

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0944763	(X3) Date Survey Completed 10/30/2023
Name of Provider or Supplier Logan Health Heart & Lung	Street Address, City, State 350 Heritage Way, Suite 2100, Kalispell, 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	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Intakes: MT00058302 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, the laboratory director failed to ensure laboratory staff did not engage 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 2021 to August 2023. (Cross Refer 2015).</p>
D2011	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(3)</p> <p>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</p>

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 an off-site review of College of American Pathologists (CAP) proficiency testing (PT) records, policy, and interviews with two of two point of care (POC) coordinators (POC #1 and POC #2), the point of care office 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 the 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 CAP WP9-A 2022 Telcor's raw data for Lab #6 revealed results for sample WP9-05 contained data from two different devices from two different laboratories: BSFM 4 (Lab #2) and RMHL-U76028544 (Lab #6).

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 an off-site review of College of American Pathologists (CAP) Whole Blood Coagulation proficiency testing (PT) records and an email with one of the two point of care (POC) coordinators (POC #1 and POC #2), 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 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." 3. An email on August 29, 2023, at 10:25 PM from POC #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.