

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0998437	(X3) Date Survey Completed 02/28/2018
Name of Provider or Supplier Pediatric Dermatology - Childrens Specialty Grp	Street Address, City, State 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-Childrens Speciality Group on February 28, 2018 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:
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy and procedure manual, 2016 and 2017 Patient Dermatophyte Test Medium (DTM) patient logs, and an interview, the laboratory failed to follow the established procedure for incubation timeframe for one hundred twenty-eight (128) of eight hundred twenty-two (822) DTM culture results reviewed. Findings include: 1. Review of the laboratory's policy and procedure manual revealed a DTM procedure (Policy Number Derm-010). The procedure outlined that the laboratory utilizes Accuderm's ACU-DTM culture media to detect dermatophytes from patient cutaneous sources. The procedure stated "Incubation instructions are to incubate patient DTM culture vial at room temperature for up to fourteen (14) days". 2. Review of the laboratory's 2016 and 2017 DTM patient logs revealed: DTM patient cultures read and resulted beyond fourteen (14) incubation days in 2016: (Listed by chart number identifier) 627141, 5037933, 5069905, 5242762, 728509, 5066841, 687675, 721806, 680435, 734152, 5194528, 5209953, 596820, 620493, 5188897, 772950, 701775, 5091093, 5009861, 5190342, 5094243, 5069905, 735852, 667280, 633389, 5048736, 581278, 5223962, 5188497, 5091832, 5161864, 5182379, 5085406, 5154047, 664910, 676262, 510755, 771484, 747834,</p>

520541, 5262164, 762386, 5263583, 635668, 651343, 5211865, 5263079, 525994; a total of forty-eight (48), out of three hundred six (306) DTM results reviewed. DTM patient cultures read and resulted beyond fourteen (14) incubation days in 2017: (Listed by chart number identifier) 5160473, 5186171, 5263376, 735354, 5024746, 651343, 663589, 694352, 623786, 5100197, 762645, 609803, 5174858, 5268753, 553099, 5266371, 654534, 5109173, 5143807, 631165, 676844, 5155171, 5252722, 5252681, 640039, 5240821, 5270317, 5087706, 762207, 675564, 521543, 5010706, 5112469, 5176987, 5256713, 5240451, 570767, 426627, 489792, 5243278, 654534, 5276997, 5202565, 5079453, 5162383, 548903, 587640, 5275753, 525003, 671604, 559121, 5176987, 661390, 5156042, 5193042, 5283629, 5194379, 698917, 5180326, 653406, 5145943, 560828, 5245769, 5189729, 5118186, 5055390, 5272869, 594889, 5041604, 669805, 5245641, 5218175, 675314, 568206, 775938, 5026135, 5152693, 5197491, 443347, 5191544; a total of eighty (80), out of five hundred sixteen (516) DTM results reviewed. 3. In an interview with the laboratory's speciality procedure nurse at approximately 2:45 PM on 2/28/18, it was confirmed that the laboratory failed to follow the established procedure for DTM culture incubation time limit in calendar years 2016 and 2017 for the one hundred twenty-eight (128) patient charts identified and listed above.