

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0442304	(X3) Date Survey Completed 07/26/2023
Name of Provider or Supplier Malden Medical Center	Street Address, City, State 806 N Douglas Street, Malden, MO	
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
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the technical consultant (TC), the laboratory failed to include the name and address of the laboratory location where the test was performed on the patient test report. Findings: 1. Review of the patient test reports showed no name and address of the laboratory location where the test was performed. 2. Interview with the TC on July 26, 2023 at 11:00 AM confirmed the laboratory failed to include the name and address of the laboratory location where the test was performed on the patient test report.</p>
D5807	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of the laboratory's reference range procedure, patient reports and interview with the technical consultant (TC), the laboratory failed to ensure the procedure manual reference ranges matched the references ranges on the patient reports. Findings: 1. Review of the laboratory's "Laboratory Reference Range" procedure showed the reference ranges as: Glucose 74 - 106 mg/dL Blood Urea Nitrogen (BUN) 7 - 18 mg/dL Creatinine 0.55 - 1.30 mg/dL Sodium 136 - 145 mmol/L Potassium 3.5 - 5.1 mmol/L Chloride 98 - 107 mmol/L ECO2- Enzymatic Carbonate 21.0 - 32.0 mmol/L Calcium 8.5 - 10.1 mg/dL Triglycerides 30 - 150 mg/dL HDL- Cholesterol 40 - 60 mg/dL Total Protein 6.4 - 8.2 g/dL Albumin 3.4 - 5.0 g/dL Aspartate Aminotransferase (AST/SGOT) 15 - 37 U/L Bilirubin, Total 0.2 - 1.0 mg/dL Alkaline Phosphatase 50 - 136 U/L Alanine Aminotransferase (ALT/AST) 12 - 78 U/L White blood cell count (WBC) 4.0 - 11.0 K/uL Red blood cell (RBC) male 4.6 - 6.2 *10 Red blood cell (RBC) female 4.2 - 5.4 *10 Hemoglobin male 14 - 16 g/dL Hemoglobin female 11.5 - 16.0 g/dL Hematocrit male 40 - 52 % Hematocrit female 37 - 47 % Mean corpuscular volume (MCV) male 80 - 94 fL Mean corpuscular volume (MCV) female 82 - 100 fL Mean corpuscular hemoglobin (MCH) 26 - 33 pg Mean corpuscular hemoglobin concentration (MCHC) 31 - 36 g/dL Platelet count 150 - 450 K/uL % lymphocyte 24 - 44 % % mixed 0 - 8 % % neutrophil 36 - 66 % # lymphocyte 1.0 - 4.6 *10 # mixed 0.0 - 0.8 *10 # neutrophil 1.8 - 7.7 *10 Red cell distribution (RDW) 36 - 50 % Mean platelet volume (MPV) 8.6 - 11.7 fL 2. Review of the patient reports showed the reference ranges as: Glucose 75 - 109 mg/dL Blood Urea Nitrogen (BUN) 8 - 17 mg/dL Creatinine 0.56 - 1.29 mg/dL Sodium 137 - 144 mmol/L Potassium 3.6 - 5.0 mmol/L Chloride 99 - 106 mmol/L ECO2- Enzymatic Carbonate 21.1 - 31.9 mmol/L Calcium 8.6 - 10.0 mg/dL Triglycerides 31 - 149 mg/dL HDL- Cholesterol 41 - 59 mg/dL Total Protein 6.5 - 8.1 g/dL Albumin 3.5 - 4.9 g/dL Aspartate Aminotransferase (AST/SGOT) 16 - 36 U/L Bilirubin, Total 0.3 - 0.9 mg/dL Alkaline Phosphatase 47 - 115 U/L Alanine Aminotransferase (ALT/AST) 13 - 47 U/L White blood cell count (WBC) 4.1 - 10.9 K/uL Red blood cell (RBC) male 4.7 - 6.1 *10 Red blood cell (RBC) female 4.3 - 6.1 *10 Hemoglobin male 14.1 - 15.9 g/dL Hemoglobin female 11.6 - 15.9 g/dL Hematocrit male 41 - 51 % Hematocrit female 38 - 51 % Mean corpuscular volume (MCV) male 81 - 93 fL Mean corpuscular volume (MCV) female 81 - 99 fL Mean corpuscular hemoglobin (MCH) 23 - 27 pg Mean corpuscular hemoglobin concentration (MCHC) 32 - 35 g/dL Platelet count 151 - 449 K/uL % lymphocyte 22 - 50 % % mixed 4.0 - 19 % % neutrophil 38 - 69 % # lymphocyte 2.0 - 4.0 *10 # mixed 0.2 - 2.0 *10 # neutrophil 3.0 - 7.0 *10 Red cell distribution (RDW) 37 - 49 % Mean platelet volume (MPV) 8.7 - 11.6 fL 3. Interview with the technical consultant (TC) on July 26, 2023 at 11:30 AM confirmed that the laboratory's procedure reference ranges did not match the patient report reference ranges.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
Based on review of performance evaluations and interview with the technical consultant (TC), the technical consultant (TC) failed to evaluate and document the annual performance evaluation for one of one testing personnel (TP) in 2021.
Findings: 1. Review of performance evaluations showed no annual performance

evaluation for TP #1 in 2021. 2. Interview with the TC on July 26, 2023 at 11:00 AM confirmed the technical consultant failed to evaluate and document the annual performance evaluation for TP #1.