

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0407454	(X3) Date Survey Completed 07/20/2021
Name of Provider or Supplier Douglas County Memorial Hospital	Street Address, City, State 708 8th Street, Armour, SD	
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 for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 7/20/21. The Douglas County Memorial Hospital laboratory was found not in compliance with the following requirement: D2015.
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to maintain a copy of the submitted results for thirty-four of thirty-four proficiency testing (PT) events reviewed (2019, 2020 and to date in 2021). These reports documented the results submitted by the laboratory for evaluation by the PT company. Findings include: 1. Review of the laboratory's PT event records on 7/20/2021 revealed: *The laboratory subscribed to PT events through the American Proficiency Testing Institute. *PT specimens were processed and the results submitted via the company's website upon completion of testing. *The result forms had been printed before the results had been submitted electronically. Those forms stated the test results had not been submitted, and therefore could have been changed prior to submission. *The laboratory had completed and received evaluation reports for the following testing events: a. 2021</p>

API PT events -Immunology/Immunoematology- testing event 1. -Hematology /Coagulation- testing event 1. -Microbiology- testing event 1. -Chemistry Core- testing event 1 and 2. -Chemistry Miscellaneous- testing event 1. b. 2020 API PT events -Immunology/Immunoematology- testing events 1, 2, and 3. -Hematology /Coagulation- testing events 1, 2, and 3. -Microbiology- testing events 1, 2, and 3. - Chemistry Core- testing events 1, 2, and 3. -Chemistry Miscellaneous- testing events 1 and 2. -SARS CoV-2 (Severe Acute Respiratory Syndrome Coronavirus-2)- testing event 3. c. 2019 API PT events -Immunology/Immunoematology- testing events 1, 2, and 3. -Hematology/Coagulation- testing events 1, 2, and 3. -Microbiology- testing events 1, 2, and 3. -Chemistry Core- testing events 1, 2, and 3. -Chemistry Miscellaneous- testing events 1 and 2. Review of the Proficiency Testing procedure (last reviewed by the laboratory director on 10/9/20) revealed, "The worksheets, instrument printouts, and copies of the original paperwork with results submitted to API are all kept at DCMH [Douglas County Memorial Hospital]." Interview on 7/20 /21 at 10:05 a.m. with laboratory personnel A revealed she confirmed the laboratory had not kept the submitted result forms for the PT events the laboratory had completed.