Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D0722618	05/30/2024
Name of Provider or Supplier	**Street Address, City, State**	
Carroll County Memorial Hospital Laboratory	309 11th Street, Carrollton, KY	

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	A Recertification Survey was conducted on 05/30/2024. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
D2153	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(a) Failure to attain a score of at least 100 percent of acceptable responses for each analyte or test in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on policy review, document review, and confirmed in staff interview, the facility failed to score 100% for D (Rho) testing for 1 (2nd Event 2023) of 6 proficiency events reviewed. Findings included: Review of the facility's policy titled, "Proficiency Testing/Inspection/Accreditation 1.8," dated 12/2020, revealed, "Any proficiency testing failures will be researched as to possible cause and documented on the Unsatisfactory Proficiency Result Investigation form which will be filed in the Proficiency Test Binder located in the Lab office." Review of the American Proficiency Institute (API) "Performance Summary" for the immunology /immunohematology - 2nd Event for 2023, revealed D (RHO) Type was 80%. During an interview on 05/30/2024 at 1:15PM, the General Supervisor (GS) stated due to the transition period and the change in laboratory management, the failure was not identified, and no corrective actions were taken. Per the GS, the absence of a proper handover process contributed to the oversight and lack of corrective measures.
D2160	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(e) (1) For any unsatisfactory testing event for reasons other than a failure to participate,

	the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on document review, and confirmed in staff interview, the laboratory failed to take and document remedial action for an unacceptable analyte D (Rho) for 1 (2nd Event 2023) of 6 proficiency testing (PT) events reviewed. Findings included: Review of the American Proficiency Institute (API) "Performance Summary" for the immunology/immunohematology - 2nd Event for 2023, revealed D (RHO) Type was unacceptable for sample RED-08. Review of facility documents revealed no evidence of documented remedial actions or technical assistance undertaken to correct the identified issues. During an interview on 05/30/2024 at 1:34 PM, Testing Personnel (TP) 1 stated the laboratory staff were aware of the issues but did not document the corrective actions or training provided to the staff. According to TP1, due a change in management, some of the actions were missed. TP1 acknowledged the laboratory did not maintain the required documentation of remedial actions.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of facility policy, document review, and confirmed in staff interview, the laboratory failed to provide evidence of corrective action for 1 of 6 proficiency testing (PT) events that were evaluated as unacceptable by the PT provider. Findings included: Review of the facility's policy titled, "Proficiency Testing/Inspection /Accreditation 1.8," dated 12/2020, revealed, "Any proficiency testing failures will be researched as to possible cause and documented on the Unsatisfactory Proficiency Result Investigation form which will be filed in the Proficiency Test Binder located in the Lab office." Review of the American Proficiency Institute (API) "Performance Summary" for the immunology/immunohematology - 2nd Event for 2023, revealed D (RHO) Type was unacceptable for sample RED-08. Review of the API "Proficiency Testing Performance Evaluation,: for the "2023 Immunology/Immunohematology - 2nd Event," was not signed or dated by the Laboratory Director (LD) and did not reveal any notations of corrective actions for the unacceptable analyte/sample. During an interview on 05/30/2024 at 1:15PM, the General Supervisor (GS) stated due to the transition period and the change in laboratory management, the failure was not identified, and no corrective actions were taken.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must

	be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of facility policy, document review, and confirmed in staf interview, the laboratory failed to address corrective actions. Specifically, when control or calibration materials failed to meet the laboratory's established criteria for acceptability, the laboratory did not evaluate all patient test results obtained in unacceptable test runs. Furthermore, the necessary corrective actions were not taken to ensure the reporting of accurate and reliable patient test results for 3 (phosphorus, creatine phosphokinase, and folic acid) of 12 quality controls reviewed. Findings included: Review of the facility's policy titled, "Quality Control Program 1.7," dated 12/2022, revealed "If QC [quality control] is out of range, steps must be taken and documented on the corrective action log in the main lab or in the LIS [laboratory information system] Action Log Report as applicable." Review of facility documents for the timeframe 07/01/2023 to 07/31/2023, revealed the phosphorus quality control (QC) was out of range and retested seven times on 07/17/2023 without a documented correction action. The documents indicated the creatine phosphokinase (CPK) QC was out of range for 14 out of 31 days, with no corrective action documented and the folic acid QC was out of range for 27 out of 31 days with no corrective action documented. During an interview on 05/30/2024 at 4:07 PM, the General Supervisor (GS) stated due to a change in leadership, no corrective actions were documented. The GS confirmed the laboratory did not cease testing of the analytes despite the multiple QC failures.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on document review, review of facility documents, and confirmed in staff interview, the laboratory failed to follow an approved corrective action plan when proficiency testing (PT) results were found to be unacceptable for 1 (2nd Event 2023) of 6 PT events reviewed. Findings included: Review of the American Proficiency Institute (API) "Performance Summary" for the immunology/immunohematology - 2nd Event for 2023, revealed D (RHO) Type was unacceptable for sample RED-08. Review of facility documents revealed no evidence of documented remedial actions or technical assistance undertaken to correct the identified issues. During an interview on 05/30/2024 at 1:15 PM, the General Supervisor (GS) stated due to a transition period and change in laboratory management, the failure was not identified and no corrective actions were taken. The GS confirmed the laboratory did not consistently implement or document corrective actions for PT failures. According to the GS, the lack of proper documentation and follow through on corrective actions was an oversight.