Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0652515	10/06/2022
Name of Provider or Supplier	**Street Address, City, State**	
Logan Health Shelby	640 Park Ave, Shelby, 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
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of chemistry records, instrument manuals, product inserts, and policies and procedures, the laboratory failed to establish acceptable QC statistical parameters for each analyte tested on the Siemens Dimension EXL 200 analyzer (See 5469); failed to perform tHb calibration every three months and perform at least a three-point calibration verification on the OPTI CCA-TS Blood Gas Analyzer every six months (See D5535); and failed to assess the effectiveness of their quality monitoring as stated in their policy and procedure (See 5793).
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of bacteriology, hematology, and blood bank records, instrument manuals, product inserts, and policies and procedures, the laboratory failed to verify

	the performance specification of the two moderate complexity Clostridium difficile kits from different vendors prior to reporting patient test results (See D5421); failed to establish a procedure and perform function checks to verify the accuracy of pipettes used in the laboratory (See D5435); failed to perform the manufacturer's recommended calibration in 2021 for the Sysmex XS-1000 hematology analyzer (See D5439); failed to perform an external positive and negative control each day of patient testing or establish an Individualized Quality Control Plan (IQCP) for two moderate complexity Clostridium difficile kits from different vendors prior to patient testing (See D5445); and failed to perform alarm checks at the frequency dictated by their procedures to include the blood bank freezer storing fresh frozen plasma (See D5555).
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 review of records, manufacturer's instructions, and interview with the Technical Supervisor (TS) #1, the laboratory failed to have the laboratory director evaluate and approve the performance specifications for two of two moderate complexity Clostridium difficile (C. diff) kits prior to reporting patient test results. Findings: 1. Review of QC records for "Serology Procedures Logbook" labeled with "C Diff Quik Chek Complete" revealed patients testing starting 12/18/2021. 2. Review of QC records for "Serology Procedures Logbook" labeled with "Immuno Card" revealed patients testing starting 7/22/2022. 3. No performance specification study to ensure the moderate complexity C. diff kits (C. Diff Quik Chek Complete and ImmunoCard Toxins A & B) results are comparable to those established by the manufacturer were available for review. 4. The manufacturer's instruction for C. Diff Quik Chek Complete and ImmunoCard Toxins A & B used as the procedure lacked review and approval by laboratory director prior to patient testing. 5. Interview with the (TS) #1 on October 6, 2022, at 12:40 PM, confirmed the laboratory failed to verify the performance specification of the two new C. diff kits prior to patient testing from December 18, 2021, to October 6, 2022.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

	This STANDARD is not met as evidenced by: Based on observation, review of maintenance documentation, policy and procedures, and interview with technical supervisor (TS) #1 the laboratory failed to establish a procedure and perform function checks to verify the accuracy of pipettes used in the laboratory from January 1, 2021, to October 6, 2022. Findings: 1. Observation of pipettes (50 L, 100 L, and 200 L) in the laboratory available for use lacked verification labels. 2. Review of laboratory maintenance records lacked documentation of annual verification checks for pipettes from January 1, 2021, to October 6, 2022. 3. Review of policy and procedures lacked instruction to include the frequency of verification for pipettes. 4. An interview with the (TS) #1 on October 6, 2022, at 9:40 AM, confirmed pipettes were not being verified and the laboratory lacked a procedure or policy for the verification of pipettes from January 1, 2021, to October 6, 2022.
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 Sysmex XS-1000 hematology analyzer for complete blood counts (CBC) with differential, and interview with the technical supervisor (TS) #1, the laboratory failed to perform the manufacturer's recommended calibration in year 2021. Findings: 1. No calibration records for the Sysmex XS-1000 hematology analyzer for the year of 2021 were available for review. 2. Interview with the (TS) #1 on October 6, 2022 at 1:20 PM confirmed the laboratory failed to perform the manufacturer's recommended calibration in 2021 for the Sysmex XS-1000 hematology analyzer .
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 review of records, manufacturer's instructions, and interview with the Technical Supervisor (TS) #1, the laboratory failed to perform one positive and one negative external quality control (QC) each day of patient testing or establish an Internal Quality Control Plan (IQCP) for alternative QC frequency as required by the manufacture's instruction for two of two moderate complexity Clostridium difficile (C. diff) kits from December 18, 2021, to October 6, 2022 Findings: 1. Review of quality control (QC) records for "Serology Procedures Logbook", one labeled with "C Diff Quik Chek Complete" and the other labeled with "ImmunoCard", revealed the laboratory failed to perform positive and negative external controls each day of patient testing. 2. The product insert for C. Diff Quik Chek Complete states, "The reactivity of the C. Diff Quik Chek Complete kit should be verified upon receipt using the Positive Control and Negative Control (Diluent)"; and for ImmunoCard Toxins A & B states, "The reactivity of each new lot and each new shipment of the ImmunoCard Toxin A & B should be verified on receipt or before use." 3. The laboratory failed to establish an (IQCP) to encompass a Risk Assessment (RA), a Quality Control Plan (QCP), and a Quality Assessment (QA) plan for alternative external QC practices as defined by the manufacturer's instructions. 4. An interview with the (TS) #1 on October 6, 2022, at 12:45 PM, confirmed the laboratory failed to either perform an external positive and negative control each day of patient testing or establish an IQCP for the two new C. diff kits from different vendors prior to patient testing from December 18, 2021, to October 6, 2022.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of chemistry quality control (QC) records, manufacturer's inserts and manual, patient reports, and interview with the technical supervisor (TS) #1, the

	laboratory failed to establish acceptable criteria (statistical parameters/standard deviation) for unassayed controls MAS chemTRAK H level 1 (lot #22101A) and level 3 (lot #22103A) for chemistry analytes Chloride, Glucose, Lipase, Amylase, HDL Cholesterol, Triglycerides, and Iron performed on the Siemens Dimension EXL 200 from January 1, 2021 to October 6, 2022. Findings: 1. The laboratory failed to follow the Dimension EXL System Operator's Guide manual which states, "Each new quality control product of new lot of quality control material introduced should be evaluated in conjunction with the old lot during a trial period. This allows the newly established mean and standard deviation to be compared to the values of the old material."; and follow the MAS chemTRAK H product insert which states, "Instrument values provided are specific to this lot of control only and are intended to assist the laboratory in establishing its own means and ranges." 2. No concurrent studies of quality control materials to establish statistical limits were available for review. 3. Review of test volume sheet recording the last 12 months of patients' results showed 3049 Chloride, 3030 Glucose, 102 Amylase, 1221 HDL Cholesterol, 1230 Triglycerides and 87 Iron results were reported from 9/28/21 to 9/28/22. 4. Interview with (TS) #1 on October 6, 2022, at 2:10 PM confirmed the laboratory failed to establish acceptable QC statistical parameters for each analyte tested on the Siemens Dimension EXL 200 analyzer from January 1, 2021 to October 6, 2022.
D5535	ROUTINE CHEMISTRY CFR(s): 493.1267(a)(d) For blood gas analyses, the laboratory must perform the following: (a) Calibrate or verify calibration according to the manufacturer's specifications and with at least the frequency recommended by the manufacturer. (d) Document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of blood gas calibration records for the OPTI CCA-TS, Individualized Quality Control Plan (IQCP), instrument manual, and interview with Technical Supervisor (TS) #1, the laboratory failed to follow their blood gas IQCP to perform quarterly tHb calibration and the manufacturer's instructions to perform at least three-point (a minimal, mid-point, and maximum) calibration verification every six months from January 1, 2021, to October 6, 2022. Findings: 1. Review of blood gas IQCP revealed the laboratory failed to perform tHb calibration verification as stated, "Every 3 months the Hb Calibrator cassette is performed on the OPTI CCA-TS Blood Gas Analyzer." 2. Calibration records lacked three out of four tHb calibrations for the year 2021 and one out of three from January 1, 2022 to October 6, 2022. 3. Review of the OPTI CCA-TS Operator's Manual revealed the laboratory failed to perform calibrations and calibration verifications as stated: "4.4 Calibration Verification: Calibration verification allows for the validation of the blood gas analyzer's ability to recover known values at various points within the reportable range of all parameters and may be required by various regulatory agencies." 4. No calibration verifications performed every six months or records of three levels of controls being performed each day of testing were available for review. 5. Interview with the (TS) #1 on October 6, 2022, at 11:30 AM, confirmed the laboratory failed to perform tHb calibration every three months and perform at least a three-point calibration verification on the OPTI CCA-TS Blood Gas Analyzer every six months from January 1, 2021, to October 6, 2022.
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 observation, review of procedures, records of blood bank alarm checks, and interview with the Technical Supervisor (TS) #1, the laboratory failed to perform and document quarterly alarm inspection checks for one of one blood bank freezer to ensure the proper storage of fresh frozen (FFP) plasma from January 1, 2021 to October 6, 2022. Findings: 1. Observed one freezer storing fresh frozen plasma (FFP) on October 6, 2022, located in the laboratory. 2. Review of procedure " Maintenance and Quality Control" revealed the laboratory failed to perform alarm tests for the blood bank freezer as stated, "At least once a quarter high low check will be performed." 3. No alarms checks for the blood bank freezer storing FFP blood products were available for review. 4. An interview with (TS) # 1 on October 5, 2022, at 11:00 A.M. confirmed the laboratory failed to perform alarm checks at the frequency dictated by their procedures to include the blood bank freezer storing FFP blood products from January 1, 2021, to October 6, 2022.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review, policy and procedures, and interview with Technical Supervisor (TS) #1, the laboratory failed to assess the effectiveness of their quality monitoring as stated in their policy and procedure from January 1, 2022 to October 6, 2022. Findings: 1. Review of policy and procedures for "Laboratory Quality Assessment" revealed the laboratory failed to perform quality monitoring as stated: "1a. ...establishment and implementation of all laboratory quality control policies and procedures." "1b. Review monthly QC data, Levy Jennings charts, QC corrective actions and instrument performance and preventive maintenance." 2. The laboratory failed to review product inserts and establish the quality control policies and procedures for two moderate complexity Clostridium difficile kits from different vendors prior to patient testing (See D5445). 3. The laboratory failed to review the Siemens Dimension EXL 200 System Operator's Guide for instructions on "Quality Control Review" and failed to review Levy Jennings charts to assess acceptable QC statistical parameters for each analyte tested (refer to 5469). 4.The laboratory failed to review instrument performance and preventive maintenance documentation for the Sysmex XS-1000 hematology analyzer to ensure the vendor maintained and performed calibration for year 2021 for (See D5439). 5. Interview with (TS) #1 on

	October 6, 2022, at 4:00 PM, confirmed the laboratory failed to assess the effectiveness of their quality monitoring as stated in their policies and procedures from January 1, 2021, to October 6, 2022.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, product inserts, the manufacturer's operating manual, and an interview with technical supervisor (TS) # 1, the Laboratory Director failed to ensure laboratory staff establish and maintain the quality control program as directed by their policies and procedures. See D5793.