both Traceable brand thermometers were expired. The interview occurred 09/08/2022 at 1:15 PM. C; degrees Celsius