

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D2123757	<b>(X3) Date Survey Completed</b> 06/26/2019
<b>Name of Provider or Supplier</b> Csg Pediatric Dermatology	<b>Street Address, City, State</b> 1924 Landstown Centre Way, Virginia Beach, VA	
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>	An announced CLIA recertification survey was conducted at CSG Dermatology on June 26, 2019 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:
<b>D5215</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records and interviews, the laboratory failed to evaluate Potassium Hydroxide (KOH) Microscopy PT scores of zero (0%) received due to results marked as past due on two (2) of 2 events in calendar year 2018. Findings include: 1. Review of the laboratory's 2018 and 2019 College of American Pathology (CAP) clinical microscopy PT documentation, a total of 4 events, revealed no evaluation or verification of accuracy for: 2018 CM-A: KOH Score 0%- results received past due for evaluation; 2018 CM-B: KOH Score 0%- results received past due for evaluation; a total of 2 of 2 in calendar year 2018 (2 of the 4 events reviewed). The inspector requested to review accuracy evaluation documentation for the events in 2018 outlined above. No additional documentation was available for review. The clinical nurse manager stated: "We were not aware of the time limit on submitting the results in the program last year but have noted the due date for submissions in 2019." 2. In an interview with the clinical nurse managers, at approximately 3:00 PM, the above findings were confirmed.</p>

**D5411**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**

CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on a review of the policy and procedure manual, manufacturer's Dermatophyte Test Media (DTM) package insert, patient log of fifty (50) randomly selected DTM reports, and an interview, the laboratory failed to follow the manufacturer's instructions for incubation for three (3) of the 50 patient reports reviewed from February 6, 2018 to September 21, 2018. Findings include: 1. Review of the laboratory's policy and procedure manual revealed that the laboratory utilizes the Accuderm's ACU-DTM Dermatophyte Test Medium to detect dermatophytes from patient cutaneous sources. 2. The Accuderm's manufacturer's package insert defined the patient incubation period of up to fourteen (14) days. The package insert instructions stated "Reading should be made within fourteen days." 3. Review of 50 randomly selected patient DTM culture results in the laboratory's 2018 culture log revealed the following having incubation periods exceeding fourteen (14) days: 00466644- collected and incubated on 02/06/18 and read on 03/02/18; at 24 days 60206788- collected and incubated on 03/06/18 and read on 03/23/18; at 17 days 5022877 - collected and incubated on 09/21/18 and read on 10/11/19; at 20 days 4. In an interview with the clinical nurse managers, at approximately 3:00 PM, the above findings were confirmed.

**D6017**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(ii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:

Based on a review of proficiency testing (PT) records and interviews, the laboratory director failed to ensure the Potassium Hydroxide (KOH) Microscopy PT results for two (2) of 2 events in calendar year 2018 were submitted on time as required by the College of American Pathologists (CAP) program. Findings include: 1. Review of the laboratory's 2018 and 2019 CAP clinical microscopy PT documentation, a total of 4 events, revealed zero (0%) scores due to results received past due for: 2018 CM-A: KOH Score 0% 2018 CM-B: KOH Score 0% a total of 2 of 2 in calendar year 2018 (2 of the 4 events reviewed). 2. In an interview with the clinical nurse managers, at approximately 3:00 PM, the above findings were confirmed.