Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0522334	05/12/2021
Name of Provider or Supplier	**Street Address, City, State**	
Benewah Community Hospital	229 S 7th St, Saint Maries, 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
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 5/12/2021, 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 from the Siemens Dimension EXL identified that the laboratory did not have an acceptable result for level 1 total bilirubin QC on 6/6/2020. The laboratory performed and released six (6) patient total bilirubin tests on 6/6/2020. 2. An interview with the laboratory manager on 5/12/2021 at 3:28 pm confirmed that the laboratory failed to have two acceptable QC levels for total bilirubin on 6/6/2020.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on record review of instrument verifications and an interview with the

	laboratory manager on 05/12/2021, the Laboratory Director (LD) failed to ensure that verification procedures that were used for verification of the Sysmex CA-640 were adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method before their use in patient testing. The findings include: 1. A record review of the Sysmex CA-640 verification performed in June 2019, identified that the Laboratory Director failed to approve verification of performance of prothrombin time, partial thromboplastin time and D-dimer testing before implementation of patient testing. 2. An interview with the laboratory manager on 5/12 /2021 at 11:20 am confirmed that the Laboratory Director failed to approve and sign the performance verification of the Sysmex CA-640 before patient testing was implemented.