

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0382831	(X3) Date Survey Completed 07/23/2026
Name of Provider or Supplier Greene County Medical Center	Street Address, City, State 1000 W Lincoln Way, Jefferson, 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
D0000	An onsite revisit was performed on 9/23/2026 for the Conditions: Hematology CFR: 493.1215 & General Laboratory Systems CFR: 493.1230 and associated standard level deficiencies cited on 07/23/2026. All condition level and associated standard level deficiencies have been corrected, and no new noncompliance was found. The facility is in compliance with the condition and associated standard level regulations.
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of coagulation reagent studies, observations of the CA-660 coagulation analyzer, and confirmed by interview with General Supervisor #3 (GS #3) at 12:50 pm on 07/23/2026, the laboratory failed to meet the hematology (coagulation) requirements for test system/equipment/reagent verification as specified in the standard D5411.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.

	This CONDITION is not met as evidenced by: Based on review of proficiency testing records and confirmed by interview with General Supervisor #3 (GS #3) at 10:40 am on 07/23/2026, the laboratory failed to meet the general systems requirements for documenting PT evaluation and verification of activities as specified in the standard D5221.
D5219	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2) (c)(2) Any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the Laboratory Test List and Annual Volume form, lack of proficiency testing records, and confirmed by general supervisor identifier #3 (GS #3) at 10:40 am on 7/23/2026, the laboratory failed to verify the accuracy twice annually three out of three time periods from 1/1/2025 - 7/23/2026 for the analyte, Helicobacter pylori (H. pylori). The findings include: 1. The Laboratory Test List and Annual Volume form confirmed the laboratory performed non-waived H. pylori testing. 2. The laboratory did not enroll in proficiency testing for non-waived H. pylori testing. 3. GS #3 confirmed the laboratory did not verify the accuracy twice annually for non-waived H. pylori testing using other methods.
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 proficiency testing (PT) records and confirmed by general supervisor identifier #3 (GS #3) at 10:40 am on 7/23/2026, the laboratory failed to document the evaluation of patient testing when they failed chemistry proficiency testing on two out of four events from 1/1/2025 - 7/23/2026 for the analytes: cholesterol and ferritin. The findings include: 1. For 2025 event 1, the laboratory received a score of zero for the analyte, cholesterol. The laboratory documented corrective action as, "We found that calibration was bad; QC was adjusted. Patients were not affected." The laboratory had no documentation indicating they had evaluated patient testing during the time of the failed PT. 2. For 2025 event 2, the laboratory received a score of zero for the analyte, ferritin. The laboratory documented corrective action as, "Recalibrated the test with a new lot of reagent & reran the (PT) samples. The rerun was within the allowable range." The laboratory had no documentation indicating they had evaluated patient testing during the time of the failed PT. 3. GS #3 confirmed at the time of the survey, the laboratory did not have documentation indicating they had evaluated patient cholesterol and ferritin testing performed during the time of the failed PT events.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)

(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on review of coagulation reagent studies, observations of the Dade CA-660 coagulation analyzer, and confirmed by interview with General Supervisor #3 (GS #3) at 12:50 pm on 7/23/2026, the laboratory failed to program the correct normal patient mean into the coagulation instrument for one out of one lot number of prothrombin time reagent (lot number 564696, expiration 9/30/2028). The findings include: 1. Review of the coagulation reagent verification records for prothrombin time reagent lot number 564696 indicated that the laboratory established a normal patient mean of 10.25 seconds. 2. Observation of the coagulation instrument showed that the laboratory programmed a normal patient mean of 10.0 seconds in for prothrombin time reagent lot number 564696. 4. GS #3 confirmed at the time of the survey, the laboratory failed to program the correct normal patient mean into the coagulation instrument for prothrombin time reagent lot number 564696 (expiration 9/30/2028).

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

(b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on review of chemistry calibration verification records and confirmed by general supervisor identifier #3 (GS #3) at 12:03 pm on 7/23/2026, the laboratory failed to perform calibration verification every six months for two out of three time periods from 1/1/2025 - 7/23/2026 for the analytes: sodium, potassium, chloride and glycosylated hemoglobin. The findings include: 1. The laboratory performed calibration verification on the analytes: sodium, potassium, chloride and glycosylated hemoglobin on 2/25/2025. 2. GS #3 confirmed at the time of the survey, the laboratory had not performed calibration verification for the analytes: sodium, potassium, chloride and glycosylated hemoglobin since 2/25/2025.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(13) (e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on lack of policies and procedures, review of the Laboratory Personnel Report and confirmed by general supervisor identifier #3 (GS #3) at 10:07 am on 7/23/2026, the laboratory director failed to ensure the laboratory had policies and procedures established for monitoring individuals who conduct preanalytical, analytical and post analytical phases of testing. In addition, the laboratory director failed to ensure that testing personnel maintained their competency for six out of seven testing personnel. The findings include: 1. The laboratory did not have a policy or procedure used to specify the need for semiannual and annual competency assessments. 2. The laboratory did not perform semiannual competency assessments on two out of seven testing personnel. Refer to D6127. 3. The laboratory did not perform 2025 annual competency assessments on four out of seven testing personnel. Refer to D6128. 4. GS #3 confirmed at the time of the survey, the laboratory did not have a competency policy and the laboratory did not perform competency as required for the above testing personnel.
D6121	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to-- (b)(8)(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; This STANDARD is not met as evidenced by: Based on review of 2026 competency assessments and confirmed by general supervisor identifier #3 (GS #3) at 10:07 am on 7/23/2026, the technical supervisor failed to ensure that the competency assessments performed in 2026 included the direct observation of routine non-waived patient test performance for six of out seven testing personnel. The findings include: 1. The laboratory performed 2026 competency assessments on testing personnel identifiers #1 - #6. 2. Review of the competency assessment confirmed that they did not include the direct observation of routine non-waived patient test performance for all test systems. 3. GS #3 confirmed at the time of the survey, the competency assessments did not include a direct observation of routine non-waived patient test performance for all test systems.
D6124	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iv) (b)(8)(iv) Direct observation of performance of instrument maintenance and function checks;

	This STANDARD is not met as evidenced by: Based on review of 2026 competency assessments and confirmed by general supervisor identifier #3 (GS #3) at 10:07 am on 7/23/2026, the technical supervisor failed to ensure that the competency assessments performed in 2026 included the direct observation of non-waived instrument maintenance and function checks for six of out seven testing personnel. The findings include: 1. The laboratory performed 2026 competency assessments on testing personnel identifiers #1 - #6. 2. Review of the competency assessments confirmed that they did not include the direct observation of non-waived instrument maintenance and function checks. 3. GS #3 confirmed at the time of the survey, the competency assessments did not include the direct observation of non-waived instrument maintenance and function checks.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the Laboratory Personnel Report and personnel records and confirmed by general supervisor identifier #3 (GS #3) at 10:07 am on 7/23/2026, the technical supervisor failed to ensure the laboratory performed semiannual competency assessments on two out of seven testing personnel hired since the last survey on 6/19 /2024. The findings include: 1. On 10/28/2024, the laboratory hired testing personnel identifier #6 to perform high complexity testing. 2. On 6/16/2025, the laboratory hired testing personnel identifier #5 to perform high complexity testing. 3. GS #3 confirmed at the time of the survey the laboratory did not perform semiannual competency assessments on the above testing personnel.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals 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 the Laboratory Personnel Report and personnel records and confirmed by general supervisor identifier #3 (GS #3) at 10:07 am on 7/23/2026, the technical supervisor failed to ensure the laboratory performed annual competency assessments on four out of seven testing personnel in 2025. The findings include: 1. The Laboratory Personnel Report confirmed that testing personnel #1, #2, #3 and #4 all performed high complexity testing. 2. GS #3 confirmed the laboratory did not perform 2025 competency assessments on the above testing personnel.