Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D1055049	07/30/2024
Name of Provider or Supplier	**Street Address, City, State**	
Trokhan Dermatology, Llc	235 Closter Dock Rd, Closter, NJ	

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
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 surveyor review of the Procedure Manual (PM), observation of Staining Station (SS) and interview with the Laboratory Director (LD), the laboratory failed to follow the PM for Hematoxyilin-Eosin (H&E) staining from 12/5/22 to the date of the survey. The findings include: 1. The procedure in the PM "H&E staining procedure for MOHS" does not match the order of the labeled coplin jars in the SS or the "Hematoxylin and Eosin Stain" procedure posted on the SS. 2. The LD confirmed on 7 /30/24 at 12:30 pm the laboratory did not follow the PM.
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 surveyor review of the Test Reports (TR) and interview with the Laboratory Director (LD), the laboratory failed to ensure that the TR included all the required information on the date of survey. The finding includes: 1. The TR did not have the name and address of where histopathology testing was performed on eight out of eight TR. 2. The LD confirmed on 7/30/24 at 12:30 pm that the TR failed to include all the required information.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Laboratory Director (LD) , the LD failed to establish a Competency Assessment (CA) procedure with all the required elements for Testing Personnel at the time of survey. The LD confirmed on 7/30/24 at 12:00 pm that a CA procedure was not established.