

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 28D0453622	(X3) Date Survey Completed 09/19/2019
Name of Provider or Supplier Twelve Clans Unity Hospital	Street Address, City, State 225 S Bluff St, Winnebago, NE	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's list of tests performed, lack of documentation, and interview with the technical consultant at 1:10 PM on 9/19/2019, the laboratory failed to verify the accuracy for micro albumin. Findings are: 1. Review of the laboratory's list of tests performed revealed the laboratory performing moderate complexity micro albumin testing for the past 2 years. 2. No documentation could be presented through proficiency testing or laboratory comparison to verify the accuracy of this testing. 3. Interview with the technical consultant revealed the laboratory had not enrolled the laboratory in proficiency testing or had comparison testing performed for this analyte.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of patient test report and interview with the technical consultant at 3:08 PM on 9/19/2019, the laboratory failed to have the address of the testing location on the patient test report. Findings are: 1. Review of 1 patient test report revealed no testing location address on the report. 2. Interview with the technical consultant confirmed no testing location address was indicated on the report.