

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D1105542	<b>(X3) Date Survey Completed</b>  11/03/2020
<b>Name of Provider or Supplier</b>  Texas Dermatology Specialists PLLC	<b>Street Address, City, State</b>  21800 Katy Freeway # 200, Katy, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	<p>Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
<b>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of available proficiency testing records and interview of facility personnel it was revealed that the laboratory failed to have documentation of performing twice annual accuracy assessments for the unregulated analytes KOH, Scabies and Microscopic analysis of hair. Findings were: 1. A review of available proficiency testing records at the time of the survey for 2019 revealed no documentation of acceptable twice per year proficiency for the following tests: KOH, Scabies and Microscopic analysis of hair 2. Interview of the practice manager on 11/03 /2020 at 0930 hours in the break room confirmed the above findings. He stated he just signed up for the KOH proficiency testing with API. Key: KOH- Potassium Hydroxide Scabies- A mineral oil preparation for identification of scabies mites, eggs,</p>

	<p>and scybala Hair Analysis-Microscopic analysis of hair for telogen and anagen counts or identification of structural shaft abnormalities API- American Proficiency Institute</p>
<b>D5291</b>	<p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b> 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 personnel records, review of the laboratory proficiency testing records and staff interview, it was revealed the laboratory's quality assessment failed to identify problems in general lab systems. The findings were: 1. The laboratory's quality assurance failed to detect that twice annual accuracy assessments did not include KOH, Scabies and Microscopic analysis of hair. (refer to D5217). 2. Interview of the practice manager on 11/03/2020 at 0930 hours in the break room confirmed the above findings</p>
<b>D5401</b>	<p><b>PROCEDURE MANUAL</b> 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 a review of procedure manuals and interview of facility personnel it was revealed that the laboratory failed to have a documented procedure for 3 of 4 tests performed by the facility (KOH, Scabies, Hair Analysis). Findings were: 1. A review of the "Laboratory Manual" effective 1/10/2020 revealed that the laboratory failed to have a documented procedure for the tests: KOH, Scabies, Hair Analysis. 2. An interview with the practice manager on 11/03/2020 at 0945 in the break room and following the facility representative's own review of the records the above findings were confirmed. Key: KOH- Potassium Hydroxide Scabies- A mineral oil preparation for identification of scabies mites, eggs, and scybala Hair Analysis-Microscopic analysis of hair for telogen and anagen counts or identification of structural shaft abnormalities</p>
<b>D5433</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p>

This STANDARD is not met as evidenced by:  
 Based on a review of the laboratory's equipment maintenance records and interview of facility personnel it was revealed that the laboratory failed to document maintenance on 1 of 2 microscopes in use by the facility (Seiler Video Microscope #0905332). Findings were: 1. A review of Laboratory "Equipment Quality Control Maintenance Record" document revealed documentation of "Stage & Oculars Cleaned Daily" and "Grounding checked weekly" for the microscope used for Mohs testing. There was no documentation available for review for daily or weekly maintenance for the Seiler Video Microscope #0905332 used for KOH, Scabies, Hair Analysis preparations. 2. An interview with the practice administrator on 11/3/2020 at 1133 hours in the laboratory confirmed the above findings. Key: KOH- Potassium Hydroxide Scabies- A mineral oil preparation for identification of scabies mites, eggs, and scybala Hair Analysis-Microscopic analysis of hair for telogen and anagen counts or identification of structural shaft abnormalities

**D6054**

**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 annually, after the first year.

This STANDARD is not met as evidenced by:  
 Based on review of CMS 209 form, personnel records, and interview with staff, the Technical Consultant (TC) failed to evaluate competency annually in 2019 for 1 of 1 Testing Persons (TP-1) who perform moderate complexity KOH and Scabies testing. Findings included: 1. Review facility testing records and the CMS-209 form revealed moderate complexity KOH and Scabies preps were performed by Testing Person 1. 2. Review of personnel records from 2019 competency assessments revealed no documentation of annual competency in 2019. The Technical Consultant had not performed and documented competency assessment for TP-1 to include: a) Direct observation of routine patient test performance, including patient preparation, specimen handling, processing and testing. b) Monitoring the recording and reporting of patient test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens or external proficiency testing samples. f) Assessment of problem solving skills. 3. In an interview on 11/03/2020 at 0930 hours in the breakroom, the practice manager confirmed the above findings. Key: KOH- Potassium Hydroxide Scabies- A mineral oil preparation for identification of scabies mites, eggs, and scybala CMS-209- Centers for Medicare & Medicaid Services Laboratory Personnel Report

**D6128**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
 CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated

to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on review of CMS 209 form, personnel records, and interview with staff, the Technical Supervisor failed to evaluate competency annually in 2019 for 1 of 1 Testing Persons (TP-1) who perform high complexity Microscopic Hair Analysis. Findings included: 1. Review facility testing records and the CMS-209 form revealed high complexity Microscopic Hair Analysis was performed by Testing Person 1. 2. Review of personnel records from 2019 competency assessments revealed no documentation of annual competency in 2019. The Technical Supervisor had not performed and documented competency assessment for TP-1 to include: a) Direct observation of routine patient test performance, including patient preparation, specimen handling, processing and testing. b) Monitoring the recording and reporting of patient test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens or external proficiency testing samples. f) Assessment of problem solving skills. 3. In an interview on 11/03/2020 at 0930 hours in the break room, the practice manager confirmed the above findings. Key: Hair Analysis-Microscopic analysis of hair for telogen and anagen counts or identification of structural shaft abnormalities CMS-209- Centers for Medicare & Medicaid Services Laboratory Personnel Report