Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0411099	03/26/2024
Name of Provider or Supplier	**Street Address, City, State**	
St Luke Community Healthcare	107 6th Avenue Sw, Ronan, MT	

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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on a review of American Proficiency Institute records and an interview with the technical supervisor, the laboratory failed to achieve satisfactory performance for manual red blood cell counts (erythrocyte) and manual polymorphonuclear cell counts (leukocyte) performed with a hemocytometer for two consecutive or two out of three consecutive testing events, resulting in unsuccessful proficiency testing performance. (See D2130)
D2130	HEMATOLOGY CFR(s): 493.851(f)

	Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a review of American Proficiency Institute (API) proficiency testing (PT) scores and an interview with technical supervisor (TS) # 1, the laboratory failed to achieve a score of at least 80% for two consecutive testing events for manual red blood cell (RBC) counts for cerebrospinal fluid/body fluid performed with the hemocytometer and two out of three consecutive testing events for manual polymorphonuclear cells (PMN) counts for cerebrospinal fluid (CFS)/body fluid (BF) performed with the hemocytometer. Findings: 1. A review of the API Manual RBC cell counts of CSF/BF proficiency testing scores revealed that in 2022, Event 3 scored 50% and in 2023, Event 1 scored 50%. 2. A review of the API Manual PMN cell counts of CSF/BF proficiency testing scores revealed that in 2022, Event 1 scored 0% and Event 3 scored 50%. 3. An interview with TS #1 on March 26, 2023, at 11:00 AM confirmed the laboratory's unsuccessful proficiency testing scores were due to a calculation error based on the size of hemocytometer.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of Beckman Coulter DxH 690T and DxH 520 hematology analyzer verification records and an interview with technical supervisor (TS) #1, the laboratory lacked precision studies to assess day-to-day variation over time and failed to verify the normal reference ranges were appropriate for the laboratory's patient population prior to patient testing from February 5, 2024, to March 26, 2024. Findings: 1. A review of the Beckman Coulter DxH 690T and DxH 520 Hematology Analyzers verification records revealed the laboratory failed to have more than two days of data to assess the reproducibility of day-to-day variance over time. 2. The laboratory failed to perform patient population studies to verify reference intervals (normal values) to support the reference ranges listed in the laboratory's patient results reports. 3. The laboratory lacked a procedure for verifying new assays, instruments, or methods. 4. An interview with TS #1 on March 26, 2024, at 3:00 PM confirmed the lack of reproducibility studies over time and verification of the normal reference ranges for DxH 690T and DxH 520 hematology analyzers prior to patient testing from February 5, 2024, to March 26, 2024.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under

	appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of policies, records of blood bank alarm checks, and an interview with the technical supervisor (TS) #1, the laboratory failed to follow their policies to perform and document quarterly alarm checks for one out of one blood bank refrigerator and freezer from March 26, 2022, to March 26, 2024. Findings: 1. The laboratory failed to perform a quarterly "hi/lo alarm check" on the blood bank refrigerator and sub-zero freezer as required by their "Blood Bank Maintenance & Function Checks" procedure. 2. The laboratory lacked documentation of blood bank alarm checks for the refrigerator and freezer from March 26, 2022, to March 26, 2024. 3. An interview with TS #1 on March 26, 2023, at 2:20 PM confirmed the laboratory failed to perform and document quarterly alarm checks per their procedure from March 26, 2022, to March 26, 2024.