

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  22D0081797	<b>(X3) Date Survey Completed</b>  11/18/2022
<b>Name of Provider or Supplier</b>  Metromedic Walk-In Medical Ctr	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2007</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>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</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to test proficiency testing (PT) samples in the same manner as patient samples by testing personnel (TP) who routinely perform the testing in the specialty of Hematology. Findings include: 1. Record review on 11/18/2022 of the laboratory's American Association of Bioanalysts (AAB) 2021 and 2022 NonChemistry PT attestation sheets revealed: a. 2 of 3 Hematology TP did not participate in PT in 2021. b. 2 of 4 Hematology TP did not participate in PT in 2022. 2. Staff interview with TP #1 on 11/18/2022 at 11:00 AM confirmed the above TP did not participate in AAB NonChemistry PT. 3. The laboratory performs 2,250 tests annually in the specialty of Hematology.</p>
<b>D5415</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation, record review and staff interview, laboratory testing</p>

personnel (TP) failed to label controls with the new expiration date after opening in the specialty of Hematology. Findings include: 1. Surveyor observation on 11/18/2022 at 11:45 AM of the laboratory refrigerator contents revealed the following in use Hematology controls were not labeled with the new expiration date after opening; 'Clinical Diagnostic Solutions (CDS) Next Generation 3PD Hematology Controls', Lot # 32209-11, 32209-12 and 32209-13. 2. Record review on 11/18/2022 of the CDS Next Generation 3PD Hematology controls package insert, Storage and Stability section revealed, "Open vial stability is 14 days after opening when returned to the refrigerator after each use." 3. Staff interview on 11/18/2022 at 11:45 AM with TP #1 confirmed the above in use controls were not labeled with the new expiration date after opening. 4. The laboratory performs 2,250 tests annually in the specialty of Hematology.

**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 record review and staff interview, the technical consultant failed to evaluate testing personnel (TP) yearly to ensure competency to perform patient testing in the specialties of Hematology and Microbiology. Finding include: 1. Record review on 11/18/2022 of the laboratory's 2021 TP competency records revealed, 2 of 3 TP did not have documented competency in 2021. 2. Staff interview with TP #1 on 11/18/2022 at 11:30 AM confirmed the above TP did not have documented 2021 competency. 3. The laboratory performs 2,250 tests annually in the specialty of Hematology and 95 tests annually in the specialty of Microbiology.