Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0384315	12/14/2023
Name of Provider or Supplier	**Street Address, City, State**	
Mccrary Rost Clinic - Gowrie	1800 Main Street, Gowrie, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency (PT) testing records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 9:20 am on 12/14 /2023, the laboratory failed to attest to the routine integration of PT samples in to the patient workload for five out of six PT events from 1/1/2022 - 12/14/2023. The findings include: 1. For 2022 testing event 1, the testing personnel and laboratory director (or designee) failed to sign the hematology/coagulation/urinalysis PT attestation statement. 2. For 2022 testing event 2, the laboratory director (or designee) failed to sign the hematology/coagulation/urinalysis PT attestation statement. 3. For 2022 testing event 3, the laboratory director (or designee) failed to sign the hematology/coagulation/urinalysis PT attestation statement. 4. For 2023 testing event 1, the laboratory director (or designee) failed to sign the hematology/coagulation /urinalysis PT attestation statement. 5. For 2023 testing event 2, the laboratory director (or designee) failed to sign the hematology/coagulation/urinalysis and microbiology PT attestation statements. 6. At the time of the survey, the laboratory did not attest to the routine integration of PT samples by not signing the above PT attestation statements.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform

	test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on lack of quality assessment audits, review of the Quality Management Plan /Quality Assurance Plan and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 9:51 am on 12/14/23, the laboratory director failed to ensure the laboratory performed twice annual audits for four out of four time periods from 1/1/2022 - 12/13/2023. The findings include: 1. The Quality Management Plan/Quality Assurance Plan stated, ""McCrary-Rost clinic laboratories will be visited twice per year by a hospital lab employee and ensure quality using a quality assurance check off sheet". 2. At the time of the survey, the laboratory did not have documentation of any quality assurance checks.