

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0995364	(X3) Date Survey Completed 09/25/2019
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
D2005	<p>ENROLLMENT CFR(s): 493.801(a)(4)</p> <p>Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act.</p> <p>This STANDARD is not met as evidenced by: . Based on document review, the laboratory failed to ensure proficiency testing results for the sole regulated analyte were released to the Centers for Medicare and Medicaid Services (CMS) as required. Findings are as follows: 1. The laboratory performed Serum Human Chorionic Gonadotropin (hCG) testing as confirmed by the Nursing Director (ND) during a tour of the laboratory on 09/25/19, at 1:05 p.m. 2. Serum hCG proficiency testing (PT) results were not included in the CMS CASPER Report 0096D, CLIA Application and Survey Summary. Serum hCG PT results were not found during additional CMS database review. 3. In an email sent at 12:18 p.m. on 09/26/19, the ND was informed of the deficiency.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory</p>

failed to include a procedure in the procedure manual for one or three tests performed by the laboratory. Findings are as follows: 1. The laboratory performed Parasitology (Scabies) testing as confirmed by the Nursing Director (ND) during a tour of the laboratory on 09/25/19, at 1:05 p.m. 2. A written procedure for Scabies microscopic examination was not found during review of the Lab Procedure Manual. The laboratory was unable to provide this procedure upon request. 3. In an interview at 3:10 p.m. on 09/25/19, the ND indicated the procedure had been in place previously. The laboratory was given an opportunity to provide the missing procedure within two days of the survey. 4. In an email received at 11:39 a.m. on 09/26/19, the ND indicated a written procedure for Scabies microscopic examinations could not be found.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the technical consultant failed to ensure competency was assessed at least semiannually during the first year of patient specimen testing in 2018 for one of one new testing personnel. Findings are as follows: 1. The laboratory performed Serum Human Chorionic Gonadotropin (hCG) testing as confirmed by the Nursing Director (ND) during a tour of the laboratory on 09/25/19, at 1:05 p.m. 2. Laboratory records indicated Testing Personnel 7 (TP7) was trained and initially assessed for hCG testing competency in March 2018. A semiannual competency assessment for TP7 was not found in laboratory records. 3. The laboratory was unable to provide the missing semi-annual hCG competency documents upon request. 4. In an interview on 09/25/19, at 2:20 p.m., the ND confirmed the above findings.