Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0690175	02/01/2023
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 February 1, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows:
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) records, lack of documentation, and interviews, the laboratory failed to maintain PT documents for four (4) of 6 Chemistry Core PT (Prostatic Specific Antigen-PSA) and 6 of 6 Hematology /Coagulation (urine sediment) events for the nineteen (19) months reviewed (June 2021 to January 2023). Findings include: 1. Review of the laboratory's 2020, 2021 American Proficiency Institute (API) Chemistry Core (2021 Events 1-3 and, 2022 Events 1-3), and Hematology/Coagulation PT documentation, (2021 Events 1-3 and, 2022 Events 1-3), a total of twelve (12) events revealed the following: 2021 API Chemistry Core (PSA) Event-3-lack of attestation signature by testing personnel and laboratory director. 2021 API Hematology/Coagulation (urine sediment) Events 1

	& 2-lack of PT evaluation documents. 2021 API Hematology/Coagulation (urine sediment) Event 3-lack of attestation signature by testing personnel and laboratory director, lack of urine microscopy result documents, and lack of PT evaluation documents. 2022 API Chemistry Core (PSA) Events 1, 2 & 3-lack of attestation signature by testing personnel and laboratory director. 2022 API Hematology /Coagulation (urine sediment) Event 1-lack of attestation signature by testing personnel and laboratory director, lack of urine microscopy result documents, lack of corrective action documents. 2022 API Hematology/Coagulation (urine sediment) Event 2-lack of attestation signature by testing personnel and laboratory director, lack of urine microscopy result documents, lack of corrective action documents. 2022 API Hematology/Coagulation (urine sediment) Event 3-lack of corrective action documents. The inspector requested to review the PT documentation for the Chemistry Core and Hematology/Coagulation events listed above. The laboratory provided no documentation for review. 2. In an exit interview with Laboratory Director, Technical Consultant, Office Manager and Testing Personnel on February 1, 2023 at approximately 12:00 PM, the above findings were confirmed.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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 the review of the laboratory's proficiency testing (PT) records, lack of documentation and interviews, the laboratory failed to verify the accuracy of the urine sediment examinations twice a year in 2021 and 2022. Findings include: 1. The laboratory utilizes American Proficiency Institute (API) PT for verification of accuracy of urine sediment examinations, categorized as non-regulated analytes. 2. Review of the laboratory's PT records revealed the following: API 2021 Hematology /Coagulation (urine sediment) Event 1-Test results were not received by American Proficiency Institute. No score received. API 2021 Hematology/Coagulation (urine sediment) Event 2-Test results were not received by American Proficiency Institute. No score received. API 2021 Hematology/Coagulation (urine sediment) Event 3-Test results were not received by American Proficiency Institute. No score received. API 2022 Hematology/Coagulation (urine sediment) Event 1-50%, US-01 scored as unacceptable. API 2022 Hematology/Coagulation (urine sediment) Event 2-0%, Failure to Participate. API 2022 Hematology/Coagulation (urine sediment) Event 3-0%, Failure to Participate. The surveyor requested to review documentation of the laboratory's self-evaluation of the PT results that were not received for evaluation by API or were graded as unacceptable. In addition, surveyor requested documentation of an alternative method for verification of accuracy of urine sedimentations for 2021 and 2022. The laboratory provided no documentation for review. 3. In an exit interview with Laboratory Director, Technical Consultant, Office Manager and Testing Personnel on February 1, 2023 at approximately 12:00 PM, the above findings were confirmed.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented.

	This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) records, lack of documentation, and an interview, the laboratory failed to record an evaluation for one (1) of 1 unsatisfactory urine sediment examination reported in calendar year 2022. Findings include: 1. Review of the laboratory's American Proficiency Institute PT records (2021 Events 1-3, 2022 Events 1-3) revealed a lack of documentation of the evaluation for API 2022 Hematolgy/Coagulation (urine sediment) Event 1: US-01 scored as 50%, unacceptable. The surveyor requested to review documentation of the evaluation of the 1 unacceptable result outlined above. The laboratory provided no documentation for review. 2. In an exit interview with Laboratory Director, Technical Consultant, Office Manager and Testing Personnel on February 1, 2023 at approximately 12:00 PM, the above findings were confirmed.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the laboratory's analyzer performance verification documentation, lack of documentation and interviews, the laboratory director (LD) failed to evaluate and verify the accuracy, precision, and reportable ranges for Prostatic Specific Antigen (PSA) on a newly installed TOSOH A1A 360 chemistry analyzer from the installation date of May 11, 2021 until the date of the survey, February 1, 2023. Findings include: 1. Review of the laboratory's instrument verification/validation records revealed a new TOSOH A1A 360 chemistry analyzer (Serial Number 29300508) installed by the TOSOH Technical Specialist on May 11, 2021. 2. During an interview with the technical consultant and lead testing personnel on February 1, 2023, at approximately 10:45 AM , the surveyor requested to review the verification/validation studies for the new TOSOH analyzer. The lead testing personnel provided a TOSOH A1A installation binder with verification/validation studies for the new analyzer. Review of the binder revealed unsigned copies of the new TOSOH analyzer's verification of accuracy, precision, reportable range analysis reports (dated May 11, 2021). The surveyor requested to review documentation of the LD's review and validation of the new instrument's accuracy, precision, and reportable ranges prior to patient testing. The laboratory provided no documentation of the LD's review and validation. The lead testing personnel provided a copy of the method comparison performed on May 11, 2021 on which the lead testing personnel had written a statement that the laboratory director had approved the instrument for use on May 12, 2021. The method comparison document contained a signature date of the current laboratory director with a date of 1/4/2023. The document lacked a signature and date by the previous laboratory director. 3. In an exit interview with Laboratory Director, Technical Consultant, Office Manager and Testing Personnel on February 1, 2023 at approximately 12:00 PM, the above findings were confirmed.

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 a review of the laboratory's TOSOH A1A analyzer's maintenance records, lack of documentation, and an interview, the laboratory failed to document performance of the TOSOH A1A 360's daily, weekly, monthly and six month maintenance from May 12, 2021 until the date of the survey on February 1, 2023. Findings include: 1. Review of the laboratory's TOSOH A1A 360's manual revealed a maintenance log with the following required maintenance procedures: Daily-Empty Carousel,, Empty liquid waste reservoir, Check diluent and wash fluids, replace as needed. Replace alcohol with substrate, Check paper supply, replace if necessary, Record results from the Daily Check (Substrate Background), Check control recovery, End of day, replace substrate with 70% ethanol or 70% isopropyl alcohol. Weekly-Clean substrate line with 70% ethanol or 70% isopropyl alcohol. Monthly-Clean sample area with 70% ethanol or 70% isopropyl alcohol, Clean diluent and wash reservoirs with 1:100 dilution of common household bleach (aqueous hypochlorite), Rinse reservoirs with CAP Class 1 water. 6 Months-Clean diluent and wash tubing lines. Replace filters for diluent and wash bottles. 2. Review of the laboratory's TOSOH A1A's maintenance records from May 12, 2021 until February 1, 2023 revealed a lack of documentation of the TOSOH's daily, weekly, monthly and six-month maintenance from May 12, 2021 until February 1, 2023. The surveyor requested documentation of the performance of the daily, weekly, monthly and 6-month maintenance for the TOSOH A1A analyzer. The laboratory provided no documentation of the maintenance to review. In an interview with the lead testing personnel on February 1, 2023 at approximately 11:00 AM, the lead personnel stated they perform the maintenance but did not document it. 3. In an exit interview with Laboratory Director, Technical Consultant, Office Manager and Testing Personnel on February 1, 2023 at approximately 12:00 PM, the above findings were confirmed.
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii) 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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) records and interviews, the laboratory director failed to ensure the Hematology/Coagulation (urine sediment) PT results for five (5) of six (6) events were submitted on time as required by the American Proficiency Institute (API) program in calendar years 2021 and 2022. Findings include: 1. Review of the laboratory's API Hematology/Coagulation (urine sediment) PT documentation (2021 Events 1-3, and 2022 Events 1-3), a total of 6

	events, revealed the following results: API 2021 Hematology/Coagulation (urine sediment) Event 1-Test results were not received by American Proficiency Institute. No score received. API 2021 Hematology/Coagulation (urine sediment) Event 2-Test results were not received by American Proficiency Institute. No score received. API 2021 Hematology/Coagulation (urine sediment) Event 3-Test results were not received by American Proficiency Institute. No score received. API 2022 Hematology /Coagulation (urine sediment) Event 2-0%, Failure to Participate. API 2022 Hematology/Coagulation (urine sediment) Event 3-0%, Failure to Participate. A total of 5 events. 2. In an exit interview with Laboratory Director, Technical Consultant, Office Manager and Testing Personnel on February 1, 2023 at approximately 12:00 PM, the above findings were confirmed.