

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0410407	(X3) Date Survey Completed 03/21/2024
Name of Provider or Supplier St Peters Health	Street Address, City, State 2475 Broadway, Helena, 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
D5207	<p>COMMUNICATIONS CFR(s): 493.1234</p> <p>The laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with general supervisor (GS) #1, the facility failed to resolve a breakdown in communication between the laboratory and the ordering physician for 13 out of 13 massive transfusion events from December 31, 2021, to March 18, 2024. Findings: 1. A review of event logs revealed the facility failed to implement their policies "#020-0092 for Massive Transfusion Protocol" (MTP) and "#LAB-0013.19 for Emergency Release of Uncross Matched Blood", resulting in the following communication failures: A. Failed to request the correct order based on their protocol triggers between massive transfusion and emergency release for event reports (#) and patient date of service (DOS): #22-879 DOS 5/5/22; #22-1399 DOS 7/10/22; #22-1458 DOS 7/17/22; #22-2239 DOS 10/20/22; #23-1937 DOS 10/18/23; #23-2476 DOS 8/16/23; #23-2401 DOS 12/3/2023. B. Failed to order MTP in their electronic medical records to initiate base line labs and subsequent labs for event reports (#) and patient date of service (DOS): #21-2764 DOS 12/31/21; #22-1331 DOS 7/3/22; #22-2717 DOS 12/11/22; #23-1348 DOS 7/9/23; #23-2476 DOS 8/16/23; #24-378 DOS 2/21/24. C. Failed to notify the laboratory's blood bank section to initiate the MTP procedure to prepare blood and blood products for event reports (#) and patient date of service (DOS): #21-2764 DOS 12/31/21; #22-1399 DOS 7/10/22; #22-2842 DOS 12/29/23; #23-1348 DOS 7/9/23; #23-2476 DOS 8/16/23; #23-1937 DOS 10/18/23; #23-2401 DOS 12/3/2023. D. Failed to notify the blood bank section to terminate the MTP procedure for event reports (#) and patient date of service (DOS): #22-2717 DOS 12/11/22; #23-1937 DOS 10/18/23 #22-2842 DOS 12/29/23. E. Failed to deliver or return blood and blood products and/or provide</p>

completed documentation of blood and blood products transfused for event reports (#) and patient dates of service (DOS): #21-2764 DOS 12/31/21; # 22-1331 DOS 7/3/22; #22-1399 DOS 7/10/22; #23-1348 DOS 7/9/23; #23-2476 DOS 8/16/23; #23-2401 DOS 12/3/2023; # 24-378 DOS 2/21/24. 2. An interview with GS #1 on March 21, 2024, at 10:00 AM confirmed the lack of communication between the ordering physician and laboratory for 13 out of 13 Report Events regarding #020-0092 Massive Transfusion Protocol from December 31, 2021, to March 18, 2024.

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 a record review and interview with general supervisor (GS) #1, the laboratory failed to assess the blood bank event reports and take corrective action to prevent problems from recurring for 13 out of 13 event reports related to the Massive Transfusion Protocol (MTP) from December 31, 2021, to March 18, 2024. Findings:
1. A review of transfusion records for CSN# 259825343 dated 08/16/2023 and CSN# 265859738 dated 12/03/2023 revealed a lack of physician signature, date, and time on the "Adult Massive Transfusion Protocol" as required by their policy #020-0092 Massive Transfusion Protocol. 2. A review of Event Reports (21-2764, 22-879, 22-1331, 22-1399, 22-1458, 22-2239, 22-2717, 23-1348, 23-1937, 23-2401, 23-2476, 22-2842, and 24-378) revealed the facility failed to implement one or more steps of their policy #020-0092 Massive Transfusion Protocol from December 31, 2021, to March 18, 2024. (See D5207) 3. The laboratory failed to establish a quality assessment program to assess the effectiveness of corrective actions taken to resolve problems, revise procedures, and educate relevant staff to prevent the recurrence of problems from December 31, 2021, to March 18, 2024. 4. An interview with GS #1 on March 18, 2024, at 10:30 AM confirmed the laboratory was still in the process of evaluating their event reports for MTP from December 31, 2021, to March 18, 2024.