Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0385515	01/07/2025
Name of Provider or Supplier	**Street Address, City, State**	
Avera Holy Family Hospital	826 North Eighth Street, Estherville, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the Laboratory Test List and Annual Volume report, proficiency testing records, and confirmed by interview with general supervisor identifier #1 (GS #1) at 9:00 am on 01/07/2025, the laboratory failed to verify the accuracy of urine sediment examinations performed on the Beckman Coulter DxU 840m Iris test system twice annually for two out of two time periods from 05/01/2024 - 12/31/2024. The findings include: 1. The laboratory began using the Beckman Coulter DxU 840m Iris test system to perform urine sediment examinations in May 2024. 2. At the time of the survey, GS #1 confirmed the laboratory did not enroll in proficiency testing or perform twice annual accuracy testing for urine sediment examinations performed on the Beckman Coulter DxU 840m Iris test system by another method from 05/01/2024 - 12/31/2024.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on review of the Laboratory Test List and Annual Volume report and

	confirmed by interview with general supervisor identifier #1 (GS #1) at 2:08 pm on 01 /07/2025, the laboratory failed to perform comparison testing twice annually for two out of two time periods from 05/01/2024 - 12/31/2024 for urine sediment examinations. The findings include: 1. The laboratory began using the Beckman Coulter DxU 840m Iris test system to perform urine sediment examinations in May 2024. 2. GS #1 stated the laboratory also performs urine sediment examinations by manual microscopy method. 3. At the time of the survey, GS #1 confirmed the laboratory did not perform comparison testing for urine sediment examinations from 05/01/2024 - 12/31/2024.