Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0690175	11/07/2024
Name of Provider or Supplier	**Street Address, City, State**	
Urology Clinic Of Winchester	1712 Amherst St, Winchester, 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 Urology Clinic of Winchester on November 7, 2024 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 deficiency cite is as follows:
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 the review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (CMS-209 Form), testing personnel (TP) records, the laboratory's policies and procedures, lack of documentation and interviews, the laboratory director failed to follow the laboratory's established policy to ensure one (1) of four (4) new TP had documented training and initial competency assessment prior to performing patient chemistry testing. (Review timeframe February 2023 until November 2024) The findings include: 1. Review of the CMS 209 form identified fourteen (14) TP responsible for chemistry testing. During a discussion with the TC and primary personnel on November 7, 2024 at 9:00 AM regarding the CMS 209, TP #1, #2, #3 and #4 were identified as new TP since the previous inspection in February 2023. (See Personnel Code Sheet.) 2. An interview with the Technical Consultant (TC) and primary TP on November 7, 2024, at 9:00 AM, and a review of TP #1, 2, 3

	and 4's personnel records revealed the following: TP #1 hired and began patient testing in October 2024. Initial training and competency completed October 2024. TP #2 hired and began patient testing in August 2023. No documentation of initial training and competency. TP #3 hired and began patient testing in April 2024. Initial training and competency completed April 2024. TP #4 hired and began patient testing in September 2024. Initial training and competency completed September 2024. The surveyor requested to review training and initial competency assessment documents for TP #2. The laboratory provided no documentation of training/initial competency for TP #2 for the TOSOH A1A chemistry analyzer for review. 3. Review of the laboratory's policies and procedures revealed a policy, "Quality Assessment Plan", with the statement, "Documents and Records: A. The Laboratory ensures that documents and records are managed from creation or receipt, to archive or destruction according to established process that reflect the organization's commitment to quality, as well as to meet legal requirements...E. Training and Competencies: a. Training will be done upon hire. b. Competencies will be done at 6 month from hire and then at 1 year mark and then annually thereafter. c. Training and competencies will be completed by all staff that work in in the laboratory including physicians." 4. In an exit interview with the Lab Director, TC, and primary TP on November 7, 2024. at 12: 15 PM, the findings were confirmed.