Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0705741	04/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Nell J Redfield Memorial Hospital	150 N 200 W, Malad City, ID	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records from American Proficiency Institute (API) and an interview with the laboratory manager on 4/21/2021, the laboratory director or his/her designee failed to sign a statement attesting that PT samples were tested in the same manner as patient specimens. The findings include: 1. A review of PT testing from API for 2019 immunology/immunohematology 3rd event identified the laboratory director or his/her designee failed to sign the attestation statement. 2. An interview with the laboratory manager on 4/21/2021 at 9:40 am confirmed that the laboratory director failed to sign the attestation statement for the 2019 immunology/immunohematology 3rd event.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in

	493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of laboratory policies and procedures and an interview with the laboratory manager on 4/21/2021, the laboratory failed to have a procedure manual that included a procedure for microbiology cultures that includes step-by-step performance and instructions for reporting the patient's test results. The findings include: 1. A review of laboratory policies and procedures identified that the laboratory failed to have a procedure that included step-by-step instructions for performing microbiology cultures, referring cultures and instructions for reporting the patient's microbiology culture results. 2. An interview with the laboratory manager on 4/21/2021 at 10:20 am confirmed that the laboratory failed to have a procedure for microbiology culture testing and reporting. 3. The laboratory reports performing 580 microbiology cultures annually.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of the thromboplastin reagent package insert for the ACL TOP 300 and an interview with the laboratory manager on 4/21/2021, the laboratory failed to ensure that the correct International Sensitivity Index (ISI) value was used for calculating the International Normalized Ratio INR value. The findings include: 1. A review of the thromboplastin reagent package insert for lot number N0504107 with an ISI of 0.98 identified that the laboratory failed to have the correct ISI input in the ACL TOP 300 to properly calculate the INR since the change of reagents in January 2021. 2. An interview with the laboratory manager on 4/21/2021 at 11:00 am confirmed that the laboratory failed to use the correct ISI when calculating patient INRs.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on a random record review of Quality Control (QC) documentation and an interview with the laboratory manager on 4/21/2021, the laboratory failed to successfully perform two levels of QC daily for each quantitative procedure. The findings include: 1. A random record review of QC documents from the Beckman Coulter Access II for 2019, 2020 and 2021 identified that the laboratory failed to document level 1 QC results for free thyroxine (FT4) on 9/26/2019. The laboratory performed one FT4 patient samples on 9/26/2019. 2. An interview with the laboratory manager on 4/21/2021 at 4:00 pm confirmed that the laboratory failed to document the above QC.