Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0998437	02/04/2020
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Dermatology - Childrens Specialty Grp	301 Riverview Avenue - 3rd Floor, Norfolk, 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 February 4, 2020 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:
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) 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). This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records, lack of documentation, and interviews, the laboratory failed to evaluate Potassium Hydroxide (KOH) PT scores of zero (0%) received due to results marked as past due for evaluation 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 (2018 Events A-B, 2019 Events A-B), a total of 4 events, revealed no evaluation or verification of accuracy for: 2018 CM-A: KOH Score 0% 2018 CM-B: KOH Score 0% The inspector requested to review KOH microscopy accuracy evaluation documentation in calendar year 2018. No additional documentation was available for review. 2. In an exit interview with the Speciality Procedures Nurse at approximately 3:45 PM on 2/4/20, the above findings were confirmed.
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: **REPEAT DEFICIENCY** Based on a review of the policy and procedure manual, Dermatophyte Test Medium (DTM) patient logs, and an interview, the laboratory failed to follow the established procedure for culture incubation timeframe for nineteen (19) of two hundred sixteen (216) DTM cultures in the twenty-four (24) months reviewed. Findings include: 1. Review of the laboratory's policy and procedure manual revealed a DTM procedure (Policy Number Derm-010) that outlined utilization of Accuderm's ACU-DTM culture media to detect dermatophytes from patient cutaneous sources. The procedure stated "Instructions are to incubate patient DTM culture vial at room temperature for up to 14 days and instructions to disregard any color change in the medium after the 14 days of incubation". 2. Review of the laboratory's DTM patient logs (timeframe: February 2018 to 2/4/20) revealed the following 19 DTM patient cultures were read and resulted beyond fourteen (14) days of incubation (listed by chart number identifier): 5109507, 525894, 678238, 5161990, 77091, 5025419, 778310, 520299, 5169632 A and B, 775802, 645232, 606425, 5163109, 5031154, 483022, 5219319, 5181806, and 658956. 3. In an exit interview with the Speciality Procedures Nurse at approximately 3:45 PM on 2/4/20, the above findings were confirmed.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of proficiency testing (PT) records, policy/procedure manual, quality assurance (QA) protocols, Dermatophyte Test Medium (DTM) patient logs, lack of documentation, and interviews, the laboratory director (LD) failed to: 1. 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. (See D6017); and 2. ensure that testing personnel reported patient DTM culture results promptly and per established QA protocols in calendar years 2018 and 2019. (See D6030.)
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) PT results for two (2) of 2 events were submitted on time as required by the College of American Pathologists (CAP) program in calendar year 2018. Findings include: 1. Review of the laboratory's CAP Clinical Microscopy PT documentation (2018 Events A-B, 2019 Events A-B), a total of four (4) events, revealed scores of zero percent (0%) due to results received past the due date for: 2018 CM-A: KOH Score 0% 2018 CM-B: KOH Score 0% 2. In an exit interview with the Speciality Procedures Nurse at approximately 3:45 PM on 2 /4/20, the above finding was confirmed.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on a review of the policy and procedure manual, quality assurance (QA) protocols, Dermatophyte Test Medium (DTM) patient logs, lack of documentation, and interviews, the laboratory director (LD) failed to ensure that testing personnel reported patient DTM culture results promptly per the established QA protocols in calendar years 2018 and 2019. (See D5401.) Findings include: 1. Review of the laboratory's policy and procedure manual revealed a DTM procedure (Policy Number Derm-010) that outlined utilization of Accuderm's ACU-DTM culture media to detect dermatophytes from patient cutaneous sources. The procedure stated: "Instructions are to incubate patient DTM culture vial at room temperature for up to 14 days and instructions to disregard any color change in the medium after the 14 days of incubation". 2.. Review of the laboratory's QA protocols revealed a DTM QA protocol (dated/approved on 3/15/18) that stated "all staff are educated on DTM incubation periods and DTM policy and reading procedures. A new procedure is in place to add inspections of all DTM cultures on a daily basis. The LD will oversee and monitor and provide more strict monitoring on a weekly basis to determine compliance. Education needs will be assessed and documented to be sure all staff are aware and adhere to the DTM policy." 3. Review of the laboratory's DTM patient logs (timeframe February 2018 to 2/4/20) revealed the following nineteen (19) DTM patient cultures were read and resulted beyond 14 incubation days (listed by chart number identifier): 5109507, 525894, 678238, 5161990, 77091, 5025419, 778310, 520299, 5169632 A and B, 775802, 645232, 606425, 5163109, 5031154, 483022, 5219319, 5181806, 658956. The inspector inquired regarding QA education assessment documentation after the 19 reporting events outlined above (per the reviewed DTM QA protocol). No records were available for review. The Speciality Procedures Nurse stated, at approximately 2:30 PM on 2/4/20, "This site has shown

	improvements in adhering to the DTM cultures read/report within 14 days but turnover of staff remains an issue". 4. In an exit interview with the Speciality Procedures Nurse at approximately 3:45 PM on 2/4/20, the above finding was confirmed.