

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2173930	(X3) Date Survey Completed 02/20/2024
Name of Provider or Supplier Curtis Thompson Md & Associates Pllc	Street Address, City, State 3131 S State Street Suite 309, Ann Arbor, 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
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT 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 observation, record review, and interview with the General Supervisor, the laboratory failed to include the storage requirements, preparation, and expiration dates on 2 (12% Acetic Acid and 100% Ethanol [ETOH]) of 2 reagent bottles in use. Findings include: 1. The surveyor observed on 2/20/2024 during a tour of the laboratory at 9:20 am 2 of 2 reagent bottles lacking the storage requirements, preparation, and expiration date as follows: a. 12% Acetic Acid b. 100% "ETOH" (ethyl alcohol). 2. A review of the laboratory's "Reagent Labeling and Expiration Date Policy" states the following: "1. All reagents, working solutions and stains that are made in-house and placed into secondary containers (a container that is different than a manufacturer's container) are labeled with the chemical name. 2. In addition these containers must also show the date when the reagent was placed in the secondary container. Furthermore, the container must also be labeled with the chemical's National Fire Protection Association ratings for health, flammability, reactivity, and personal protective equipment requirements (the "HMIS" label). 3. All reagents are used by the manufacturer's stated expiration date. Any reagent that is not used by that date is disposed of in a manner that is consistent with the chemical handling procedures described in the Safety Manual. Reagents that are made in-house are used within one month." 3. An interview on 2/20/2024 at 9:30 am, the General Supervisor acknowledged the laboratory had not included the storage requirements, preparation, and expiration dates on the reagents listed above.</p>

D5433

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

. Based on observation, procedure review, and interview with the General Supervisor, the laboratory failed to establish, perform, and document maintenance for the eyewash for 4 (November 2023 to February 2024) of 4 months from the start of the laboratory. Findings include: 1. On February 20, 2024, at 9:20 am during a tour of the laboratory, the surveyor observed a Water Saver eye wash hose attached to the side of the utility sink. 2. Procedure review of multi manuals revealed the laboratory did not have a policy and procedure established for the operation and maintenance of the Water Saver eye wash hose in place for 4 (November 2023 to February 2024) of 4 months since the start of the laboratory. 3. An interview on February 20, 2024, at 2:45 pm, the General Supervisor acknowledged the laboratory had not developed or implemented a policy and procedure for the use and care of the Water Saver eye wash hose.