Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D0407323	03/12/2020
Name of Provider or Supplier	**Street Address, City, State**	
Prairie Lakes Healthcare System	401 9th Avenue Northwest, Watertown, 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 from 3/10/20 through 3/12/20. The Prairie Lakes Healthcare System laboratory was found not in compliance with the following requirements: D5407, D5411, D5477, and D5775.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on interview with the laboratory personnel and review of the laboratory's procedure manuals, the laboratory director failed to ensure six of seven reviewed procedure manuals were approved, signed, and dated by the new laboratory director prior to use. Findings include: 1. Review of the following manuals revealed they had not been approved, signed, and dated by the new laboratory director before use: *Bacteriology Procedure Manual. *Procedure Manual: Body Fluids, Urinalysis, Chemistry, POC (point of care). *Vidas Manual. *Blood Bank Procedure Manual. *Hematology Manual. *Coagulation Manual. An interview on 3/10/20 at 1:45 p.m. with laboratory personnel A revealed: *She confirmed the listed manuals had not been approved, signed, and dated by the laboratory director, to date. *The laboratory was in the process of updating the manuals and entering them into an online file system. *She was having the laboratory director review and sign the procedures as they were uploaded to the online file system. *That process was expected to take over a year to complete. *She was not aware she could not wait that long to get the procedures reviewed and signed. *As of the time of the survey only the histology manual had been reviewed and signed. An interview on 3/12/20 at 8:50 a.m. with the laboratory director revealed: *She had taken over as laboratory director 1/2/2020. *She was reviewing and signing procedures as they were uploaded to the online file system.

	*She was not aware she needed to review and sign the manuals as soon as possible upon taking over as laboratory director.
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 observation, interview with laboratory personnel B, review of the thromboplastin package insert, and the annual test volume form, the laboratory failed to enter the correct International Sensitivity Index (ISI) value in the Sysmex CA-1500 coagulation analyzer to determine an accurate International Normalized Ration (INR) patient results. Findings include: 1. Observations of the Sysmex CA-1500 coagulation analyzer on 3/11/20 at 2:30 p.m. and review of the thromboplastin package insert revealed the following: *The ISI value documented in the thromboplastin reagent package insert for lot # 549729 expiration date 2/1/21 was 1.04. *The ISI value entered in the Sysmex CA-1500 coagulation analyzer was for thromboplastin lot #549717 expiration date 9/21/20 was 1.03. *The ISI value was used to calculate the patient specimen INR value. Review of the annual test volume form revealed the laboratory reported 4776 patient INR test results during 2019. These patient test specimens could have had an inaccurate INR value reported. Interview with laboratory personnel B at the time of the observation revealed: *She had been unaware of the discrepant ISI values. *The new lot number and ISI value would be entered into the Sysmex CA-1500 coagulation analyzer prior to starting a new lot of reagent. *There was no documentation as to when the new lot # of reagent had been started. *She stated the laboratory usually received twelve boxes of thromboplastin in each shipment. There were currently only ten boxes left in the refrigerator.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on interview with laboratory personnel B, quality control (QC) record review, the laboratory failed to ensure QC had been performed on two of two different types of blood culture bottled media (Versa Trek Redox 1 and 2) for accurate and reliable performance prior to being used with patient culture specimens. Findings include: 1. Review of the media QC logs revealed no documentation of the above identified media (Versa Trek Redox 1 lot # 924880, expiration date 1/7/21 or Versa Trek Redox 2 lot # 920206, expiration date 1/15/21) for sterility and the ability to support growth

	in each type of media. Interview on 3/11/20 at 12:05 p.m. with laboratory personnel B revealed: *The laboratory had an Individual Quality Control Plan that covered media quality control. *She was not aware blood culture bottles were considered media. *The laboratory had been using the current type of bottled blood culture media since they had obtained the current analyzer several years ago. *The laboratory had not tested blood culture bottles for sterility or ability to support growth.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on interview with the laboratory supervisor, review of the current laboratory test menu, quality assessment (QA) activities, and annual test volume form, the laboratory failed to establish and monitor criteria twice a year in 2019 for acceptable differences between thirteen of thirteen tests that had been performed using different methods or analyzers: *Troponin, complete blood count (CBC), blood cell differential, sodium, potassium, chloride, carbon dioxide (CO2), comprehensive metabolic panel, magnesium, lipase, amylase, and phosphorus performed on two different analyzers. *Human chorionic gonadotropin (hCG) by two different methods (qualitative and quantitative). Findings include: 1. Review of the laboratory's test menu revealed: *The troponin test was processed on both the Vitros 5600 and on the Abbott I-Stat analyzers. *The CBC test was processed on both the Sysmex XN-1000 and the Sysmex XN-450 analyzers. *The blood cell differential test was processed on the Sysmex XN-1000, the Sysmex XN-450, and manually counted. *The CMP, magnesium, lipase, amylase, and phosphorus tests were processed on both the Vitros 5600 and the Vitros 350. *The sodium, potassium, chloride, and CO2 test methods were processed on both the Vitros 5600 and the ABL 90 Flex System. *The hCG test method was performed by two different test methods (qualitative and quantitative). Review of the laboratory's QA records revealed no documentation a comparison of the above test methods had been completed in 2019. Other records reviewed did not include documentation of that comparison. Interview on 3/10/20 at 4:20 p.m. with laboratory personnel A revealed: *The laboratory used the Abbott I-Stat, Sysmex XN-450, Vitros 350, and the ABL 90 Flex system as back-up analyzers. *The back-up analyzers were used when the primary analyzer was down for maintenance or otherwise not available for testing. *Patient test specimens were processed and reported from the back-up analyzers. *She was aware test comparison between two different methods needed to be completed. *She was aware the test comparisons had not been documented. *She was currently working on a policy for the test method comparison, but it was not available for review at the time of the survey.