

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0995364	(X3) Date Survey Completed 01/10/2018
Name of Provider or Supplier Tareen Dermatology	Street Address, City, State 1185 Town Center Drive #101, Eagan, MN	
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
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to establish and follow a written proficiency testing procedure. Findings are as follows: 1. The laboratory performed Serum HCG testing as confirmed by General Supervisor (GS) during a tour of the laboratory on 1/10/18 at 9:05 a.m. 2. The laboratory performed proficiency testing (PT) using the American Academy of Family Physicians (AAFP) as the PT provider. 3. A PT procedure was not found during review of laboratory policies and procedures. The laboratory was unable to provide a PT procedure upon request. 4. In an interview on 1/10/18 at 11:30 a.m., the GS confirmed the above findings. .</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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</p>

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 document review and interview with laboratory personnel, the laboratory failed to ensure all required elements were included in the procedure manual. Findings are as follows: 1. The laboratory performed Serum HCG testing as confirmed by General Supervisor (GS) during a tour of the laboratory on 1/10/18 at 9:05 a.m. 2. The laboratory uses Advanced MD as their Laboratory Information System (LIS) to report patient results. 3. A testing method down time procedure was not included in the procedure manuals. An LIS down time procedure was also not found. The laboratory was unable to provide these procedures upon request. 4. In an interview on 1/10/18 at 11:30 a.m., the GS confirmed the above findings. .

D5431

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(2)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

. Based on observation, record review and interview with laboratory personnel, the laboratory failed to establish and follow a procedure for maintenance and function checks of general laboratory equipment. Findings are as follows: 1. A tour of the laboratory on 1/10/18 at 9:05 a.m. revealed the presence of the following laboratory equipment: - Nikon AlphaPhot -2 (452) Microscope - Horizon Mini E Centrifuge - LG Refrigerator / Freezer with Fisher Scientific Digital Thermometer (S/N = 91027060, Calibration Expiration Date = 10 / 2016) - CDN Digital Timer (No Serial Number or Factory Calibration Expiration Date) 2. A procedure that defines the maintenance and function check tasks, frequency, acceptable outcomes, and responsible persons could not be located in the Crutchfield Dermatology Lab Procedure Manual. 3. Maintenance and function checks records from 2016 and 2017 for the equipment noted above could not be located in the laboratory's files. 4. The laboratory was unable to provide the missing procedure or records upon request. 5. In an interview on 1/10/18 at 11:30 a.m., the General Supervisor confirmed the above findings. .

D5821

TEST REPORT

CFR(s): 493.1291(k)

When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the

original report, as well as the corrected report.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the laboratory failed to establish and follow a written corrected reports procedure. Findings are as follows: 1. The laboratory performed Serum HCG testing as confirmed by General Supervisor (GS) during a tour of the laboratory on 1/10/18 at 9:05 a.m. 2. A corrected reports procedure was not found during review of laboratory policies and procedures. The laboratory was unable to provide a corrected reports procedure upon request. 3. In an interview on 1/10/18 at 11:30 a.m., the GS confirmed the above findings. .