Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0521523	06/27/2023
Name of Provider or Supplier	**Street Address, City, State**	
L William D Nowierski, Md	100 E Warm Springs Ave, Ste #A, Boise, ID	

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
D2003	ENROLLMENT CFR(s): 493.801(a)(2)(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1) This STANDARD is not met as evidenced by: Based on a record review of the laboratory's testing menu, and an interview with the laboratory Mohs manager (MM) on 6/27/2023 the laboratory failed to perform twice annual verification of accuracy for Potassium hydroxide (KOH) and Tzanck smear slide testing. Findings include: 1. Review of the laboratory records revealed a lack of documentation of twice annual verification of accuracy for KOH and Tzanck smear testing for 2022 and to date of survey 2023. 2. The laboratory MM confirmed by an interview on 6/27/2023 at 3:10 pm, the lack of documentation of twice annual verification of accuracy for KOH and Tzanck smear testing for 2022 and to date of survey 2023. 3. The laboratory records indicate the laboratory performed two Tzanck smear tests from 2022 to the date of this survey 2023, and 42 KOH tests in 2022, and 27 KOH tests to date of survey 2023.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The

	source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on a review of the laboratory Mohs patient test requisition, and an interview with the Mohs Manager (MM) on 6/27/2023, the laboratory failed to include all of the required information on the Mohs test requisition. Findings include: 1. Review of four of four patient Mohs test requisitions revealed the failure to include the name and address of the authorized person requesting the test, the name and address of the laboratory performing the testing, the sex of the patient, and the signature and date of the testing personnel. Year Site 05/24/2022 L-Nasal Tip 06/14/2022 L-Temple 04/11 /2023 L-Eye bottom 06/20/2023 L-Mid cheekbone 2. The laboratory's Mohs Map serves as the laboratory's test requisition and report format for Mohs patient testing. 3. The Laboratory Director (LD) confirmed by interview on 06/27/2023 at 3:27 pm, the laboratory failed to include all the required information on the test requisition. 4. The laboratory reports performing 18 patient Mohs tests annually.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy and procedure manual, and an interview with the Mohs Manager (MM) and the Laboratory Director (LD) on 6/27/2023, the laboratory failed to establish a procedure for Mohs Micrographic testing, Potassium Hydroxide (KOH), and Tzanck smear testing. Findings include: 1. Review of the laboratory's policy and procedure manual revealed the lack of a policy or procedure for: a) Mohs Micrographic testing. See D5305. b) Tzanck smear Methylene Blue stain reconstitution and labeling. See D5415. c) KOH and Tzanck smear procedures. 2. The MM and LD confirmed by interview on 6/27/2023 at 3:27 pm, the lack of procedures for all patient tests performed at this laboratory. 3. The laboratory performs approximately 18 Mohs Micrographic tests, 42 KOH, and two Tzanck patient tests annually.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) 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.

	This STANDARD is not met as evidenced by: Based on a review of the laboratory's patient testing log, observation of the Methylene Blue stain bottle, and interview with the Laboratory Director (LD) and the Mohs Manager (MM), the laboratory failed to label the Methylene Blue stain bottle that the laboratory prepared for performing Tzanck smear testing, and failed to include all required information. Findings include: 1. Review of the laboratories test menu identified the performance of Tzanck smear testing for Herpes Simplex Virus (HSV). 2. Observation of the laboratory's reagent bottle of Methylene Blue stain revealed the failure to include (1) the strength or concentration of the stain; (2) storage requirements, (3) the in-use date, and (4) the expiration date on the container label. 3. The LD confirmed by an interview on 6/27/2023 at 3:20 pm, the lack of required information on the label of the Methylene Blue stain used for Tzanck smear testing. 4. The laboratory reports performing two Tzank tests annually.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) 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: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observation of the laboratory's Microscopes, record review, and interview with the laboratory Mohs Manager (MM) on 6/27/2023, the laboratory failed to perform annual preventive maintenance and document daily maintenance for 2022 to date of survey 2023. Findings include: 1. Based on observation during the laboratory tour, the use of two microscopes used for Potassium Hydroxide (KOH) and Tzanck smear testing was identified. Microscopes: AO One-fifty, and Zeiss West Germany 2. The laboratory failed to have documentation of the annual preventive maintenance being performed for 2022 to date of survey 2023, for two of two microscopes used in patient testing. 3. The laboratory MM confirmed by interview on 6/27/2023 at 4:32 pm, the lack of annual maintenance (function checks) and daily maintenance for the two microscopes used in patient testing. 4. The laboratory reports performing 44 microscopic patient examinations annually.