Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2123754	01/16/2019
Name of Provider or Supplier	**Street Address, City, State**	
Csg Dermatology (Chesapeake)	500 Discovery Drive, Suite 301, Chesapeake, 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 Pediatric Dermatology-Children's Speciality Group on January 16, 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:
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of the laboratory's 2018 proficiency testing (PT) documentation, and an interview, the laboratory failed to retain copies of the PT program report forms and results for two (2) of 2 events reviewed and failed to retain attestation statements signed by the laboratory director (LD) and testing personnel for one (1) of 2 events reviewed. Findings include: 1. Review of the laboratory's 2018 College of American Pathologists (CAP) PT documentation, a total of 2 events, revealed: CM-A 2018 - KOH Prep CMMP 21- no copy of the CAP program report forms or results; CM-B 2018 - KOH Prep CMMP 31- no signed attestation statements by the LD or testing personnel, no copy of the CAP program report forms, no CAP PT results. The inspector requested to review the attestation documentation and copies of the CAP

	program report forms and results for the events listed above. No documentation was available for review. 2. In an interview with the Speciality Procedures Nurse at approximately 4:00 PM, it was confirmed that the laboratory failed to retain copies of the CAP program report forms, results, and attestation statements for the PT events as outlined above in calendar year 2018.
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 proficiency testing (PT) records and an interview, the laboratory failed to evaluate the accuracy of Potassium Hydroxide (KOH) microscopy testing twice annually in calendar year 2018. Findings include: 1. Review of the laboratory's 2018 College of American Pathologists (CAP) PT documentation, a total of two (2) events, revealed no copies of the CAP program report forms, results, and evaluation or verification of accuracy for the non-graded responses for: CM-A 2018 -KOH Prep CMMP 21, CM-B 2018 - KOH Prep CMMP 31. The inspector requested to review copies of the CAP program report forms, results, and evaluation documentation for the events listed above. No documentation was available for review. The Speciality Procedures Nurse stated that: "the laboratory failed to send results in by CAP's deadline and did not receive reports". 2. In an interview with the Speciality Procedures Nurse at approximately 4:00 PM, it was confirmed that the laboratory failed to evaluate the accuracy of KOH microscopy testing twice annually in calendar year 2018 as outlined above.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a laboratory tour and an interview, the laboratory failed to ensure that one (1) bottle of Health Link Potassium Hydroxide (KOH) 20% stored in the laboratory for use in patient KOH microscopy testing was within the manufacturer's expiration date. Findings include: 1. During a laboratory tour at approximately 1:00 PM on 1/16 /19, the inspector noted that one (1) bottle of Health Link Potassium Hydroxide (KOH) 20%, Lot Number 1727510, had a manufacturer's expiration date of 10/2/18. The inspector asked if the bottle was used for patient testing. The facility's Speciality Procedures Nurse indicated the bottle was in use for patient testing. 2. During an interview with the Speciality Procedures Nurse at approximately 4:00 PM, it was confirmed that the laboratory failed to ensure that the KOH reagent listed above was not used beyond the manufacturer's expiration date.
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, procedure manual, and an interview, the technical consultant (TC) failed to document annual competency evaluations for two (2) of three (3) testing personnel in 2018. Findings include: 1. Review of the CMS Form 209 revealed that the laboratory director (LD) also performs the duties of TC and that there are 3 testing personnel (TP) who perform patient Dermatophyte Test Medium (DTM) culture and Potassium Hydroxide (KOH) microscopy testing. 2. Review of the laboratory personnel files revealed no 2018 annual competency evaluation for: TP A, TP B. (See Personnel Code Sheet.) 3. Review of the laboratory's procedure manual revealed a policy (CSG Division of Dermatology Annual Competency Policy) which stated: "annual competency course in Microscopy and Dermatophyte Test Medium Reporting is to demonstrate continuation in roles of testing personnel". The inspector requested to review documentation of the annual competency course for TP A and B in calendar year 2018. No documentation was available to review. 4. In an interview with the Speciality Procedures Nurse at approximately 4:00 PM, it was confirmed that the TC failed to document the 2018 competency evaluations for TP A and B as outlined above.