

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0709112	(X3) Date Survey Completed 12/19/2018
Name of Provider or Supplier Us Dermatology Partners - Centreville	Street Address, City, State 13880 Braddock Rd Suite 301, Centreville, VA	
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
D0000	An announced CLIA initial survey was conducted at Dermatology and Skin Cancer Specialists, LLC on December 19, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D5217	<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 a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS 209), laboratory's policies and procedures, patient test log, and an interview, the laboratory failed to verify the accuracy of Potassium Hydroxide (KOH) mycology and Scabies Prep parasitology testing twice annually for the twenty-four (24) of 24 months reviewed from January 2017 until December 2018. Findings include: 1. Review of the laboratory's CMS 209 personnel form revealed that seven (7) testing personnel perform patient KOH and Scabies Prep microscopy examinations. (See Testing Personnel Code Sheet.) 2. Review of the laboratory's policies and procedures revealed no policy for the twice annual verification of the KOH and Scabies Prep testing. 3. Review of the laboratory's patient test log, revealed the laboratory failed to verify KOH and Scabies Prep accuracy twice annually. The surveyor requested documentation of the twice annual verification of accuracy of KOH and Scabies Prep testing. The lead medical assistant stated that they had not performed the twice annual verification of accuracy for 2017 and 2018. 4. In an interview with the practice manager and lead medical assistant at approximately 9:30 AM, it was confirmed that the laboratory failed to verify, twice annually, the accuracy of KOH and Scabies Prep testing in the twenty-four (24) months reviewed.</p>

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(a)

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.

This STANDARD is not met as evidenced by:

Based on a laboratory tour, records review, and interview, the laboratory failed to have written procedures for KOH and Scabies Prep slide reading during the twenty-four (24) of 24 months reviewed from January 2017 to December 2018. Findings include: 1. During a laboratory tour with the office manager, and lead medical assistant at approximately 9:15 AM, the inspector noted a microscope in the laboratory's adjacent testing area. It was revealed by the office manager and lead medical assistant that the physicians and mid-level providers perform KOH and Scabies Prep slide readings. 2. During a review of the laboratory's policy and procedure manuals, the inspector noted that there was no written procedures for the KOH or Scabies Prep slide tests including patient preparation, specimen labeling, storage preservation, transportation, criteria for specimen acceptability or rejection, step-wise procedure or system for entering the patient results. 3. In an interview with the office manager, and lead medical assistant at approximately 11:30 AM, it was confirmed that the procedure manual did not include written procedure for KOH and Scabies Prep slide reading.

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 a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, and an interview, the technical consultant (TC) failed to perform annual Potassium Hydroxide (KOH) and Scabies Prep competency assessments for seven (7) of 7 testing personnel in 2017. Findings include: 1. Review of the CMS Form 209 revealed that there are 7 testing personnel performing KOH and Scabies Prep patient testing and that the lab director (LD) performs the duties of TC. (See Personnel Code Sheet.) 2. Review of the laboratory personnel files revealed no record of KOH and Scabies Prep annual competency assessments or split sample documentation in calendar year 2017 for: Testing personnel A, Testing personnel B, Testing personnel C, Testing personnel D, Testing personnel E, Testing personnel F, Testing personnel G. The inspector requested to review the 2017 annual competency documentation. The documentation was not available for review. 3. In an interview with the office manager and lead medical assistant at approximately 12:30 PM, it was confirmed that the laboratory failed to document KOH and Scabies Prep competency assessments for the 7 testing personnel outlined above in calendar year 2017.