

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2274291	(X3) Date Survey Completed 01/02/2025
Name of Provider or Supplier Hal M Weitzbuch, Md Med Corp	Street Address, City, State 1000 Newbury Rd Ste 180, Thousand Oaks, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2023 laboratory records, the lack of records, and interview with laboratory personnel, it was determined the laboratory failed to verify the accuracy of Biopsy pathology reports. Findings included: 1. The laboratory performed high complexity testing: reporting Biopsy pathology (CMS116, CLIA Application, 12/01/24). 2. Biopsy records randomly selected from 2023 for this CLIA survey were, as follows: Date ID ----- 11/02/23 JS BD23-2481 A, B, C, D 12/14/23 SH BD23-2788 A, B, C, D 3. The laboratory failed to have records verifying the accuracy of biopsy pathology reports in 2023. 4. Laboratory Assistants affirmed (1/02/25 at 1:30 pm) that Testing Personnel began reading biopsy slides and issuing pathology reports from Thousand Oaks in October 2023, and the aforementioned lack of records for reviewing reported biopsy slides to verify accuracy of pathology. 5. And thus, the reliability and quality of biopsy pathology reported in 2023 was not assured during this onsite CLIA survey.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p>

This STANDARD is not met as evidenced by:
 Based on review of laboratory records, the lack of an approved written policy and procedure, and interview with laboratory personnel, it was determined the laboratory failed to have a written procedure for staff to follow to ensure that Biopsy and Mohs slides were reviewed for each Testing Person, at least twice annually for each type of test. Findings included: 1. See D5217. 2. The laboratory failed to have an approved written policy and procedure for at least twice within each calendar year verifying the accuracy of each Testing Person in reporting biopsy pathology and the final stage of clearing tumor in Mohs procedures. 3. Laboratory Assistants affirmed (1/02/25 at 1:30 pm) no written policy and procedure had been approved or implemented for use at the Thousand Oaks location. 4. And thus, the reliability and quality of tests performed at Thousand Oaks could not be assured during this /onsite CLIA survey: a. The Testing Personnel Reports (CMS209-CLIA, 12/01/24, and LAB116-State, 12/01/24) named two Testing Persons performing histopathology: reporting biopsy pathology and/or performing Mohs procedures. b. The laboratory's annual test volume in histopathology is 2,599 (CMS116 CLIA Application, 12/01/24). . .

D5805

TEST REPORT
 CFR(s): 493.1291(c)

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.

This STANDARD is not met as evidenced by:
 . Based on review of laboratory reports and interview with laboratory personnel, it was determined that reports failed to accurately state the address and laboratory director of the laboratory location where the test was performed. Findings included: 1. Biopsy reports were randomly selected from 2023 - 2024 Pathology Log Books for this survey. Five out of 10 Biopsy reports failed to state that the biopsy slides were read and reported from the Thousand Oaks location, as follows: Date ID
 ----- 11/30/23 DB #2674 12/14/23 SB #2782 1/11
 /24 CH #069 5/16/24 ER #1144 11/21/24 RW #3028 2. Laboratory Assistants affirmed (1/02/25 at 1:45 pm) the aforementioned findings. 3. The reliability and quality of pathology reports was not assured during this CLIA survey.