Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0385663	01/28/2026
Name of Provider or Supplier	**Street Address, City, State**	
Stewart Memorial Community Hospital	1301 West Main Street, Lake City, 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
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing (PT) records and confirmed by interview with technical supervisor #1 (TS #1) at 9:30 am on 01/28/2026, the laboratory failed to take and document corrective action for four unacceptable PT scores from three out of six PT testing events from 01/01/2024- 12/31/2025. The findings include: 1. For 2024 testing event 1, the laboratory received unacceptable PT test scores for the following: *2024 Chemistry Core- creatine kinase (specimen CH-02) 2. For 2025 testing event 1, the laboratory received unacceptable PT test scores for the following: *2025 Chemistry Core- high density lipoprotein (specimen CH-03) 3. For 2025 testing event 3, the laboratory received unacceptable PT test scores for the following: *2025 Chemistry Core- Folate (specimen IA-14) and free thyroxine (THY-15) 4. At the time of the survey, TS #1 confirmed the laboratory did not take and document corrective action for the unacceptable PT test scores listed above.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on lack of performance specification records and confirmed by interview with technical supervisor #1 (TS #1) at 11:50 am on 01/28/2026, the laboratory failed to verify the performance specifications of accuracy, precision, reference range, and reportable range prior to testing and reporting patient specimens for the Alcor Mini iSED test system. The findings include: 1. The laboratory began using the Alcor Mini iSED test system to perform erythrocyte sedimentation rate (ESR) testing in October 2025. 2. At the time of the survey, TS #1 confirmed the laboratory failed to have performance specification records for the Alcor Mini iSED test system.
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of personnel records, lack of Mini iSED performance verification records, and confirmed by interview with technical supervisor #1 (TS #1) at 11:50 am on 01/28/2026, the technical consultant failed to document training for the Mini iSED test system prior to reporting patient test results for nine out of nine testing personnel (identifiers TP #1- TP #9). The findings include: 1. The laboratory began using the Mini iSED test system in October 2025. 2. At the time of the survey, TS #1 confirmed the laboratory failed to have training records on the Mini iSED test system for testing personnel identifiers TP #1- TP #9.