Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D2069577	08/22/2023
Name of Provider or Supplier	**Street Address, City, State**	
Logan Health Lakeside	306 Stoner Loop Road, Lakeside, 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
D0000	Definitions: LAB #7 located in Lakeside, MT LAB #2 located in Kalispell, MT LAB #6 located in Kalispell, MT LAB #8 located in Kalispell, MT
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on an off-site review of College of American Pathologists (CAP) proficiency testing (PT) records, laboratory policy, and interviews with two of two point of care (POC) coordinators (technical consultant (TC) #1 and POC #2 (not listed on the CMS-209 form)), the laboratory engaged in inter-laboratory communications (Cross Refer D2011); and failed to document the handling, preparation and processing of proficiency testing samples including maintaining accurate copies of all records for a minimum of two years from August of 2021 to August of 2023. (Cross Refer 2015).
D2011	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample (s) until after the date by which the laboratory must report proficiency testing results

to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.

This STANDARD is not met as evidenced by:
Based on a combination of off-site and on-site review of College of American Pathologists (CAP) proficiency testing (PT) records, laboratory policy, CMS-209 Laboratory Personnel Report, and interviews with two of two point of care (POC) coordinators (technical consultant (TC) #1 and POC #2 (not listed on the CMS-209 form)), the point of care coordinators engaged in inter-laboratory communication with nine out of nine separate CLIA laboratories by reviewing and submitting proficiency test results prior to the event deadline for College of American Pathologists (CAP) Whole Blood Coagulation Survey (WP9) for 2023 Events A and B, 2022 Events A, B, and C and 2021 Events B and C. Findings: 1. A review of Policy No: POC.118 revealed the "POC Coordinator oversees PT deadlines and result entry into appropriate forms" and the POC coordinators failed to follow their policy to prevent "Inter-Laboratory or site communication about PT samples is prohibited until after deadline for submission of results." 2. A review of PT records for CAP Whole Blood Coagulation Survey revealed Telcor (software used to interface testing devices to any laboratory information system or electronic medical records) PT raw data being reviewed and submitted to CAP for nine separate CLIA Laboratories (Lab #1, Lab #2, Lab #3, Lab #4, Lab #5, Lab #6, Lab #7, Lab #8, and Lab #9) by the POC coordinators prior to the event due dates for the following events: 2023 WP9-A Event Due Date: 2/14/2023 Lab# (Dates of Telcor raw data): Lab #1 (2/13/2023), Labs #2, #5, and #7 (1/25/2023), Lab #3 (02/01/2023), Lab #4 (02/08/2023), Lab #6 and #9 (1 /26/2023), Lab #8 (2/08/2023) 2023 WP9-B Due Date: 6/06/2023 Lab# (Dates of Telcor raw data): Lab #1 (5/22/2023), Lab #2 (5/19/2023), Lab #3 (06/01/2023), Lab #4 and #5 (5/31/2023), Lab #6 (5/23/2023), Lab #7 (5/24/2023), Lab #8 (6/05/2023), Lab #9 (5/25/2023) 2022 WP9-A Due Date: 3/15/2022 Lab# (Dates of Telcor raw data): Lab #1, Lab #4 (3/01/2022), Lab #3 (03/15/2022), Lab #5 (3/07/2022), Lab #6 and #2 (2/23/2022), Lab #8 (3/02/2022), Lab #9 (3/09/2022) 2022 WP9-B Due Date: 6 /07/2022 Lab# (Dates of Telcor raw data): Lab #1 (6/07/2022), Lab #2, #3, and #7 (5 /25/2022), Lab #4, #6, and #8 (5/26/2022), Lab #5 (6/08/2022), Lab #9 (5/31/2022) 2022 WP9-C Due Date: 9/20/2022 Lab# (Dates of Telcor raw data): Lab #1 (9/16 /2022), Lab #2 (9/06/2022), Lab #3 (09/09/2022), Lab #4 (09/20/2022), Lab #5 (9/14 /2022), Lab #6 and #7 (9/07/2022), Lab #8 and #9 (9/15/2022) 2021 WP9-B Due Date: 6/08/2021 Lab# (Dates of Telcor raw data): Lab #1, Lab #7 (5/19/2021), Lab #9 (6/4/2021) 2021 WP9-C Due Date: 9/21/2021 Lab# (Dates of Telcor raw data): Lab #1 (9/20/2021), Lab #3 (9/21/2021), Lab #7 (9/08/2021), Lab #9 (9/09/2021) 3. An interview with POC #2 on August 22, 2023, at 3:30 PM confirmed that the POC coordinators print the PT raw data from Telcor and enter the data into the CAP website for all POC laboratories for years 2021, 2022, and 2023. 4. A review of an email communication regarding WP9 2023 Event B on May 24, 2023 at 4:58 PM between Lab #7 and the POC coordinators revealed sample WP9-10 was repeated until no more sample was available due to failed results and sample WP9-07 was run twice. 5. A review of Lab #7 Telcor raw data for WP9-07 revealed the sample was performed on 5/24/2023 at 1:52 PM by TP #1 and at 4:13 PM and by TP#2 with a written note, "I Think This is suppose to be WP9-10?". No records of raw data through Telcor for WP9-10 failed results were available for review. (Cross refer D2015) 6. A review of Lab #7 CAP WP9-B 2023 Evaluation revealed results were

	submitted to CAP by the TC #1 for specimen WP9-10. 7. An email communication from TC #1 on 8/29/2023 at 5:50 PM revealed, "The second WP9-07 is done 2 hours later which to me means that it should not have been the original sample 7 (The samples usually gel within 30 min of reconstitution) that they used but sample 10 labeled incorrectly (this is quite common) so I noted it as sample 10 on the print outs from the interface dated 05/30 and on the forms for submission."
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of College of American Pathologists (CAP) Whole Blood Coagulation proficiency testing (PT) records, and an email with the technical consultant (TC) #1, the laboratory failed to document the handling, preparation and processing of proficiency testing samples including maintaining accurate copies of all records for a minimum of two years from the date of the proficiency testing event from August 2021 to August 2023. Findings: 1. No documentation of sample handling, preparation, and processing of PT samples were available for review for nine out of nine laboratories (Lab #1, Lab #2, Lab #3, Lab #4, Lab #5, Lab #6, Lab #7, Lab #8, and Lab #9). 2. A review of Lab #7 Telcor raw data for WP9-B 2022 lacked raw data records for failed runs for sample WP9-10. (Cross Refer D2011) 3. A review of Lab #7 CAP WP9-B 2023 attestation statement lacked one of two testing personnel signatures. 4. A review of Lab #7 CAP WP9-A 2022 records lacked Telcor raw data records. 5. A review of policy POC.118 revealed Labs #2, #4, #5, #6, and #8 failed to retain their PT records as stated, "PT Survey results and all documentation is maintained within the POC department in an organized manner for no less than two years." 6. An email on August 29, 2023, at 10:25 PM from TC #1 confirmed that the laboratory failed to maintain the proficiency records as required by their policy for two years from August 2021 to August 2023.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a recertification survey on 08/22/2023, a review of proficiency testing (PT) records from the College of American Pathologists (CAP), and communication with

	the point of care coordinator (TC #1), the laboratory director failed to provide overall management and direction for the laboratory in handling, processing, and reporting of PT samples (Refer to D6016), ensuring competency assessment was established (Refer to D6030), ensure an approved procedure manual was available to testing personnel (Refer to D6031), and provide in writing the responsibilities and delegation of duties for personnel (Refer to D6032).
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of proficinecy testing (PT) records and communication with the point-of-care coordinator (TC #1), the laboratory director failed to ensure that the coagulation proficiency testing samples from the College of Pathologists (CAP) were processed and reported as required by subpart H of 42 CFR 493 since 2021. (Refer to D2000). Findings include: 1. A review of the CAP coagulation PT records revealed the laboratory director failed to ensure the PT samples were processed, handled, and reported in the same manner as patient samples. 2. A record review and communication with the TC #1, confirmed the reporting of PT samples was performed by the TC #1.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of employees' competency files, CMS-209 Laboratory Personnel Report, and interview with the technical consultant, the laboratory director failed to assess the competency of one of one technical consultant (TC) #1 from August 22, 2021, to August 22, 2023. Findings: 1. No records of a technical consultant's competency assessment approved by the laboratory director was available for review. 2. Interview with the TC #1 on August 22, 2023, at 4:15 PM, confirmed the laboratory director listed on the CMS-209 form failed to perform a technical consultant's competency assessment from August 22, 2021, to August 22, 2023.

D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on a review of laboratory policies and an interview with the practice manager (not listed on the CMS-209 form), the laboratory director failed to ensure that an approved policy manual was available to all personnel responsible for any aspect of the testing process from August 22, 2021, to August 22, 2023. Findings: 1. No policy manual signed by the laboratory director listed on the CMS-209 form was available for review on August 22, 2023. 2. An interview with the practice manager (not listed on the CMS-209 form) and two of two testing personnel (TP #1 and TP #2) on August 22, 2023, at 2:10 PM confirmed the lack of an onsite policy manual approved by the laboratory director from August 22, 2021, to August 22, 2023.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: . Based on review of employees' competency files, CMS-209 Laboratory Personnel Report, and interview with the practice manager (not listed on the CMS-209 form), the technical consultant failed to perform a six-month evaluation for one of two testing personnel (TP) performing moderate-level diagnostic tests on the Coagucheck XS Pro for prothrombin time (PT) and International Normalized Ratio (INR) from February 2, 2022, to August 22, 2023. Findings: 1. A review of employees' competency evaluations for TP-2 lacked documentation of six-month competency to include the six regulatory requirements for assessment of competency. 2. Interview with the practice manager (not listed on the CMS-209 form) on August 22, 2023, at 1: 30 PM, confirmed the technical consultant was responsible for competency evaluations and could not locate a six-month evaluation for one of two testing personnel from February 2, 2022, to August 22, 2023.