Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D0081797	08/05/2024
Name of Provider or Supplier	**Street Address, City, State**	
Metromedic Walk-In Medical Ctr	46 Foster St, New Bedford, MA	

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
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Administrator the laboratory failed to test the negative reactivity of BBL Taxo A disc (bacitracin) using the organisms required by the manufacturer's package insert. Findings Include: 1. Record review on 8/5/2024 of the laboratory's BBL Taxo A disc reagent log revealed: a. Two packages of BBL Taxo A discs, Lot number 3181001, expiration date 12/29 /2024 were received on 8/1/2023. b. The positive control was logged as performed for the above lot and shipment. c. The negative control was not logged as performed. 2. Record review on 8/5/2024 of the Taxo A Disc package insert User Quality Control Section revealed, "Check performance with pure cultures of stable control organisms producing known desired reactions. One or more beta-hemolytic streptococcal species belonging to groups B, C, D and/or G may be employed to demonstrate lack of zone formation." 3. During staff interview with the Laboratory Administrator on 8/5/2024 at 11:30 AM, the Laboratory Administrator stated, "I do not use an organism to check the negative reactivity of the A discs. I use a plate without any organisms for the negative control." 4. The laboratory performs 75 cultures annually in the specialty of Microbiology.
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 staff interview the laboratory failed to ensure the reference ranges on final patient test report (FPTR) matched the reference ranges in the procedure manual (PM) in the specialty of Hematology. Findings include: 1. Record review on 8/5/2024 of a FPTR compared to the procedure manual revealed the following differences for white blood cell count (WBC), red blood cell count (RBC), Hemoglobin (Hgb), Hematocrit (Hct), Mean Corpuscular Volume (MCV), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration (MCHC), Red Cell Distribution Width (RDW), Platelet (PLT), Mean Platelet Volume (MPV), Lymphocyte Percent (lymph%), Mid range Percent (Mid%), and Granulocyte percent (Gran%). Note: Range on FPTR is the same for both male and female. Test FPTR PM WBC 10^3mm^3 4.1-10.9 4.7-10.3 K/uL RBC 10^6/uL 4.2-6.3 4.03-5.46 M/uL Hgb g/dL 12-18 12.4-16.9 g/dL Hct % 37-51 36.6 - 48.3% MCV fL 80-97 81.5-96.8 fL MCH pg 26-32 27.5-33.1 pg MCHC g/dL 31-36 32.4-35.7 g/dL RDW % 11.5-14.5 11.8-14.9 % PLT 10^3/uL 150-450 165-385 K/uL MPV fL 0.0-49.9 7.2-10.2 fL Lymph% 10-58.5 12.7-47.8 Mid% 0.1-24 6.3-14.0 Gran% 37.0-92.0 43.5-78.9 2. Record review on 8/5/2024 of the laboratory procedure manual for the new Abbott Emerald hematology analyzer, Section 4, Characteristics and Specifications revealed, "These ranges do not represent globally applicable intervals, but reflect combined reference ranges tested in the validation study. Each lab should establish/verify its own reference intervals." 3. Staff interview with the Laboratory Administrator on 8/5/2024 at 11:45 PM confirmed the above reference ranges found in the procedure manual do not match the reference ranges on the final patient test report. 4. The laboratory performs 2,905 tests annually in the specialty of Hematology.