Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D0658864	07/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Landmann Jungman Memorial Hospital	600 Billars Avenue, Scotland, 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 7/21/21. The Landmann Jungman Memorial Hospital laboratory was found not in compliance with the following requirements: D5215 and D6028.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to review proficiency testing (PT) results to ensure their accuracy for twenty-two of twenty-two "not graded" PT samples reviewed (American Proficiency Testing Institute [API] Hematology/Coagulation 2019 2nd testing event, 2020 2nd and 3rd testing events, and 2021 1st testing event). Findings include: 1. Review of PT records for 2019, 2020 and through 7/21/21 revealed: *There had been no documentation the following samples had been reviewed for their accuracy. These samples had not been graded due to lack of consensus. -API 2019 Hematology/Coagulation 2nd testing event specimen US-06. -API 2020 Hematology/Coagulations 3rd testing event specimen BC1-11. *There had been no documentation of the following samples had been reviewed for their accuracy. These samples had not been graded due to their designation as educational challenges. -API 2020 Hematology/Coagulation 2nd testing event samples ECI-06, 07, 08, 09, and 10. -API 2020 Hematology/Coagulation 3rd testing event samples ECI-11, 12, 13, 14, and 15. -API 2021 Hematology/Coagulation 1st testing event samples ECI-1, 2, 3, 4, and 5. Review of the quality assessment (QA) records revealed: *QA

	General Laboratory Systems reports were completed on a quarterly basis. *"All ungraded PT results for education purpose were evaluated" were incorrectly marked as acceptable on the following quarterly QA reports: -2020 1st quarter -2020 2nd quarter -2020 3rd quarter -2020 4th quarter -2021 1st quarter *There was no other documentation those ungraded results had been evaluated for their accuracy. Review of the Laboratory Consultation Summary reports revealed: *The technical consultant reviewed the proficiency testing reports. *The technical consultant had documented on her 1/31/21 and 4/23/21 quarterly visit summary reports that the 2020 Hematology /Coagulation 3rd Testing event ECI an BC-11 specimens had not been reviewed. Interview on 7/21/21 at 10:10 a.m. with laboratory personnel A revealed: *She confirmed she did review the PT evaluation reports. *She confirmed the "not graded" PT results had not been reviewed or checked for accuracy.
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to ensure competency evaluations for two of three laboratory staff (B and C) were completed by qualified personnel for the nonwaived test methods they performed under the laboratory's certificate. Findings include: 1. Review of employees' files for laboratory staff revealed: *Laboratory staff B had a competency evaluation performed on 4/21/21. *Laboratory staff C had a competency evaluation performed on 7/31/20. The above competency evaluations had been conducted and signed by laboratory staff A. There was no indication the laboratory director was involved in the competency assessment process. Review of the the Centers for Medicare Services 209 Laboratory Personnel Report Form signed by the laboratory director on 7/16/21 laboratory personnel A had been listed as testing personnel only. Review of laboratory personnel A's education revealed she had received an associates degree. There was no documentation of a higher degree had been obtained. Interview at 10:10 am on 7/21/21 with laboratory personnel A revealed: *She confirmed she had performed the competency evaluations for laboratory personnel B and C. *She confirmed she did not have a minimum of a bachelor's degree as required by Clinical Laboratory Improvement Act to qualify as a technical consultant. *She was not aware she would need to qualify as a technical consultant to perform employee competency evaluations.