Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2237022	11/01/2024
Name of Provider or Supplier	**Street Address, City, State**	
Warren Memorial Hospital Coagulation Clinic	1077 North Shenandoah Ave Suite A, Front Royal, 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 Warren Memorial Hospital Coagulation Clinic on October 31, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The survey also included an offsite follow up interview with the Quality and Accreditation Coordinator on 11/1/24. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods 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), CMS CLIA Laboratory Application for Certification form (CMS 116), proficiency testing (PT) records, and interviews, the laboratory failed to rotate PT among three (3) testing personnel (TP) performing patient coagulation testing during the twenty-two (22) months reviewed (January 2023 to the date of the validation survey on 10/31/24). Findings include: 1. During an interview on 10/31/24 at 2:00 PM, the inspector reviewed the laboratory's CMS 209 and CMS 116 forms with the Technical Consultant (TC) and Quality/Accreditation Coordinator. The review revealed that TP #1 - #3 were identified as qualified /responsible for operating an Abbott iSTAT analyzer for non waived Prothrombin Time and International Normalized Ratio (PT/INR) testing during the 22 months reviewed (January 2023 to 10/31/24). *See Personnel Code Sheet. 2. Review of the laboratory's 2023 American Proficiency Institute (API) PT and 2024 College of American Pathologists (CAP) PT records, a total of six (6) testing modules, revealed

	that TP #1 signed attestations as having performed the following PT/INR testing events reviewed: 2023 API Hematology/Coagulation Events 1-3 2024 CAP Hematology/Coagulation Events 1-3 TP #1 performed six (6) of the 6 coagulation PT module events (30 challenges) for the 22 months reviewed. 3. An interview with the TC and Quality/Accreditation Coordinator on 10/31/24 at 3:30 PM confirmed the above findings.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records, lack of documentation, and interview, the laboratory failed to document review/evaluation for two of three hematology/coagulation PT modules in calendar year 2023. Findings include: 1. Review of the laboratory's 2023 American Proficiency Institute (API) PT records (Events 1-3) revealed no retained results or documentation of a review/evaluation for: 2023 API Event 2: PT and INR coagulation module's five of five challenge samples (PT-06, PT-07, PT-08, PT-09, PT-10); 2023 API Event 3: PT and INR coagulation module's five of five challenge samples (PT-11, PT-12, PT-13, PT-14, PT-15). 2. The inspector requested to review the API results and evaluation documentation for the two PT events outlined above. The documentation was not available for review on the date of the survey. 3. An offsite follow up interview on 11/1/24 at 10:15 AM confirmed the above findings. The Quality/Accreditation Coordinator communicated, "The two PT evaluations were not signed".