Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0386746	03/23/2022
Name of Provider or Supplier	**Street Address, City, State**	
Wchc Family Medicine	1230 South Iowa Avenue, Washington, IA	

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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by laboratory personnel identifier #5 (refer to the Laboratory Personnel Report) at approximately 10: 25 am on 03/23/2022, the laboratory failed to perform a self evaluation of ungraded PT scores for two out of six PT testing events from 01/01/2020- 12/31/2021 (2020 event 3 and 2021 event 3). The findings include: 1. For 2020 testing event 3, the laboratory received ungraded PT test scores for the following: *2020 Hematology /Coagulation 3rd event: urine sediment (specimen US-06) 2. For 2021 testing event 3, the laboratory received ungraded PT test scores for the following: *2021 Hematology /Coagulation 3rd event: vaginal wet prep (KOH) (Specimen VKP-03) 3. At the time of the survey, the laboratory did not have additional documentation or corrective action for the ungraded PT test scores.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of Individualized Quality Control Plan (IQCP) records, review of quality control (QC) records, and confirmed by laboratory personnel identifier #5 (refer to the Laboratory Personnel Report) at approximately 10:30 am on 03/23/2022, the laboratory failed to perform a positive and negative control each day of patient testing for the Medtox Scan test system. The findings include: 1. The laboratory began using the Medtox Scan test system to perform urine drug screen testing for patients in October 2020. 2. The laboratory performed controls with each new lot of tests for the Medtox Scan test system. 3. Laboratory personnel identifier #5 indicated that the laboratory intended to follow the manufacturer's instructions for performing QC. 4. At the time of the survey, the laboratory did not have an IQCP for the Medtox Scan test system.