Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0410237	10/04/2022
Name of Provider or Supplier	**Street Address, City, State**	
Logan Health - Chester	315 West Madison Ave, Chester, 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
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 chemistry, serology, immunology, and blood bank records and procedures, the laboratory failed to perform calibration verification every six months as required by their procedures (Refer to D5439); failed to establish and perform external quality controls as dictated by either their IQCP, policies and procedure or manufactures instructions (Refer to D5445); failed to perform and document quarterly alarm inspection checks (See D5555); failed to identify and document corrective action (See D5783) and failed to assess the effectiveness of their quality monitoring as stated in their policies (See D5793).
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 calibration records for the Abbott i-STAT Analyzers using CHEM 8+, CG4+, and cTnl cartridges, laboratory policies and procedures and interview with the Technical Supervisor (TS) #1, the laboratory failed to follow their procedure and perform twice a year calibration verification every six months from January 1, 2021, to October 4, 2022. Findings: 1. Review of calibration records for Abbott i-STAT analyzer lacked twice a year documentation of a calibration verification for the following analytes: cardiac troponin I, sodium, potassium, chloride, ionized calcium, glucose, blood urea nitrogen, creatinine, hematocrit, total carbon dioxide, lactate, pH, PCO2 and PO2. 2. Review of "Blood Gas and Lactic Acid Analysis" revealed the laboratory failed to follow their policies and procedures which states, "Abbott i-State TriControls Calibration Verification: These will be run twice a year". 3. Interview with the TS #1 on October 4, 2022, at 2:00 PM, confirmed the laboratory failed to perform at least a three-point calibration verification for analytes performed on the i-STAT analyzer every six months or after CLEW software updates from January 1, 2020, to June 16, 2022.
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 quality control (QC) records, laboratory policies and procedures, Individualized Quality Control Plan (IQCP) and interview with the Technical Supervisor (TS) #1, the laboratory failed to establish, follow, and perform external control at the frequency required by their policies and procedures, IQCP or manufacturer's instructions from March 24, 2021, through October 4, 2022. Findings: 1. Review of QC records for Abbott i-STAT analyzer for cartridges CHEM 8+, CG4+, and cTnl cartridges lacked monthly external QC for April, August, and October of 2021 and January, May, June, July and August of 2022. 2. Review of

	"Blood Gas and Lactic Acid Analysis" revealed the laboratory failed to follow their policies and procedures which states, "Abbott i-State TriControls (Level 1 and Level 3) will be run upon arrival of a new lot shipment of cartridges and monthly". 3. Review of ISTAT IQCP revealed the laboratory failed to perform external QC at the frequency defined, "Run Quality control specimens (multiple levels of I-Stat controls) under the following conditions: with each new lot of cartridges in each shipment and monthly." 4. Review of "Erythrocyte Sedimentation Rate (ESR or Sedrate)" policies and procedure lack the same frequency of quality control testing as the manufacture's ESR- Chex Streck IFU of "Daily use of ESR-Chex provides assurance that the erythrocyte sedimentation rate procedure is being performed properly." 5. Review of D-Dimer (CS Stratus) policies and procedure states "Refer to D-Dimer IQCP located in the IQCP policy manual". No D-Dimer IQCP was available for review. 6. Interview with the TS #1 on October 4, 2022, at 3:45 PM, confirmed the laboratory failed to establish, follow, and perform external frequency as required by either their policies and procedures, IQCP or manufacturer's instruction from March 24, 2021, through October 4, 2022 for the above listed platforms.
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 policies and 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 1 of 1 blood bank refrigerator and freezer from March 1, 2021 to October 4, 2022. Findings: 1.Observed in the computer storage room on October 4, 2022, one blood bank refrigerator and one freezer containing blood and blood products for storage. 2. Review of policies and procedure " Blood Bank Alarm Test " revealed the laboratory failed to perform alarm tests as stated, "To comply with this requirement, quarterly checks for alarm activation are necessary." and "Record length of the time the responder took to notify the lab on the log sheet. Write the name of the person who responded, along with their title." 3. Review of "Blood Bank Alarm Monthly Test" log revealed the laboratory failed to perform alarms checks from March 1, 2021, to October 4, 2022. 4. No documentation of length of time and name of responder with title was available for review. 5. An interview with TS #1 October 4, 2022, at 12:20 PM. confirmed the laboratory failed to follow their policies and procedure for performing blood bank alarm test from March 1, 2021 to October 4, 2022.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must

	be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on record review, policies and procedures, and interview with technical supervisor (TS) #1, the laboratory lacked corrective actions documents for missed external quality controls (QC) for the i-STAT from March 24, 2021, through October 4, 2022. Findings: 1. Review of "Quality Assurance" policies and procedures revealed the laboratory failed to identify and document corrective action as stated, "The QA program must: 2. Identify and correct problems" and "The lab must also initiate corrective action when problems occur and document all quality assurance activities." 2. Review of Accession #2104150037 Patient Results Report dated 04/15/2021 for Arterial Blood Gas lacked monthly QC performed prior to patient testing and reporting. 3. No corrective or remedial action to ensure accurate patient test results was available for review. (Cross Refer D5445) 4. Interview with the TS #1 on October 4, 2022, at 1:25 PM. confirmed these findings.
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, policies and procedures, and interview with Technical Supervisor (TS) #1, the laboratory failed to assess the effectiveness of their quality monitoring as stated in their policies to identify Immunohematology's lack of quarterly alarm checks, chemistry's lack of calibration verification and monthly quality control (QC) checks, and lack of annual review of their Individual Quality Control Plan (IQCP). Findings: 1. Review of policies and procedures, "Quality Assurance" revealed the laboratory failed to assess the effectiveness of their quality monitoring as stated in their policies: "3. Test calibration and verification as applicable; 6. Annual review of policy and procedure manuals; 7. Monthly review of quality control charts; 8. Monthly review of equipment maintenance logs and function checks; and 12. Monthly review report of pre-analytic, analytic, and post-analytic processes in the laboratory. Results are documented and communicated to the laboratory director and staff with corrective action taken as needed. " 2. The laboratory failed to perform calibration verification every six months for the i-STAT analyzer for 2021 and 2022. (Cross refer D5439) 3. The laboratory failed to have an IQCP for the Stratus analyzer, failed to have the manufacture's frequency of external QC in the ESR procedure, and failed to perform monthly external QC as defined in their IQCP or policies for the i-STAT analyzer. (Cross refer D5445) 4. The laboratory failed to perform quarterly alarm checks their blood bank refrigerator and freezer to monitor blood and blood products storage conditions since March of 2021. (Cross refer D5555). 5. Review of "IQCP E-Optimizer" documents revealed the laboratory failed to follow their policies as stated, "Monitor and review QC results procedure and review your IQCP for effectiveness as required by your regulatory agency. Re-

	evaluate your IQCP and revise if performance failures have been identified." No documentation of annual IQCP review was available for review from January 1, 2021, to October 4, 2022, for the Stratus CS, DCA Vantage, i-STAT, GeneXpert and moderate level kits. (Cross refer D5783 and D5793) 6. Interview with TS #1 on October 4, 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 4, 2022.
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 record review, policies and procedures, Individual Quality Control Plan (IQCP), and interview with the technical supervisor (TS) #1, the laboratory director (LD)#1 failed to ensure that the quality assessment programs for chemistry, serology, microbiology and immunohematology were monitored effectively by laboratory staff from January 1, 2021, to October 4, 2022. Findings: 1. The laboratory director failed to establish a D-Dimer IQCP to support current external QC frequencies. 2. The laboratory director failed to ensure the laboratory staff perform an annual IQCP review for its effectiveness from January 1, 2021, to October 4, 2022, for the Stratus CS, DCA Vantage, i-STAT, GeneXpert, and moderate level kits as required (i.e. serum hCG, mono, h pylori). (Cross refer D5793) 3. The laboratory director failed to ensure that staff follow laboratory policies and procedures as defined in their job descriptions: "Adhere to the laboratory's quality control polices, document all quality control activities, instrument and procedural calibrations and maintenance performed." (Cross refer D5439, and D5445). 4. The laboratory director failed to ensure the technical supervisor follow laboratory policies and procedures as defined in their job description, "Ensuing that patient test results are not reported until all corrective action have been taken and the test system s functioning properly. (Cross refer D5555, and D5783) 5. Interview with the TS #1 on October 4, 2022, at 5:00 PM confirmed the laboratory director (LD)#1 failed to establish and maintain quality assessment program from January 1, 2021 to October 4, 2022.