Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D0407454	09/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Douglas County Memorial Hospital	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 9/12/18. The Douglas County Memorial Hospital laboratory was found not in compliance with the following requirements: D5217, D5421, and D6091.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) documentation, immunohematology patient testing log, and laboratory supervisor interview, the laboratory failed to verify and document the accuracy of the test method used for patient direct antiglobulin testing (DAT) twice a year for 20 of 20 months reviewed (January 2017 through August 2018). Findings include: 1. Review of the laboratory's PT documentation revealed there had been no documentation the accuracy of the DAT test had been verified twice a year for the above time frame. Review of the immunohematology patient testing log revealed one patient DAT test had been reported during the twenty months reviewed. Interview on 9/12/18 at 11:15 a.m. with the laboratory's supervisor revealed PT had not been ordered for the DAT test. It was an oversight on her part. DAT testing was rarely ordered as they no longer provided obstetrical services.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the

	manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the performance specification verification records for the Beckman AU480 chemistry analyzer, patient record review and interview with laboratory supervisor, the laboratory failed to verify and approve the accuracy for 1 of 31 analytes (lipase) before patient specimens had been tested and their results reported. Findings include: 1. Review of the performance specification verification records for the lipase test method on the Beckman AU 480 chemistry analyzer revealed accuracy had not been verified and approved prior to testing of patient specimens. There was documentation of precision, reportable ranges, and normal range verifications. The laboratory director had signed off the performance specification verification records as acceptable on 4/11/18. Review of patient records revealed the accuracy of the lipase test method had not been verified before twelve patient lipase specimens had been reported between 4/1/18 (when the analyzer went live) and 9/12/18. Interview on 9/12/18 at 1:30 p.m. with the laboratory supervisor revealed: *The accuracy/comparison studies had not been included in the performance specification verification as the previous analyzer did not report lipase. *She had been told by the technical specialist who installed the analyzer the studies were complete.
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) events, quality assurance (QA) activities, QA policy, and interview with the laboratory's supervisor, the laboratory (lab) failed to ensure PT results had been reviewed, evaluated, and those activities documented for 3 of 23 events (Microbiology 2017 1st, Chemistry Core 2017 1st and 2018 2nd events) reviewed. Findings include: 1. Review of the 2017 and to-date 2018 American Proficiency Institute PT events revealed: *Microbiology 2017 1st event gram stain GS-03 was reported as gram positive. The acceptable response was gram negative. *Chemistry Core 2017 1st event gentamycin CH-05 was reported as 4.5 ug/ml. The acceptable response was 2.2-3.8 ug/ml. Chemistry Core 2017 1st event phenytoin CH-03 was reported as 39.5 ug/ml. The acceptable response was 23.0-38.5 ug/ml. *Chemistry Core 2018 2nd event pCO2 BG-07 was reported as 52 mmHg. The acceptable response was 54-65 mmHg. *The performance review and the corrective action sheets had been left blank but had been signed by the lab director. *There had been no other documentation unacceptable results had been reviewed or evaluated. *There had been no corrective actions documented for the unacceptable results. Review of the laboratory's QA Proficiency Testing Results Review policy effective July 2010 and last signed by the laboratory director 8/15/18 revealed: "All results and scores will be reviewed, signed and dated by the laboratory supervisor upon receipt. Any unsuccessful participation will be communicated to the laboratory director and South Dakota Department of Health upon receipt. A plan of correction will be follow.

	Results and scoring paperwork will be reviewed, signed, and dated by the laboratory director at quarterly visits." Review of the laboratory's 2017 1st quarter QA activities revealed no documentation of unacceptable gram stain, gentamycin and/or phenytoin results having been evaluated. Review of the laboratory's 2018 3rd quarter QA activities was not yet available for review. Interview on 9/12/18 at 9:50 a.m. with the laboratory supervisor revealed she was unaware the unacceptable results had not been investigated.