

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0576827	(X3) Date Survey Completed 09/25/2025
Name of Provider or Supplier William P Baugh, Md Inc	Street Address, City, State 333 W Bastanchury Rd Ste 110, Fullerton, 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 observation of the Cryostat and Microscope, review of 2022-2024 laboratory records for Mohs procedures, the lack of laboratory records, and interview with laboratory personnel, it was determined the laboratory failed to verify the accuracy of Mohs procedures to remove/clear tumor. Findings included: a. A few laboratory records selected for this Survey documented Mohs procedures were performed during the timeframe 2022-2024, as follows: Date Mohs # ----- 3/07/22 #26 -- B,R 9/19/22 #96 -- B,J 11/28/22 #120--S,A 3/06/23 #38 -- B,C 10/23/23 #137--A,J 1/05/24 #07 -- H,R 7/08/24 #95 -- K,J 9/09/24 #123 --C,R b. The laboratory failed to have records of peer review verifying the accuracy of Mohs procedures to clear tumor, at least twice each calendar year for 2022, 2023, and 2024. c. The office manager affirmed (9/25/25 at 1:30 PM) the aforementioned findings, that the laboratory lacked the practice of peer review of Mohs slides to verify tumor was cleared; and that the laboratory lacked a written policy and procedure to do so. d. And thus, the reliability and quality of Mohs procedures to clear tumor could not be assured during this Survey. The laboratory reported 2,795 Histopathology tests annually including Mohs procedures. .</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for</p>

specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on observation of Chlorazol Black E reagent (EDM3, lot # 001080, expiration date 11/06/26) for KOH microscopy, DTM (Dermatophyte Test Medium, Hardy X15, lot #667553, expiration date 3/01/26) for Fungal Cultures, Cryostat (Advantik QS12, serial number S15069278), and Microscope (Leica DM1000, serial number 266664-082005); review of laboratory records, the lack of laboratory written policies and procedures, and interview with laboratory personnel, it was determined the laboratory failed to have a complete Laboratory Manual approved by the Laboratory Director for staff use and reference. Findings included: a. The laboratory stated testing, as follows (form CMS116 CLIA Application, 9/30/2025; form LAB144A Laboratory Testing Declaration, 9/23/25) : KOH and Wet Mounts DTM Fungal Cultures Histopathology: Biopsy pathology reporting; and Mohs procedures to clear tumor b. A review of laboratory test records documented testing, as follows: Date Test Patient ID
 ----- 9/25/25 KOH R, C 2/14/22 DTM E, D 11/27/23 DTM M, G 11/14/24 DTM D, A 1/15/25 DTM L, K 2/25/22 Biopsy pathology WB22-159 5/17/23 Biopsy pathology WB23-417 10/02/24 Biopsy pathology WB24-744 9/16/25 Biopsy pathology WB25-599 3/07/22 Mohs #26--B, R 10/23/23 Mohs #137--A, J 7/08/24 Mohs #95--K, J 9/08/25 Mohs #92--W, D c. Except for Mohs procedures, the laboratory failed to have a Laboratory Manual of written and approved policies and procedures for the aforementioned tests. d. The office manager affirmed (9/25/25 at 1:30 PM) the laboratory didn't have a Laboratory Manual for staff use and reference. e. The laboratory included the Laboratory Director/Testing Person and four assistants (State form LAB116 Laboratory Personnel Report, 9/23/25). .

D6082

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(1)

(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 Survey findings and deficiency cited, the Laboratory Director is herein cited for deficient practice in ensuring a complete Laboratory Manual was approved

for staff use and addressed preanalytic, analytic, and postanalytic phases of testing with quality assessment monitoring at each phase. See D5403. .

D6093

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:

Based on the lack of laboratory records and deficiency cited, the Laboratory Director is herein cited for deficient practice in ensuring that Mohs procedures slides are assessed by peer review at least twice each calendar year to verify accuracy of tumor being cleared. See D5217.