

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0023027	(X3) Date Survey Completed 09/27/2022
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	A recertification survey was conducted on September 27, 2022. Madison County Memorial Hospital Clinical Laboratory was not in compliance with 42 CFR 493, Requirements for Laboratories.
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Manager, the laboratory failed to include all Respiratory Testing Personnel (TP) for the testing of Blood Gas Proficiency samples for four testing events in 2021 and 2022. Findings include: Review of the CMS-209 Laboratory Personnel Report signed and dated by the Laboratory Director on 9/16/2022 revealed there were eight Respiratory TP (#A, #B, #C, #D, #E, #F, #G, #H). Record review of American Proficiency Institute attestation sheets for three testing events in 2021 and one testing event in 2022, revealed Respiratory TP #A tested all Blood Gas Proficiency samples in all four testing events. Interview with the Laboratory Manager on 9/27/2022 at 06:00 p.m. confirmed only Respiratory TP #A tested Proficiency samples for three testing events in 2021 and one testing event in 2022.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p>

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory failed to perform and document competency evaluations for Testing Personnel (TP) #A for 2021 and 2022. Findings include: Review of the CMS-209 Laboratory Personnel Report revealed nine TP (#A, #B, #C, #D, #E, #F, #G, #H, #I). Review of employee competency records found no annual competency evaluations for TP #A had been documented for 2021 and 2022. Interview with the Technical Supervisor (who is also TP #A) on 9/27/2022 at 06:00 p. m. confirmed no competency evaluation had been performed and documented for 2021 and 2022. This is a repeat deficiency.

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for 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 record review and interview, the Technical Supervisor (TS) failed to document a semiannual competency for 1 out of 9 Testing Personnel (TP) in 2021. Findings include: Review of the CMS-209 Laboratory Personnel Report signed and dated by the Laboratory Director (LD) on 9/16/2022 revealed there were nine TP (#A, #B, #C, #D, #E, #F, #G, #I.) Review of Laboratory Employee personnel records revealed there was no semiannual evaluation on TP #G hired in March of 2021. Interview with the TS on 9/27/2022 at 06:00 p.m., confirmed no semiannual competency had been documented on TP #G.