Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0899072	12/07/2022
Name of Provider or Supplier	**Street Address, City, State**	
Mitchell Medical Center	1209 10th Street, Port Huron, MI	

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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant, the laboratory failed to follow its specimen stability policy for its Complete Blood Count (CBC) testing for 3 (Patients 211155, 206332, and 202607) of 10 patient test reports reviewed. Findings include: 1. A review of the laboratory's Beckman Coulter DxH hematology analyzer manufacturer's instructions revealed a section titled "Specimen Stability and Storage- Whole Blood" stating, "Sample stability may be evaluated as the change (drift) of the parameter during 24 hours at 18 to 26 degrees C (64 to 79 degrees F). For a refrigerated temperature of 2 to 8 degrees C (35.6 to 46.4 degrees F), drift may be evaluated at 8 hours for WBC and differential parameters, and at 24 hours for the remainder of the parameters. The drift should be within the difference or percent difference, whichever is greater. Samples stored at refrigerated temperatures are removed from storage, mixed by inversion 20 times, allowed to remain at ambient room temperature for 30 minutes, and remixed by inversion 20 times prior to analysis." 2. A review of patient test reports revealed the following patients had Complete Blood Count (CBC) testing more than 24 hours after the specimen was collected: a. Patient 211155 had a specimen collected on 11/15/22 at 10:02 am and testing was performed and reported on 11/16/22 at 1:35 pm. b. Patient 206332 had a specimen collected on 4/26/22 at 8:28 am and testing was performed and reported on 4 /27/22 at 5:13 pm. c. Patient 202607 had a specimen collected on 12/7/21 at 8:50 am

	and testing was performed and reported on 12/8/21 at 11:01 am. 3. An interview on 12 /7/22 at 1:08 pm with the Technical Consultant confirmed the patients listed above had CBC testing performed on specimens that had exceeded their stability.