Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	23D0915078	06/14/2021
Name of Provider or Supplier	**Street Address, City, State**	
Huron Medical Center Pc	1221 Pine Grove Ave, 2nd Floor, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Consultant #1 (TC1), the laboratory failed to rotate proficiency testing samples among all testing personnel routinely performing patient testing for 6 (1 event in 2021, 3 events in 2020, and 2 events in 2019) of 6 testing events reviewed. Findings include: 1. Review of the laboratory's CMS-209 form revealed it had 7 testing personnel for moderate complexity testing. 2. A review of the laboratory's American Proficiency Institute (API) proficiency testing attestations revealed Testing Personnel #1 performed testing for all specimens in the following proficiency testing events: a. 2021 Hematology /Coagulation 1st Event b. 2020 Hematology/Coagulation 3rd Event c. 2020 Hematology/Coagulation 2nd Event d. 2020 Hematology/Coagulation 1st Event e. 2019 Hematology/Coagulation 3rd Event f. 2019 Hematology/Coagulation 2nd Event 3. An interview on 6/14/21 at 12:12 pm with TC1 confirmed the laboratory did not rotate its proficiency testing specimens among its routine testing staff.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity.

	(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Consultant #1 (TC1), the laboratory failed to monitor the temperature for the refrigerator storing hematology quality control materials for 1 week (6/8/21 to 6/14/21) in June 2021. Findings include: 1. A review of the laboratory's temperature monitoring logs revealed a lack of documentation of temperature monitoring for the refrigerator storing hematology quality control materials since 6/7/21. 2. A review of the laboratory's "Table of Expected Values" for the hematology quality control materials revealed a section showing the temperature range for storage was 2-8 degrees Celsius. 3. An interview on 6/14/21 at 12:05 am with TC1 confirmed the laboratory had not recorded temperatures for the refrigerator since 6/7/21.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Consultant #1 (TC1), the laboratory failed to obtain accuracy performance specifications within manufacturer ranges for the Beckman Coulter DxH 520 hematology analyzer for 1 (percent basophils) of 21 total whole blood parameters. Findings include: 1. A review of the laboratory's verification of performance specifications for the Beckman Coulter DxH 520 hematology analyzer revealed the method comparison for percent basophil (BA%) had a bias percentage of -30.2%. 2. A review of the laboratory's copy of the Beckman Coulter System Overview Performance revealed a section titled "Method Comparison" stating, "Accuracy was assessed using a minimum of 40 morphologically normal samples collected into K2 or K3EDTA, stored at operational temperature, and analyzed within 8 hours of collection on the DxH 520 and a comparator. Results with system messages were excluded. The mean difference was calculated according to CLSI EP09-A3. Mean difference results should be within the limits defined below." and "BA% measuring range 0.00 to 100.00 bias or percent bias range plus or minus 1% to plus or minus 10%." 3. An interview on 6/14/21 at 10:48 am with TC1 confirmed the accuracy for BA% did not meet the manufacturer specifications and the laboratory director did not address the discrepancy.