Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0023027	(X3) Date Survey Completed 10/02/2020
Name of Provider or Supplier Madison Co Memorial Hospital Clinical Laboratory	**Street Address, City, State** 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 County Memorial Hospital Laboratory on October 1-2, 2020. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of American Proficency Institute (API) and interview with the Laboratory Supervisor, the laboratory failed to score at least 80% for 5 analytes (Albumin, Total Calcium, Potassium, Total Protein, Alcohol) in the Specialty of Chemistry for 1 (1st event 2020) out of 6 testing events (3rd 2018, 1st, 2nd, 3rd 2019 and 1st, 2nd 2020) reviewed for 2 years (2018-2020). Findings Included: Review of API proficiency testing revealed a score of 60 % for albumin, 60 % Total Calcium, 60 % Potassium, 40 % Total Protein and 60 % for Alcohol in the 1st testing event of 2020 . During an interview on 10/1/2020 at 10:30 AM, the Laboratory Supervisor confirmed the failed proficiency testing scores.
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 American Proficiency Institute (API) proficiency testing results and interview with the Laboratory Supervisor, the laboratory failed to score 100% on Compatibility Testing for 1 (1st event 2020) out of 6 testing events (3rd 2018, 1st, 2nd, 3rd 2019 and 1st, 2nd 2020) reviewed for 2 years (2018-2020). Findings Included: Review of API proficiency testing results for the 1st testing event in 2020 revealed a score of 60% for Compatibility Testing. During an interview on 10/01/20 at 10:30 AM , the Laboratory Supervisor confirmed the proficiency testing failure.
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 with the Laboratory Supervisor, the laboratory failed to have competency evaluations on 8 out of 17 testing personnel in 2019 for 2 out of 2 (2018-2020) years reviewed. Findings Included: Review of competency evaluations found that Testing Person # C, D,E F,G,H,I and J did not have competency evaluations completed for 2019. During an interview on 10/02/20 at 10: 30 AM, the Laboratory Supervisor confirmed that the competency evaluations were not completed in 2019 for Testing Person # C,D,E,F,G,H,I and J.
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 proficiency testing records, and interview with the Laboratory Supervisor, the laboratory failed to review proficiency test scores for 3 of 3 events for 2019 out of 2 years (2018-2020) reviewed for Chemistry, Hematology, Immunohematology and Bacteriology. Findings Included: 1. Review of American Proficiency Institute (API) proficiency test records revealed the laboratory failed to review test scores for the Specialties of Chemistry , Hematology, Immunohematology and Subspecialty of Bacteriology for 1st, 2nd, and 3rd events in 2019. 2. During interview on 10/02/20 at 1:00 PM, the Laboratory Supervisor confirmed the laboratory did not document review of proficiency test scores for the specialties and events listed above.