Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0023027	11/20/2024
Name of Provider or Supplier	**Street Address, City, State**	
Madison Co Memorial Hospital Clinical Laboratory	224 Nw Crance Ave, Madison, FL	

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 announced CLIA recertification survey was conducted at Madison Co Memorial Hospital Clinical Laboratory on 10/31/2024 - 11/20/2024. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D5200 General Laboratory Systems 493.1230
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 the procedure manual and the America Proficiency Institute (API) proficiency testing (PT) records; and interview, the Laboratory Director failed to sign the attestations for four (2023 1st, 2nd, 3rd, 2024 1st) of five events (2023 1st, 2nd, 3rd; 2024 1st, 2nd) for Chemistry Core; and two (2023 3rd, 2024 1st) of five events (2023 1st, 2nd, 3rd; 2024 1st, 2nd) for Microbiology; and the laboratory testing personnel failed to sign the attestation for two (2023 1st, 2nd) of six events (2023 1st, 2nd, 3rd; 2024 1st, 2nd, 3rd) for Chemistry Core. Findings included: 1. Review of the procedure title Proficiency Testing noted "The lab manager signs the attestation statement as director." The procedure also noted "The technologist performing the testing signs printed attestation statement. Review of the attestation form noted "For all PT results, an attestation must be signed by testing personnel and the laboratory director and retained for a minimum of 2 years." The form indicates the attestation can be signed by a designee instead of the laboratory director. 2. Review of the attestation forms showed their was no signature for the laboratory director of designee for Chemistry Core for 2023 1st, 2nd, 3rd, and 2024 1st events and for Microbiology for 2023 3rd, and 2024 1st events. Review of the attestation forms showed their was no signature for the testing personnel for 2023 1st and 2nd events for Chemistry Core. 3.

	During an interview on 10/31/24 at 4:30 PM, the Technical Supervisor acknowledged the attestations were not signed.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of the procedure manual and the America Proficiency Institute (API) proficiency testing (PT) records; and interview, the laboratory failed to retain all the API Work Cards used to record the reactions for Immunohematology testing for three (2023 1st, 3rd; 2024, 2nd) of five events (2023 1st, 2nd, 3rd; 2024 1st, 2nd) reviewed. Findings included: 1. Review of the procedure title Proficiency Testing Policy noted "Primary records related to PT and alternative assessment testing are retained for two years (unless a longer retention is required elsewhere in this checklist for specific analytes or disciplines). These include all instrument tapes, work cards, computer printouts, evaluation reports, evidence of review, and documentation of follow-up /corrective action." 2. Review of the API PT records showed there are five samples sent to the laboratory to test tested for each event. Review of the laboratory's PT records showed the work cards were missing for 2023 1st event for sample #3 and #5, 2023 3rd event sample #11 and #13, and 2024 2nd event sample #6, #7, and #10. 3. During an interview on 10/31/2024 at 4:30 PM, the Technical Supervisor acknowledge the work card were missing.
D2173	COMPATIBILITY TESTING CFR(s): 493.863(a) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of the America Proficiency Institute (API) proficiency testing (PT) records and interview, the laboratory failed to obtain a passing score of 100% in Immunohematology Compatibility test for the 2024 2nd event. Findings included: 1. Review of the API records showed the for the 2024 2nd event for Compatibility testing the laboratory received a score of 80%. 2. During an interview on 10/31/24 at 1:10 PM, the Testing Personnel F acknowledged the failure in Compatibility Testing.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)

	Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on lack of documentation, interview, and review of Record Retention procedure the laboratory failed to retain quality control and records documenting all analytic systems activities for at least 2 years (2023-2024). Findings included: 1. Hematology analytic records for 04/2023 were requested for review. No documentation was presented for review. 2. Testing Personnel F confirmed on 10/31 /2024 at 1:50 pm the requested documentation was not retained for 2 years. 3. The Record Retention procedure, approved by the Laboratory Director on 2/06/2024- stated analytic records were to be retained for 2 years.
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 record review and interview, the laboratory failed to have competency evaluations for 8 (Testing Person #B, #C, #D, #G, #H, #I, #J, and #N) out of 14 Testing Personal (#A-#N) reviewed (See D5209).
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have competency evaluations for 8 (Testing Person #B, #C, #D, #G, #H, #I, #J, and #N) out of 14 Testing Personal (#A-#N) reviewed. This is a repeat deficiency from the 09/27/2022 recertification survey. Findings Included: 1. Review of the policy titled "Competency Skills Assessment" signed by the Laboratory Director on 10/20/2022 revealed that "Each laboratory employee must have a Competency Skills Assessment completed for each area of the laboratory in which he/she works within six (6) months of employment and annually thereafter". 2. Review of Testing Personnel competency records revealed the following: a. Testing Person #B did not have 2023 competency. b. Testing Person #C did not have 2023 competency. c. Testing Person #D did not have 2023 competency. d. Testing Person #G did not have 2023 competency. e. Testing Person #H did not have a 2023 competency signed by the supervisor. f. Testing Person #I did not have 2023 competency. g. Testing Person #J did not have a

	2023 competency signed by the supervisor. h. Testing Person #N did not have 2023 competency. 3. Interview on 10/31/2024 at 4:20 PM the General Supervisor confirmed the missing 2023 competency evaluations and that #H and #J had competencies not signed by the supervisor. 4. Review of the plan of correction (signed by the Laboratory Director on 10/20/2022) from the 09/27/2022 recertification survey revealed that "The Laboratory Manager/Technical Supervisor will verify the competency of all laboratory personnel annually per the updated policy and address areas of concern."
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 the procedure manual and America Proficiency Institute (API) proficiency testing (PT) records; and interview, the laboratory director or designee failed to sign the API Performance Evaluation for two (2023 2nd, 3rd) of six events (2023 1st, 2nd, 3rd; 2024 1st, 2nd 3rd) for Chemistry Core; one (2023 1st) of three events (2023 1st, 2nd; 2024 1st) for Chemistry Miscellaneous; one (2023 3rd) of five events (2023 1st, 2nd, 3rd; 2024 1st, 2nd) for Hematology; and one (2023 3rd) of five events (2023 1st, 2nd, 3rd; 2024 1st, 2nd) for Microbiology. Findings included: 1. Review of the procedure title Proficiency Testing section titled Reviewing Graded Results noted "The Pathologist reviews proficiency testing results and signs the attestation statement." 2. Review of the API Performance Evaluation showed there was no signatures on the for Chemistry Core 2023 2nd and 3rd events, Chemistry Miscellaneous 2023 1st event, Hematology 2023 3rd, and Microbiology 2023 3rd event. 3. During an interview on 10/31/24 at 4:30 PM, the Technical Supervisor acknowledged the performance reviews were not signed.
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 the procedure manual and America Proficiency Institute (API) proficiency testing (PT) records; and interview, the laboratory failed to document corrective actions for proficiency testing (PT) score that were less than 100% for two (2023 2nd, 3rd) of six events (2023 1st, 2nd, 3rd; 2024 1st, 2nd 3rd) for Chemistry Core; and one (2023 3rd) of three events (2023 1st, 2nd, 3rd; 2024 1st, 2nd) for Hematology. Findings included: 1. Review of the Proficiency Testing Policy section Unsatisfactory Proficiency Testing (PT) Performance noted "Investigate the problem utilizing the Incident Investigation Form, Determine the cause, Implement corrective action." 2. Review of the API Performance Evaluation showed for Chemistry Core 2023 2nd event the laboratory received a score of 80% for Phosphorus, Free Thyroxin and Thyroid Stimulating Hormone; and for Chemistry Core 3rd events the laboratory received a score of 80% for NT pro-BNP (N-terminal pro-B-type Natriuretic Peptide), pCO2 (partial pressure carbon dioxide), Troponin, CK (Creatinine Kinase) total and CK-MB. Review of the API Performance Evaluation showed for Hematology 2023

	3rd showed the laboratory received a score of 80% for RDW-CV (Red Cell Distribution Width-Coefficient of Variation) and RDW-SD (Red Cell Distribution Width-Standard Deviation). Review of the performance Evaluation showed the evaluations were not signed, and there was no corrective action documents. 3. During an interview on 10/31/2024 at 4:30, the Technical Supervisor acknowledged the performance reviews were not signed and there was no corrective action documentation.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of monthly hematology quality control records and interviews it was determined the control procedure of the laboratory failed to monitor over time the accuracy and precision of hematology test performance for one of one (8/2024) month reviewed. Findings included: 1. Two months of Hematology analytic records were requested (4/2023 and 8/2024), however only 8/2024 Hematology records were presented for review. 2. The Coagulation Hematology monthly quality control (QC) charts for 8/2024 reviewed by the Technical Supervisor 10/28/24 and by the Laboratory Director on 10/29/24 did not document any issues or concerns. The Partial Thromboplastin Time (PTT) coagulation hematology QC Level 1 chart for 8/2024 documented 60 of 60 data points were shifted below the mean. 3. The Technical Supervisor confirmed on 10/31/2024 at 1:50 pm the PTT level 1 QC monitoring had not identified the shift below the mean and no corrective actions had been taken. 4. The laboratory used Insight program, a QC program provided by the Hematology Complete Blood Count (CBC) instruments in the laboratory. Reports with interpretations were provided monthly. The XS-1000i for 8/28/24 to 09/01/24 and XP-300 for 8/07/24 to 9/01/24 the CBC Instruments reports were reviewed by Technical Supervisor on 9/21/2024 and Lab Director on 10/29/2024 with no documentation of issues or corrective actions. 5. The XS-1000i for 8/28/24 to 09/01/24 documented for platelet level 2 the coefficient of variance (C.V.) used to quantify variation was 2.5 in bold type. The XP-300 for 8/07/24 to 9/01/24 documented for White Blood Count the C.V. was 2.9 in bold type. The interpretation of report stated "If your C.V. is 1.5 times greater than group CV your result is presented in bold type and investigation is warranted." 6. The Technical Supervisor confirmed on 10/31/2024 at 1:50 pm the Insight QC program monitoring had not identified the high C.V.s and investigation had not been performed.
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. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on observation, staff interview, and lack of documentation the laboratory failed to have a system that twice a year evaluated test results using the different instruments Hematology instruments to perform Complete Blood Counts (for 2 of 2 years (2023-2024). Findings Included: 1. During a tour of the laboratory on 10/31/2024 at 10:30 am two Hematology instruments to perform Complete Blood Counts (CBC) were observed-Sysmex XS-1000i serial number 75071 and Sysmex XP-300 serial number A9122. 2. No instrument to instrument comparisons for 2023-2024 were provided for review as requested. 3. The Technical Supervisor confirmed on 10/31/2024 at 3:15 pm the laboratory had not performed twice a year evaluation of CBC test results using the two different instruments for 2 of 2 years (2023-2024).
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interviews, the Laboratory Director failed to ensure the proficiency testing samples were tested as required under subpart H for 2023 and 2024. Findings included: 1. The Laboratory Director failed to sign the attestations for Chemistry Core 2023 1st, 2nd, 3rd, and 2024 1st events; and Microbiology 2023 3rd, 2024 1st events; and the Laboratory Director failed to ensure the testing personnel signed the attestation for Chemistry Core 2023 1st, and 2nd events. (See D2009) 2. The Laboratory Director failed to ensure the laboratory retained all the API Work Cards used to record the reactions for Immunohematology testing for 2023 1st, 3rd; and 2024, 2nd events (See D2015).
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview, the previous Laboratory Director failed to ensure PT results were reviewed for two (2023 2nd, 3rd) of six events (2023 1st, 2nd, 3rd; 2024 1st, 2nd, 3rd) for Chemistry Core; one (2023 1st) of three events (2023 1st, 2nd; 2024 1st) for Chemistry Miscellaneous; one (2023 3rd) of five events (2023 1st, 2nd, 3rd; 2024 1st, 2nd) for Hematology; and one (2023 3rd) of five events (2023 1st, 2nd, 3rd; 2024 1st, 2nd) for Microbiology. Findings included: The Laboratory Director or the designee failed to document the review the

	proficiency testing (PT) Chemistry Core 2023 2nd and 3rd events, Chemistry Miscellaneous 2023 1st event, Hematology 2023 3rd, and Microbiology 2023 3rd event. (See D5211)
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 review of the procedure manual and America Proficiency Institute (API) proficiency testing (PT) records; and interview, the Laboratory Director failed ensure the laboratory document corrective actions for proficiency testing (PT) score that were less than 100% for two (2023 2nd, 3rd) of six events (2023 1st, 2nd, 3rd; 2024 1st, 2nd 3rd) for Chemistry Core; and one (2023 3rd) of 3 events (2023 1st, 2nd, 3rd; 2024 1st, 2nd) for Hematology. Findings included: The laboratory failed to have corrective action for Chemistry Core 2023 2nd and 3rd events, and Hematology 2023 3rd. (See D5221)
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of records observations, interviews, and lack of documentation it was determined the laboratory director failed to ensure that a quality assessment programs was established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur for 2 of 2 years (2023-2024). Findings included: 1. A quality assessment (QA) program approved by the Laboratory Director failed to be provided for review. 2. Testing Personnel F stated 10/31/2024 at 2:30 pm the laboratory was included in the hospital QA program but did not have one specific for the laboratory. 3. There was no documentation the laboratory had identified the following deficient practices through an established QA program. 4. As cited at D3031- the laboratory failed to retain quality control and records documenting all analytic systems activities for at least 2 years (2023-2024), D5441-the laboratory failed to monitor over time the accuracy and precision of hematology test performance for one of one (8/ 2024) month reviewed, and D5775-the laboratory failed to have a system that twice a year evaluated test results using the different instruments Hematology instruments to perform Complete Blood Counts for 2 of 2 years (2023-2024).