

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2258471	(X3) Date Survey Completed 08/16/2024
Name of Provider or Supplier Wave Medical Group Inc	Street Address, City, State 720 Paularino Ave, Ste 102, Costa Mesa, CA	
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 the surveyor's observation during the laboratory's tour and interviews with the technical consultant (TC) and testing personnel (TP), it was determined that the laboratory failed to label various reagents used for test performance to indicate the reagent's opening, preparation, and expiration dates when such materials are used in the laboratory. The findings include: 1. Based on the surveyor's observation during the laboratory tour on August 16, 2024, at approximately 1:10 pm, no opening, preparation, or open stability expiration date labels were used or documented for all test reagents used for the Routine Chemistry and Endocrinology subspecialties. For example, TPO Ab conjugate, Substrate reagent II, B12 Pre-treatment, Vitamin D Pre-treatment, TPO Ab/Tg Ab sample diluent, etc. 2. The TP affirmed by interview on August 16, 2024, at approximately 1:10 p.m. that the reagents used in the laboratory as mentioned in statement #1 were not labeled with the opening, preparation, and expiration dates or documented in a reagent preparation log. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 7,960 Routine Chemistry and Endocrinology patients' specimens for which testing materials were not labeled.</p>
D6007	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1)</p>

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (E) The laboratory director must-- (E)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:

Based on the deficient practice cited, the laboratory director is herein cited for deficient practice in overall administration of the laboratory to ensure that reagents are labeled with expiration and opening date as indicated by the manufacturer is established. See D5415