Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0221472	06/27/2018
Name of Provider or Supplier	**Street Address, City, State**	
Us Dermatology Partners - Fairfax	8316 Arlington Boulevard #400, Fairfax, 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 Dermatology and Skin Care Specialists on June 27, 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:
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of the laboratory's policy manual, quality assurance (QA) records, patient logs, and an interview, the laboratory failed to enroll in proficiency testing (PT) for Dermatophyte test medium (DTM) fungal cultures in calendar years 2016, 2017, and year to date 2018. Findings include: 1. Review of the laboratory's Dermatology Practice Administration CLIA Manual revealed a QA policy for proficiency testing. The policy states that the laboratory will participate in PT or perform split sample for the DTM testing performed. 2. Review of the available QA records revealed no PT or split sample study documentation in calendar years 2016, 2017, or 2018. The inspector requested to review documentation of split sample or proficiency testing for DTM cultures. The documentation was not available for review. 3. Review of the DTM patient log books from 6/14/16 to 6/27/18 revealed that the laboratory performed and reported thirty-six (36) patient cultures. 4. In an

	interview with the primary testing personnel at approximately 2:30 PM on 6/27/18, it was confirmed that the laboratory failed to participate in PT for DTM cultures in calendar years 2016, 2017, and 2018.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of patient test culture logs, temperature monitoring records, available quality control (QC) records, and interviews, the laboratory failed to document monitoring and corrective action for their patient fungal culture testing for twenty-four (24) of twenty-four (24) months reviewed by: 1. failing to follow the manufacturer's instructions for incubation time for twenty-five (25) of thirty-six (36) patient fungal cultures (See D 5411); 2. failing to follow manufacturer's requirements for monitoring Dermatophyte Test Medium (DTM) incubation temperature (See D 5413); 3. failing to document, before or concurrent with use, the DTM media's ability to grow and inhibit growth (See D 5477 **REPEAT DEFICIENCY).
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 manual, manufacturer's Dermatophyte Test Media (DTM) package insert, DTM patient logs, and an interview, the laboratory failed to follow the manufacturer's instructions for incubation time for twenty-five (25) of thirty-six (36) patient tests reviewed from June 14, 2016 to June 27, 2018. Findings include: 1. Review of the laboratory's Dermatology Practice Administration CLIA 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 defines the patient incubation period as up to fourteen (14) days and instructions to disregard any color change in the medium after the 14 days of incubation. The package insert instructions states: "Reading should be made within fourteen days. Color interpretation of the test is questionable after fourteen (14) days due to the possibility of false positives". 3. Review of thirty-six (36) patient DTM culture results in the test logs revealed the following patient test date entries having incubation periods exceeding fourteen (14) days: 08/08/16 incubated thirty-eight (38) days; 08/10/16 incubated thirty-six (36) days; 08/15/16 incubated twenty-eight (28) days; 08/25/16 incubated twenty-two (22) days; 09/13/16 incubated twenty-one (21) days; 10/05/16 incubated seventy-nine (79)

	days; 11/10/16 incubated forty-two (42) days; 11/28/16 incubated twenty-two (22) days; 11/30/16 incubated twenty-five (25) days; 12/05/16 incubated twenty-five (25) days; 02/13/17 incubated twenty-six (26) days; 05/03/17 incubated thirty-four (34) days; 06/22/17 incubated nineteen (19) days; 07/20/17 incubated thirty-one (31) days; 08/16/17 incubated twenty-one (21) days; 11/30/17 incubated forty-eight (48) days; 01/08/18 incubated one hundred five (105) days; 01/15/18 incubated twenty-nine (29) days; 02/27/18 incubated fifty-nine (59) days; 04/02/18 incubated twenty-one (21) days; 04/05/18 incubated eighteen (18) days; 04/23/18 incubated sixteen (16) days; 04/26/18 incubated eighteen (18) days; 05/30/18 incubated nineteen (19) days; 05/31/18 incubated seventeen (17) days; a total of twenty-five (25) of thirty-six (36) patient results were recorded beyond of the manufacturer's recommended incubation time. 4. In an interview with the laboratory director at approximately 2:00 PM and with the primary testing personnel at approximately 2:30 PM on 6/27/18, it was confirmed that the laboratory did not follow the manufacturer instructions for DTM incubation for the twenty-five (25) patent test dates listed above in calendar years 2016, 2017, and 2018.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a tour, review of manufacturer's package insert instructions, temperature log sheets, patient logs, and an interview, the laboratory did not follow manufacturer's requirements for monitoring Dermatophyte Test Medium (DTM) incubation temperature for thirty-six (36) patient cultures resulted from 6/14/16 to 6/27/18. Findings include: 1. During a lab tour at approximately 1:00 PM, the inspector noted four (4) DTM patient cultures incubating at room temperature. 2. Review of the Accuderm's ACU-DTM Dermatophyte Test Medium package insert for DTM cultures revealed instructions to: "Incubate the inoculated media at 20 to 30 degrees Celsius for up to 14 days." 3. Review of the laboratory's temperature logs for calendar year 2016 and up to the date of survey revealed no room temperature monitoring records. The inspector requested temperature logs recording the DTM culture room temperature for the timeframe of 6/14/16 to 6/27/18. No documentation was available. The primary testing personnel stated: " The room temperature for incubation used to be recorded but we stopped recording it. I am not sure why we stopped". 4. Review of the laboratory's DTM patient log book for the review period listed above revealed thirty-six (36) patient DTM cultures were tested and reported. 5. In an interview with the primary testing personnel at approximately 2:30 PM, it was confirmed that the laboratory failed to monitor the incubation room temperature for the thirty-six (36) patient DTM cultures resulted from 6/14/16 to 6/27/18.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g)

	(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the patient log book, quality control (QC) log sheets, manufacturer's package insert instructions, and an interview, the laboratory failed to document, before or concurrent with use, the Dermatophyte Test Medium (DTM) media's ability to grow and inhibit growth from 06/14/16 to 06/27/18 while reporting thirty-six (36) patient test results. **REPEAT DEFICIENCY Findings include: 1. Review of the DTM patient logs from 06/14/16 to 06/27/18 revealed thirty-six (36) patient fungal cultures utilizing Accuderm's ACU-DTM Dermatophyte Test Medium. The inspector requested to see documentation of the lot numbers of media used during the review timeframe. The laboratory provided documentation of one (1) lot: D-1273-0518 received 6/12/18. The primary testing personnel stated: "we have not retained all of the lot number information". 2. Review of the laboratory's QC log sheets revealed no documentation of the fungal media's demonstration of ability to grow and inhibit growth for any lot numbers utilized from 06/14/16 to 06/27/18. The inspector requested to review the QC. The laboratory was unable to provide documentation. 3. Review of the Accuderm's ACU-DTM Dermatophyte Test Medium manufacturer's package insert revealed quality control instructions that state: "the end user laboratory is required to perform a minimum of a positive and negative control on each new lot or batch purchased". 4. During an interview with the primary testing personnel at approximately 2:30 PM on 06/27/18, it was confirmed that QC was not performed on the fungal culture media during the review timeframe outlined above.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of the quality assurance (QA) policy, quality control (QC) records, temperature logs, manufacturer's package insert, logsheets, and an interview, the laboratory director failed to ensure that the QA programs were maintained from 06/14/16 to 06/27/18. Findings include: 1. Review of the laboratory's Quality Assurance Policy revealed a QA and QC plan for detecting system errors that includes: monthly QC log review, temperature documentation, a policy for corrective action documentation, and a proficiency testing (PT) policy. 2. Review of the laboratory's Dermatophyte Test Medium (DTM) logs from 06/14/16 to 06/27/18 revealed thirty-six (36) patient fungal cultures were tested and reported. Review of the laboratory's available QC log sheets for the same review period revealed no documentation of

	demonstration of ability to grow and inhibit growth for the Accuderm's ACU-DTM media utilized. 3. Review of the laboratory's 2016, 2017, and year to date 2018 temperature logs revealed no room temperature monitoring documentation for the area in which DTM cultures were incubated and no evidence of monthly review. 4. Review of the Accuderm's ACU-DTM Test Media package insert revealed the procedure defined the incubation period of up to fourteen (14) days. Review of the laboratory's DTM patient log book for 06/14/16 to 06/27/18 revealed twenty-five (25) of thirty-six (36) patient DTM cultures were incubated beyond the manufacturer's guidelines without evidence of monthly log review or corrective action. 5. Review of all available DTM logs revealed no evidence of PT or split sample testing. The inspector requested to review documentation of split sample, peer review, or proficiency testing for DTM cultures from 2016 through the date of the inspection. Documentation was not available for review. 6. In an interview with the lab director at approximately 2:00 PM and with the primary testing personnel at approximately 2:30 PM, it was confirmed that the laboratory director failed to ensure the established QA programs, outlined above, were maintained in the twenty-four (24) of twenty-four (24) months reviewed.