Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0690175	05/12/2021
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 off-site CLIA recertification survey was conducted for Urology Clinic of WMC on May 12, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The survey included an entrance interview on April 14, 2021 and virtual record review conducted on May 3, 2021. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies are as follows:
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of manufacturer's package insert, quality control (QC) records, daily patient testing records, and interviews, the laboratory failed to ensure that the Prostatic Specific Antigen (PSA) quality control (QC) materials were not used beyond the manufacturer's expiration date from December 1, 2019 up to December 31, 2019 while reporting a one hundred sixty-three (163) patient results. Findings include: 1. Review of the laboratory's QC records revealed the laboratory used BioRad Lyphochek Immunoassay Plus Controls Level 2 (lot number 40342) and Level 3 (lot number 40343) for PSA QC on the TOSOH A1A from 4/23/2019 until 12/31/2019. 2. Review of the BioRad QC package insert for lot numbers 40342 and 40343 revealed the published manufacturer expiration date for lot numbers 40342 and 40343 was 11 /30/2019. 3. Review of the daily patient testing records revealed one hundred and sixty-three patient PSA tests were performed on the TOSOH A1A from December 1, 2019 until December 31, 2019. 4. In an exit interview with the practice manager on May 12, 2021 at approximately 11:30 AM, the above findings were confirmed.
D5449	CONTROL PROCEDURES

	CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review laboratory's procedures, quality control (QC) records, patient records, lack of documentation, and interviews, the lab failed to perform a positive and negative QC material each day of patient testing for urine sediment examinations from January 2019 until May 12, 2021 while reporting twenty-two thousand two hundred and seventy-one (22,271) patients. Findings include: 1. Review of the laboratory's urine sediment procedure revealed a lack of quality control policy for patient urine sediment examinations. 2. Review of the laboratory's QC documents revealed a lack of documentation of a positive and negative urine sediment QC material performed each day of patient testing from January 2019 until May 2021. In an email dated May 3, 2021 the surveyor requested documentation of the urine sediment QC from January 2019 to May 2021. On May 6, 2021, the practice manger replied to the request for urine sediment QC, "Don't have." 3. Review of the patient records revealed 22,271 patient urine sediment examinations were performed from January 2019 to May 12, 2021. 4. In an exit interview with the practice manager on May 12, 2021 at approximately 11:30 AM, the above findings were confirmed.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, quality control (QC) records, lack of documentation, and interviews, the laboratory failed to perform evaluations to verify six (6) of 6 new lot numbers of BioRad Lyphochek Prostatic Specific Antigen (PSA) QC materials used for monitoring the accuracy of patient PSA testing during the twenty-eight (28) months reviewed. Findings include: 1. Review of the laboratory's procedure manual revealed no TOSOH A1A chemistry instrument procedure for the verification of new lot numbers of BioRad Lyphochek PSA QC assayed ranges. 2. Review of the TOSOH A1A QC records from 1/1/2019 to 4/20 /2021 revealed the following 6 BioRad PSA QC lot numbers were utilized to monitor

	patient PSA test results analyzed on the laboratory's TOSOH A1A instrument: 40342, 40343, 40362, 40363, 40382 and 40383. The inspector requested to review documentation that each of the QC lot numbers outlined above were confirmed (verified). The laboratory provided no documentation to review. 3. In an exit interview with the practice manager on May 12, 2021 at approximately 11:30 AM, the above findings were confirmed.
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 Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, policy and interviews, the laboratory director failed to ensure three (3) of five (5) new TP had documented training and initial competency assessments prior to performing patient testing procedures from January 2019 until May 12, 2021. Findings include: 1. Review of CLIA CMS-209 form revealed the following: TP A was hired in June 2020; TP F was hired in September 2019; TP G was hired in July 2020. (See attached TP Code Sheet). 2. Review of the testing personnel competency records revealed a lack of training documentation for TP F and G and initial competency assessments available for review for TP A, F and G. The surveyor requested documentation of the training for TP F and G and initial competencies for TP A, F and G. The laboratory provided no documentation for review. 3. In an exit interview with the practice manager on May 12, 2021 at approximately 11:30 AM, the above findings were confirmed.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), testing personnel competency assessment records, Quality Assessment policy and interview, the technical consultant (TC) failed to follow their established policy and document the semi-annual competency assessment for two (2) new laboratory testing personnel (TP) from November 2018 to date of survey on May 12, 2021. Findings include: 1. Review of the CMS 209 revealed sixteen (16) TP identified as responsible for moderate complexity patient testing. The following TP were identified as being new since the last survey in November 2018: TP F was identified as being a new TP in September 2019; and TP G was identified as

	being a new TP in July 2020. (See Personnel Code Sheet.) 2. Review of personnel records revealed a lack of documentation of the semi-annual competency assessments for TP F and G. The surveyor requested to review the semi-annual competency assessments for TP F and G. The laboratory provided no documentation to review. 3. Review of the laboratory's Quality Assessment policy revealed a section, "VIII. COMPETENCY" which stated, "A. New employees are checked for competency twice during their first year of employment in the laboratory." 4. In an exit interview with the practice manager on May 12, 2021 at approximately 11:30 AM, the above findings were confirmed.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, Quality Assessment policy, and an interview, the technical consultant (TC) failed to follow the laboratory's established policy and document annual competency evaluations for eight (8) of fifteen (15) testing personnel in 2019 and 2020. Findings include: 1. Review of the CMS Form 209 revealed that the laboratory director (LD) also performs the duties of TC and that there are 15 testing personnel (TP) who performed moderate complexity testing in 2019 and 2020. 2. Review of the laboratory personnel files revealed a lack of documentation of the 2019 or 2020 annual competency evaluations for: TP B, TP C, TP D, TP E, TP F, TP H, TP I, and TP J. (See Personnel Code Sheet.) 3. Review of the laboratory's Quality Assessment policy revealed section, "VIII. COMPETENCY" which stated, "Existing employees are checked annually and periodically as needed." The inspector requested to review documentation of the 2019 and 2020 annual competencies for the above listed TP. The laboratory provided no documentation for review. 4. In an exit interview with the practice manager on May 12, 2021 at approximately 11:30 AM, the above findings were confirmed.