Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2252612	08/26/2026
Name of Provider or Supplier	**Street Address, City, State**	
Winchester Medical Center Anticoagulation	333 West Cork Street Suite 100, 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 validation survey was conducted at WMC EPO/Anticoagulation Clinic on August 26, 2026 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 deficiencies cited are as follows:
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) 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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on a review of the laboratory's Clinical Laboratory Improvement Amendments (CLIA) Application for Certification form (CMS-116) , policy and procedure manual, Individualized Quality Control Plan (IQCP), quality control (QC) records, patient test records, and interview, the laboratory failed to follow their established Quality Control policy/IQCP for the Abbott i-STAT One PTPlus cartridge and perform two levels of QC monthly for one (1) of twenty-four (24) months with 504 patients resulted. Review timeframe: August 2024 through the date of the survey on August 26, 2026. The findings include: 1. A review of the laboratory's CMS-116 revealed the laboratory utilizes the Abbott i-Stat One and PTPlus cartridge for International Normalized Ratio (INR) testing. 2. Review of the laboratory's i-Stat One PTPlus Procedure (PO-7013-SYS) and IQCP revealed the statement, "Quality Control-PTPlus

	Liquid Control Level 1 and Level 2...Frequency-Two levels of control are performed on each inventory shipment, once each month and on new lots." 3. Review of the i-STAT One PTPlus QC records from August 2024 through the date of the survey on August 26, 2026, revealed two levels of PTPlus Liquid Control were performed /documented from August 2024 through December 2024 (5 months) and February 2025 through July 2026 (18 months). The i-Stat One PTPlus QC records lacked documentation of the performance of 2 levels of QC for January 2025. The surveyor requested to review documentation of the PTPlus Liquid Control Levels 1 & 2 for January 2025. The laboratory provided no documentation for review. 5. Review of the RALS laboratory information system from January 1, 2025, through January 31, 2025 revealed 504 patient specimens were tested/resulted utilizing the PTPlus cartridge during January 2025. 6. In an exit interview with the Clinical Manager, Quality & Accreditation Coordinator, Winchester Medical Center Laboratory Director and Clinic Laboratory Director on August 26, 2026, at 11:30 AM, the above findings were confirmed.
D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b(8)(i) (b)(8)(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, and an interview, the technical consultant (TC) failed to document annual competency assessments that included direct observation of International Normalized Ration (INR) patient test performance for six (6) of 6 testing personnel (TP) in calendar year 2025. The findings include: 1. During an entrance interview with the laboratory's Quality & Accreditation Coordinator (QAC) and Winchester Medical Center (WMC) Laboratory Director LD on August 26, 2026, at 9:00 AM, a review of the CMS 209 form revealed 6 TP responsible for moderate complexity INR test performance utilizing the Abbott i-STAT One analyzer. 2. Review of the TP competency assessment documentation for calendar years 2024 and 2025 revealed the laboratory's 2025 annual competency assessments for the i-STAT analyzer lacked documentation of the required competency element of direct observation of routine INR patient test performance for TP A, B, C, D, E and F. The surveyor noted the 2024 competencies for the above listed TP included documentation of direct observation of patient testing utilizing the i-STAT One. (See Personnel Code Sheet.) The surveyor requested to review documentation of the direct observation of INR test performance for the i-STAT One analyzer for calendar year 2025. The QAC stated they had changed their competency forms in 2025. The new forms did not include a section for documentation of direct observation. They stated that they have changed their competency forms to include direct observation for 2026. 3. In an exit interview with the Clinical Manager, QAC, WMC LD and Clinic Laboratory Director on August 26, 2026, at 11:30 AM, the above findings were confirmed.