Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0665300	04/06/2021
Name of Provider or Supplier	**Street Address, City, State**	
Livingston Healthcare	320 Alpenglow Lane, Livingston, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the chemistry procedures and interview with general supervisor (GS)#1, the laboratory failed to include in their procedure manuals step by step procedure, and reference intervals (normal values) for the analytes: sodium, potassium, and chloride performed on the Siemens Dimension EXL 200 chemistry analyzer Findings: 1. No reference intervals (normal values) was available in the chemistry procedure manual for the analytes: sodium, potassium, and chloride. 2. No procedure for the analytes: sodium, potassium, and chloride performed on the Siemens Dimension EXL 200 chemistry analyzer was available for review. 3.

	Interview with the GS #1 on April 6, 2021 at 11:00 AM confirmed the laboratory failed to include normal values and a step-by-step procedure for the analytes: sodium, potassium, and chloride performed on the Siemens Dimension EXL 200 chemistry analyzer.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the calibration records for the Siemens Dimension EXL 200 chemistry analyzer for the analytes of sodium, potassium, and chloride, and review of the Tosoh analyzer for analytes carcinoembryonic antigen (CEA) and prolactin, plus interview with the general supervisor (GS) #1, the laboratory failed to perform at least a three point (a minimal, mid-point, and maximum) calibration verification every six months. Findings: 1. Review of 2019 and 2020 calibration records for the Siemens Dimension EXL 200 analyzer for the analytes: sodium, potassium, and chloride, revealed the laboratory failed to perform a calibration including, at least, a minimal, midpoint, and maximum value for each analyte, every six months. 2. Review of 2019 and 2020 calibration records for the Tosoh analyzer for analytes: carcinoembryonic antigen (CEA) and prolactin, revealed the laboratory failed to perform a calibration including, at least, a minimal, midpoint, and maximum value for each analyte, every six months. 3. Interview with the GS #1 on April 6, 2021 at 10:45 AM confirmed the laboratory failed to perform at least a three-point calibration for sodium, potassium, and chloride on the Siemens Dimension EXL 200 analyzer and the Tosoh analyzer for analytes: carcinoembryonic antigen (CEA) and prolactin every six months.
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 record review of instrument comparison documentation and interview with general supervisor (GS) #1, the laboratory failed to perform instrument comparison for the Siemens Dimension EXL and the Abbott iSTAT for basic metabolic panel testing two times a year. Findings: 1. Review of laboratory instrument comparison documentation showed the laboratory failed to perform and document comparison studies for the Siemens Dimension EXL and the Abbott iSTAT analyzers performing sodium, potassium, chloride, ionized calcium, total CO(2), glucose, blood urea nitrogen (BUN) and creatinine analyte testing for 2019 and 2020. 2. Interview with GS #1 on April 6, 2021 at 11:15 AM confirmed the laboratory failed to perform twice a year instrument comparison.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the Blood Bank records, policy and procedures, and interview with the general supervisor (GS) #1, the laboratory director (LD)#1 failed to establish and maintain the quality assessment programs for Blood Bank in year 2020. Findings: 1. No Blood Bank Review worksheets for year 2020 were available for review. 2. Policy #LABB-290 states "Purpose: The goals of blood utilization review are to improve the processes involved in the ordering, distribution, handling, dispensing and administration of blood as well as to monitor the effects of transfusion. Scope: Review will include: 1. Quarterly blood bank statistics a. Monthly cross match/transfusion. b. Total counts of Various Blood Components, 2. Transfusion Reaction Workups and Results. 3. All cases in which the indication of blood usage was not justified by the approved criteria." 3. Interview with the GS #1 on April 6, 2021 at 9:00 AM confirmed the laboratory director (LD)#1 failed to establish and maintain quality assessment of Blood Bank in year 2020.