Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0386760	01/12/2021
Name of Provider or Supplier	**Street Address, City, State**	
Washington County Hospital & Clinics	400 East Polk Street, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of proficiency testing records and confirmed by laboratory personnel identifiers #5 and #6 (refer to the Laboratory Personnel Report) at approximately 9:30 am on 01/12/2021, the laboratory failed to enroll in an approved proficiency testing program for the subspecialty, bacteriology (methacillin resistant staphylococcus aureus [MRSA] screen by PCR) for two out of two years from 2020- 2021. The findings include: 1. The laboratory began performing MRSA screening by PCR in December 2019. 2. At the time of the survey, personnel identifiers #5 and #6 confirmed that the laboratory failed to enroll in an approved proficiency testing program for the subspecialty, bacteriology (MRSA screen by PCR) in 2020 and 2021.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different

	concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of OCD Vitros 7600 quality control (QC) records and confirmed by laboratory personnel identifiers #5 and #6 (refer to the Laboratory Personnel Report) at approximately 11:30 am on 01/12/2021, the laboratory failed to perform two levels of QC each day of patient testing for 6 out of 30 days of patient testing in November 2020. The findings include: 1. Review of chemistry QC records revealed that the laboratory only performed one level of QC on the following dates for the specified analytes: * 11/04/2020- Urine total protein (level 1) * 11/09/2020- Glycated hemoglobin (level 2) * 11/14/2020- Thyroid stimulating hormone (level 1); ferritin (level 1) * 11/24/2020- Procalcitonin (level 2); thyroid stimulating hormone (level 1); free triiodothyonine (level 1) * 11/25/2020- Iron (level 2) * 11/26/2020- N-terminal pro B-type natriuretic peptide (level 1) 2. Personnel identifiers #5 and #6 confirmed that the laboratory did not have additional QC records for the dates and analytes listed above.