Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0521160	12/06/2022
Name of Provider or Supplier	**Street Address, City, State**	
Syringa Hospital & Clinics	607 W Main St, Grangeville, 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
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 review of laboratory policies and procedures and an interview with the laboratory manager on 12/5/2022, the laboratory director failed to approve, sign and date laboratory policies and procedures for the Cepheid. The findings include: 1. A record review of laboratory policies and procedures identified that the laboratory director failed to approve, sign and date the Cepheid individual quality control plan (IQCP), Cepheid Xpert CT-NG procedure and Xpert Xpress SARS-COV-2 proccedure. 2. An interview with the laboratory manager on 12/6/202 at 8:23 am, confirmed that the laboratory director has not approved, signed and dated the above Cepheid laboratory policies and procedures. 3. The laboratory reports performing 257 Cepheid tests annually.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on a review of hematology quality control (QC) documentation, patient logs, and an interview with the laboratory manager on 12/5/2022, the laboratory failed to perform two levels of QC material every day of patient testing. The findings include: 1. A random record review of complete blood count (CBC) QC identified that the laboratory failed to perform two levels of QC when patient testing occurred on 8/4 /2022. 2. A review of the laboratory's patient results identified 19 patient CBC reported on 8/4/2022. 3. An interview with the laboratory manager on 12/5/2022 at 12: 30 pm confirmed that the laboratory failed to perform two levels of CBC QC on 8/4 /2022. 4. The laboratory reports performing 6,132 CBC tests annually.