Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D0407513	04/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Huron Regional Medical Center	172 Fourth Street Se, Huron, 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 4/24/18. The Huron Regional Medical Center laboratory was found not in compliance with the following requirements: D2007, D5413, D5471, and D6127.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) attestation statements, the Laboratory Personnel Report form 209, review of the External Assessment policy, and interview with laboratory employee A, the laboratory failed to ensure all testing personnel routinely testing patient samples participated in PT testing during 12 of 12 months (January through December 2017). The laboratory did not implement their established policy regarding staff participation in PT. Findings include: 1. Review of the College of American Pathologist (CAP) PT attestation statements for 2017 revealed the following: a. Laboratory employee B participated in three of three general chemistry testing events, two of two cardiac marker testing events, two of two urine chemistry testing events, and three of three special chemistry testing events. Laboratory personnel C participated in one of three general chemisty events. No other laboratory employee who routinely tested patient samples participated in any of the events. b. Laboratory employee D participated in three of three hematology testing events, two of two body fluid cell count testing events, two of two coagulation testing events, and two of two clinical microscopy testing events. c. Laboratory employee E participated in three of three blood bank testing events. d. Laboratory employee F participated in three of three plasma cardiac marker testing events. e. Laboratory employee G also

	performs patient testing in all areas of the laboratory and did not participate in PT events during this time period. Review of the External Assessment policy revealed "the proficiency test should be rotated and assigned among the various lab personnel assigned to the section to assess individual proficiency and competency." Interview with laboratory employee A at 3:30 p.m. on 4/23/18 revealed all personnel are proficient to work in all areas of the laboratory. He stated there is no set schedule for PT assignments among the testing personnel. He left it up to the individual department heads to assign PT testing within their individual areas.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation, review of maintenance logs and instrument manuals, and interview with laboratory employee A and maintenance employee B, the lab failed to maintain humidity levels within the optimal humidity ranges for instruments used to test patient specimens for 9 of 15 months (January, February, March, April, May, October, November and December 2017 and January through March 2018) reviewed in the main laboratory and histology areas. Findings include: 1. Review of 2017 and 2018 maintenance logs revealed the accetable humidity range to be LL (below lower limit) - 50 percent. Review of the package insert accompanying the hygrometer /thermometer indicated the lower limit of humidity measurement was 25 percent. The recorded humidity within the main laboratory area was below 25 percent for the following in 2017: * 30 of 31 days in January 2017 * 24 of 28 days in February 2017 * 26 of 31 days in March 2017 * 10 of 30 days in April 2017 * 5 of 31 days in May 2017 * 14 of 31 days in October 2017 * 28 of 30 days in November 2017 Review of the Sysmex CA-560 operators manual revealed the performance specifications required optimal performance of the instrument required 30 to 85 percent humidity. Interview with laboratory employee D on 4/24/18 at 12:10 p.m. revealed that the concentrated stain in the automatic stainer was evaporating sooner due tolow humidity leading to poor quality hematology slides. The recorded humidity in the histology area was below 30 percent for the following in 2017: * 31 of 31 days in January 2017 * 28 of 28 days in February 2017 * 31 of 31 days in March 2017 * 30 of 30 days in April 2017 * 31 of 31 days in October 2017* 30 of 30 days in November 2017 * 31 of 31 days in December 2017 * 31 of 31 days in January 2018 * 28 of 28 days in February 2018 * 31 of 31 days in March 2018 Review of the Tissue Tek Stainer operators manual revealed the performance specifications required optimal perforance of the instrument required 30-85 percent humidity. Interview on 4/24/18 at 1:40 p.m. with maintenance employee A revealed he had been aware of the low room humidity levels. He stated the building was old and due to the steam heating system it was difficult to maintain acceptable humidity levels especially in the winter months. They tried to maintain humidity levels at a minimum of 20 percent by pulling in outside air

	to mix with the heated air. Interview with laboratory employee A at the same time revealed he did not think the laboratory was experiencing any analyzer issues due to the low humidity.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the package insert for 0.8% Resolve Panel A, review of the annual test volume form, and interview with laboratory employee A, the laboratory failed to check each lot number or shipment of 0.8% Resolve Panel A cells for their positive and negative reactivity prior to patient testing for 15 of 15 patients tested during 2017. Findings include: 1. Review of available records revealed no documentation of quality control (QC) having been done on the 0.8% Resolve Panel A cells in 2016, 2017, or 2018. Review of the package insert for 0.8% Resolve Panel A (last revised October 2015) revealed the manufacturer stated: "for quality assurance 0.8% Resolve Panel A should be tested with a known weak antibody." Review of the annual testing volume form indicated fifteen patient antibody identification procedures had been performed using 0.8% Resolve Panel A during 2017. Interview on 4/2/8/18 at 2:05 p.m. with laboratory employee A revealed he was unaware QC was required of a new lot number or shipment before use on patient samples.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of personnel records, review of the Competency Assessment Program policy, and interview with laboratory personnel A, the technical supervisor failed to ensure employee competencies had been performed semi-annually during the first year for 1 of 1 laboratory employees (laboratory employee G). Findings include: 1. Review of personnel records revealed laboratory employee G had no competency assessments recorded. Laboratory employee G had been hired on 1/23/17. This individual had not had a competency performed in the 15 months of her employment. Review of the Competency Assessment Program policy revealed in section 5-Evaluations: "Each new employee will be evaluated biannually the first year of employment and annually thereafter." Interview with laboratory employee A on 4/23 /18 at 4:25 p.m. indicated a six month human resources evaluation had been

	performed, but no competency assessment had been performed to date for laboratory employee G. The human resources evaluation had been an employment evaluation and did not address the competency assessment.