

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0915078	(X3) Date Survey Completed 12/07/2022
Name of Provider or Supplier Huron Medical Center Pc	Street Address, City, State 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
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant, the laboratory failed to verify the accuracy of its hematology testing for analytes the American Proficiency Institute had not assigned a score for 1 (2021 2nd Event) of 4 testing events reviewed. Findings include: 1. A review of the laboratory's American Proficiency Institute (API) testing results revealed the laboratory received results of "Not Graded" for the second event in 2021 for basophil and lymphocyte percentage. 2. The surveyor requested verification of accuracy for the basophil and lymphocyte percentage on 12/7/22 at 9:36 am and it was not made available. 3. A review of the laboratory's "Proficiency Testing" policy on 12/7/22 revealed a section stating, "If there are any results that are marked with a ? or # sign, they will be evaluated in the same manner as a failing score." 4. An interview on 12/7/22 at 9:36 am with the Technical Consultant revealed the basophil and lymphocyte percentages with not graded results had not been evaluated.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for</p>

specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Testing Personnel #1, the laboratory failed to establish imminently life-threatening, or panic, values for its hematology testing for 2 (December 2020 to December 2022) of 2 years reviewed. Findings include: 1. A review of the laboratory's procedure manual on 12/7/22 revealed a lack of values that would be considered imminently life-threatening for its Complete Blood Count (CBC) testing. 2. An interview on 12/7/22 at 10:24 am with Testing Personnel #1 confirmed the laboratory had not established imminently life-threatening or panic values for its CBC testing.

D5783

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Technical Consultant, the laboratory failed to perform and document corrective action when calibration had failed for 1 (4/5/22) of 3 calibrations reviewed for the Beckman Coulter DxH 520 analyzer. Findings include: 1. A review of the laboratory's Beckman Coulter DxH 520 hematology analyzer calibration records on 12/7/22 revealed calibration had failed for White Blood Cells (WBC) and Platelets (PLT) when its most recent event was performed on 4/5/22. Below the failed results stated, "reviewed QC all ok will not change factor but will monitor 4/8/22." 2. A review of the laboratory's manufacturer calibration procedure on 12/7/22 revealed a section stating, "The instrument comes calibrated from the factory. You should verify the calibration status. If verification fails, proceed with calibration. Your laboratory is responsible for the final calibration of the CBC parameters" and "You should verify the calibration of your instrument: As dictated by your laboratory procedures and local or national regulations." 3. An interview on 12/7/22 at 10:00 am with the Technical Consultant revealed there was an issue with the

calibration factor at the time of calibration. The calibration was performed again and had failures for WBC and PLT analytes. No corrective action was performed for patients as a result of the failed calibration.

D5807

TEST REPORT

CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Technical Consultant, the laboratory failed to ensure the correct reference ranges for its Complete Blood Count (CBC) testing were on the patient's test report for 10 (Patients 25276, 23932, 22668, 20693, 18095, 16230, 12841, 11217, 9187, and 7833) of 10 patient test reports reviewed. Findings include: 1. A review of the 10 patient test reports (Patients 25276, 23932, 22668, 20693, 18095, 16230, 12841, 11217, 9187, and 7833) revealed a discrepancy between the Beckman Coulter DxH 520 analyzer's reference ranges established by the manufacturer and the reference ranges on the patients' test reports: a. White blood Cells i. Beckman Coulter range: 3.77 to 11.03 ii. Test report range: 3.8 to 10.8 b. Lymphocyte % i. Beckman Coulter range: 18.51 to 48.98 ii. Test report range: 20 to 55 c. Monocyte % i. Beckman Coulter range: 4.72 to 11.35 ii. Test report range: 0-10 d. Neutrophil % i. Beckman Coulter range: 41.35 to 72.27 ii. Test report range: 42 to 75 e. Eosinophil % i. Beckman Coulter range: 0.71 to 6.09 ii. Test report range: 1-7 f. Basophil % i. Beckman Coulter range: 0.05 to 0.47 ii. Test report range: 0-2 g. Absolute Neutrophil i. Beckman Coulter range: 2.03 to 7.67 ii. Test report range: 1.5 to 8 h. Red Blood Cells i. Beckman Coulter range: 3.83 to 5.06 ii. Test report range: 3.8 to 5.1 i. Hemoglobin i. Beckman Coulter range: 11.59 to 15.11 ii. Test report range: 11.7 to 15.5 j. Hematocrit i. Beckman Coulter range: 34.6 to 44.1 ii. Test report range: 35 to 45 k. Mean Corpuscular Volume i. Beckman Coulter range: 80 to 98 ii. Test report range: 80 to 99 l. Mean Corpuscular Hemoglobin i. Beckman Coulter range: 26.6 to 33.5 ii. Test report range: 27 to 31 m. Mean Corpuscular Hemoglobin Concentration i. Beckman Coulter range: 32.9 to 50.6 ii. Test report range: 32 to 36 o. Platelet Count i. Beckman Coulter range: 169.1 to 368.3 ii. Test report range: 140 to 400 2. An interview on 12/7/22 at 10:40 am with the Technical Consultant confirmed the reference ranges on the test reports were not accurate.