

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2145568	(X3) Date Survey Completed 02/15/2022
Name of Provider or Supplier Us Dermatology Partners College Station	Street Address, City, State 1605 Rock Prairie Rd, Suite #300, College Station, 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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Review of proficiency testing records, the CMS 116 Application and interview of facility personnel found the laboratory failed to enroll in a proficiency testing program for Bacteriology, or have another means to assess the accuracy of results at least twice each year for Mycology and Parasitology procedures using the Potassium Hydroxide (KOH) wet mount and the Scabies scrapings oil preparations. The Findings included: 1. Review of proficiency testing records found three Mohs surgical cases submitted for peer review in February 2022. 2. Review of the CMS 116 application found the laboratory reported an annual volume of 200 KOH wet mounts and 30 Scabies oil preparations 3. Interview of testing person three on the CMS report 209 Laboratory Personnel Report conducted February 15, 2022 at 2:46 PM confirmed the laboratory was not enrolled in a proficiency testing program for Mycology and Parasitology and did not have another means of assessing the accuracy of results at least twice each year.</p>
D5219	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2)</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.

This STANDARD is not met as evidenced by:

Based on review of the laboratory semi-annual proficiency Test Survey Results, and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessment for MOHS surgical procedures in the second half of 2021. Findings included: 1. Review of the laboratory's Semi-Annual Proficiency Test Survey Results dated February 11, 2022 found: "U.S. Dermatology Partners of College Station conducts a semiannual proficiency test to ensure quality, accurate interpretation of slides and documentation of Mohs surgical cases. Random selections of Mohs surgical cases are chosen from a three month period. Each case is reviewed to ensure correct mapping of specimen, marking of positive margins , correct labeling of the slides, quality of the slides(stain quality, correct embedding of tissue and acceptable completeness of tissue sections), interpretation and correct documentation of the procedure." 2. Review of peer review records found one case for the assessment of accuracy of results for the Mohs testing performed February 11, 2022. Evidence of Peer reviews performed in the second half of 2021 were requested but not provided. 3. The laboratory certificate of compliance has an effective date of April 15, 2021. 4. Interview of testing person three listed on the CMS report 209 Laboratory Personnel Report confirmed that the laboratory did not have any accuracy assessments performed in 2021. She stated they sent three cases from 2021 to a peer for review in February 2022.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of the competency Exams and interview of facility personnel, the technical consultant failed to ensure all components of the competency evaluation were included in the competency assessment for testing personnel performing moderately complex procedures in Parasitology and Mycology The findings included: 1. Review of the Competency Exams for testing person two (dated 5/3/2021) found: a. "The Parasitology and KOH competency /exam (to be completed q 6 months for the (first) year, then annually thereafter to remain in compliance with the CLIA requirements.)" b. 10 slides to be identified by writing the answer in the provided area. 2. Interview of testing person three on the CMS form 209, on February 15, 2022 at 2:46 PM confirmed the form did not include the six components of competency assessment.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of

the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Review the CMS 209 Laboratory Personnel Report, laboratory records and interview of facility personnel found that the laboratory director failed to specify in writing the responsibilities and duties for three of four testing personnel performing moderate and high complexity testing procedures in Histopathology, and Bacteriology. The findings included: 1. Review of this CMS 209 laboratory personnel report found that the laboratory designated three testing personnel (one, three and four) performing high complexity testing; and testing person two performing moderate complexity testing. 2. Review of laboratory records found no written delegation of responsibilities and duties for testing persons one, two and four. 3. Interview of testing person three conducted February 15, 2022 at 1:59 PM confirmed that written delegation of duties were not available for three of four testing personnel.