

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0866867	(X3) Date Survey Completed 05/12/2023
Name of Provider or Supplier Noam Glaser Md Pc	Street Address, City, State 727 Broadway Suite C2, Massapequa, NY	
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
D5203	<p>SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: Based on the review of laboratory's Standard Operating Procedure 3.3 Specimen Handling step f, the procedure failed to include second identifier unique to the patient. Confirmed finding on an interview with testing person on 5/12/2023 about 12:30pm.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's standard procedure manual, lack of a written Quality Assessment (QA) procedure and an interview with the laboratory testing person, the laboratory failed to establish a written QA procedure to monitor, evaluate all phases of the laboratory's pre analytic, analytic and post analytic systems. FINDINGS 1. The laboratory's standard operating procedure manual did not contain a written QA procedure to monitor, evaluate all phases of the laboratory's pre analytic, analytic and post analytic systems. 2. The testing person confirmed on 5/12/2023 at</p>

approximately 12:45 PM, that the laboratory did not have a written procedure to monitor, evaluate all phases of laboratory testing.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 the review of standard operating procedure and sample Mohs map integrated into the procedure, the laboratory failed to clearly define Mohs map inking chronograph. The sample Mohs map states "Glaser Dermatology: we use blue and green dye. But the chronograph states green and red. Confirmed the finding with testing person on 5/12/2023 about 12:30pm.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on the review of preventative maintenance records, the fume hood annual preventative maintenance was not performed for the calendar year 2022. Confirmed the finding on an interview with testing person on 5/12/2023 about 12:30pm.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and

maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's standard operating procedure (SOP) manual, lack of a written Quality Assessment (QA) procedure and confirmed in an interview with the laboratory testing person, the laboratory director failed to establish a written QA for all phases for the general laboratory system. Refer to D5291.