Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2123757	08/24/2023
Name of Provider or Supplier	**Street Address, City, State**	
Csg Pediatric Dermatology	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An announced CLIA recertification survey was conducted at CSG Pediatric Dermatology (Virginia Beach) on August 23, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The survey also included a follow up interview with the Clinical Practice Manager on 8/24/23. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. 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), procedures, dermatophyte test medium (DTM) proficiency test logs, lack of documentation, and interviews, the laboratory failed to confirm twice annual accuracy of DTM culture testing for four (4) of 4 testing personnel (TP) in calendar year 2022 per laboratory policy. Findings include: 1. Review of the CMS 209 personnel form revealed that the laboratory director (LD) identified TP 1, TP 2, TP 3, and TP 4 as responsible for performing non-waived patient DTM culture testing during the review timeframe of November 2021 to the date of the inspection on August 23, 2023 (see Personnel Code Sheet). 2. Review of the laboratory's procedures revealed a written Proficiency Testing policy that outlined, "Proficiency Testing/Split Specimen Analysis is an important aspect of our laboratory's overall assessment of quality. It serves as an external check to verify the accuracy of test results. Specimens for DTM must be sent to a reference laboratory for split specimen analysis twice a year. At least two specimens for testing personnel will be selected to send for comparison/split specimen analysis a minimum of twice a year." 3. Review of the laboratory's 2022 DTM proficiency test logs revealed records

	for TP #1 - TP #4 had comparison study/split samples verified in the timeframe of April 2022. The inspector requested additional records of split sample accuracy checks in calendar year 2022 for the 4 TP outlined above. No documentation was available for review. The inspector inquired regarding the laboratory's scheduling protocol for the twice annual accuracy checks. The Clinical Practice Manager stated on 8/23/23 at 11:30 AM, "The protocol has been to send DTM proficiency sample split samples out for each testing personnel at least 2 samples each twice a year." 4. A follow up interview with the Clinical Practice Manager on 8/24/23 at 9:30 AM confirmed the above findings.
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, forty-five (45) randomly selected DTM patient reports, and interviews, the laboratory failed to follow the manufacturer's culture incubation instructions for eight (8) of 45 selected patient reports reviewed (timeframe: November 2021 to the date of the inspection on August 23, 2023). 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 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 45 randomly selected patient DTM culture results from the laboratory's culture logs from November 2021 to 8/23/23 revealed the following 8 patient ID's having incubation periods outside of the manufacturer's instructions: 601271 - collected 02/07/23 with results pending as of 8/23/23 788218 - collected 06 /24/23 read/resulted on 6/14/23 (day 18) 5462381, 5289654, 5519723, 5308938, 5138487, 5236570 - collected 06/13/23 with results pending as of 8/23/23 4. The inspector asked the lead nurse to describe the protocols for timeliness of DTM culture reading. The lead nurse stated on 8/23/23 at approximately 12:30 PM, "Our protocol has been to have the staff pull the DTM culture samples on the date the results are due and place the samples with the ordering provider to review/report and are actively working with our IT department to develop a system to alert the provider to enter the results so that they do not miss a reading." 5. A follow up interview with the Clinical Practice Manager on 8/24/23 at 9:30 AM confirmed the above findings.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

	This STANDARD is not met as evidenced by: Based on a review of policies, manufacturer's package insert, patient test reports, lack of documentation, and interviews, the laboratory director (LD) failed to ensure that testing personnel reported mycology culture results for one (1) of eight (8) samples collected in February 2023, and six (6) of twenty-three (23) in June 2023 as noted during the inspection on August 23, 2023. Findings include: 1. Review of the laboratory's policies revealed that the laboratory utilizes the Accuderm ACU-DTM Dermatophyte Test Medium to detect dermatophytes from patient cutaneous sources. 2. The Accuderm 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 DTM test logs for February and June in calendar year 2023 revealed the following 7 patient ID's with missing DTM culture results: 601271 collected on 02/07/23; and 5462381, 5289654, 5519723, 5308938, 5138487, 5236570 collected on 06/13/23. 4. The inspector asked the lead nurse to describe protocols for the LD's quality assurance checks of DTM culture results. The lead nurse stated on 8/23/23 at 12:30 PM, "We are are actively working to have our practice manager review DTM log sheets to help with monitoring overdue or missing culture results." 5. A follow up interview with the Clinical Practice Manager on 8/24 /23 at 9:30 AM confirmed the above findings.