

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2146570	(X3) Date Survey Completed 07/10/2019
Name of Provider or Supplier Tru-Skin Dermatology	Street Address, City, State 701 E Whitestone Blvd Ste 150, Cedar Park, TX	
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
D5219	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of the CMS 116 database, lack of documentation and confirmation by the facility staff, the laboratory failed to verify the accuracy of histopathology diagnosis at least twice annually in 2018. Findings included: 1. Review of the CMS 116 database found that the laboratory was issued a certificate of registration April 2, 2018. 2. There were no written policies and procedures available for review that defined the procedure for performing and documenting the verification of accuracy of results for histopathology. Laboratory records documenting the verification of accuracy of results for histopathology for tests performed in 2018 and 2019 were requested but not provided. 3. Interview of the office manager conducted on July 10, 2019 out 1:26 PM confirmed that the laboratory did not verify the accuracy of histopathology results at least twice each year in 2018, and has not done one in 2019.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>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</p>

acceptability.

This STANDARD is not met as evidenced by:

Review of pathology reports and interview of facility personnel found that the laboratory failed to ensure the name and address of the laboratory performing the microscopic analysis appeared on five of six reports reviewed. The findings included:

1. Review of six pathology reports found no documentation of the name and address of the laboratory performing microscopic analysis for five of six reports: Accession Number S 18-04440 reported October 8, 2018. Accession number That S 19-03040 reported June 11, 2019. Accession number S 19-02518 reported April 16, 2019. Accession Number S 19-00016 reported January 8, 2019. Accession number S 19-02361 reported April 12, 2019. 2. Interview of the office manager conducted on July 10, 2019 at 10:25 AM confirmed that the name and address of the laboratory performing the microscopic tissue examination did not appear on the final report.