Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0975698	11/01/2018
Name of Provider or Supplier	**Street Address, City, State**	
Excel Dermatology	7921 Jones Branch Drive, Suite 320, Mclean, 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 Anne Arundel Dermatologyl on November 1, 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:
D2003	ENROLLMENT CFR(s): 493.801(a)(2)(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1) This STANDARD is not met as evidenced by: Based on a review of the laboratory's 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 available 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. 2. Review of the DTM patient log books from September 9/14/16 to 11/1/18 revealed that the laboratory performed and reported three hundred and thirty-seven (337) patient cultures. 3. In an interview at approximately 10:30 AM, the CLIA coordinator confirmed that the laboratory failed to participate in PT for DTM cultures in calendar years 2016, 2017, and 2018.
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 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 one hundred and seventy-one (171) of three hundred and thirty-seven (337) patient tests reviewed from September 14, 2018 to November 1, 2018. Findings include: 1. Review of the laboratory's Dermatology Procedure Manual revealed a manufacturer's package insert for AccuDTM (Dermatophyte Test Medium) which stated: "Color interpretation of test is questionable after 14 days due to the possibility of false positives." 2. Review of the DTM test logs revealed 171 of 337 patient results were recorded outside the manufacturer's recommended incubation time. 3. In an interview at approximately 11: 30 AM , the CLIA coordinator confirmed that the laboratory did not follow the manufacturer instructions for DTM incubation for 171 of 337 patients.
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 the review of ACU-DTM (Dermatophyte Test Medium) manufacturer's package insert (PI), temperature logs and interview, the laboratory failed to monitor the storage of the ACU-DTM (Dermatophyte Test Medium) media for five-hundred and forty (540) of five-hundred and forty (540) days reviewed from September 14, 2016 through November 1, 2018. Findings include: 1. Review of the ACU-DTM (Dermatophyte Test Medium) test media PI for storage requirements revealed: "ACU-DTM should be stored at 2-8 degrees Celsius." 2. Review of the temperature logs revealed no temperatures were taken for the refrigerator where the ACU-DTM was stored for the following number of days: September 2016- 13 days October 2016- 21 days, November 2016- 22 days, December 2016- 17 days, January 2017- 20 days, February 2017- 20 days, March 2017- 23 days, April 2017- 20 days, May 2017- 22 days, June 2017- 22 days, July 2017- 19 days, August 2017- 24 days, September 2017- 20 days, October 2017- 22 days, November 2017- 20 days, December 2017- 16 days, January 2018- 22 days, February 2018- 20 days, March 2018- 22 days, April 2018- 21 days, May 2018- 22 days, June 2018- 22 days, July 2018- 21 days, August 2018- 23 days, September 2018- 20 days, October 2018- 25 days, November 2018- 1 day, A total of 540 days. 3. The surveyor requested the refrigerator temperature documentation for the months listed above. No documentation was available for review. 4. In an interview at approximately 12:00 PM, the CLIA coordinator confirmed that the laboratory failed to monitor the storage of the ACU-DTM (Dermatophyte Test Medium) media for the months and number of days listed above.

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 DTM 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 09/14/16 to 11/1/18 while reporting three- hundred and thirty-seven (337) patient test results. Findings include: 1. Review of the DTM patient logs from 09/14/16 to 11/1/18 revealed 337 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 three (3) lots: D-1256-0218 received 3/2018, D-1273-0518 no received date, D-1279-0618 no received date. The CLIA coordinator stated: "I was unable to find any other lot number documentation." 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 09/14/16 to 11/1/18. The inspector requested to review the QC for the DTM media. No documentation was available for review. 3. Review of the Accuderm's ACU-DTM Dermatophyte Test Medium manufacturer's package insert revealed quality control instructions that stated: "the end user laboratory is required to perform a minimum of a positive and negative control on each new lot or batch purchased". 4. In an interview at approximately 11:45 AM, the CLIA coordinator confirmed that QC was not performed on the fungal culture media.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and an interview, the laboratory failed to establish a written Quality Assessment policy. Findings include: 1. Review of the laboratory's policy and procedure manual revealed no policy for the quality assessment of the analytic system. 2. In an interview with at approximately 12:00 PM, the CLIA coordinator confirmed the laboratory did not have a quality assessment policy.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)

	(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on the review of Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, and interviews, the technical consultant failed to perform and document annual competency assessments for three (3) of three (3) TP in 2016 and 2017. Findings include: 1. Review of the CMS-209 form revealed that there were 3 TP performing patient testing in 2016 and 2017. (See attached personnel code list.) 2. Review of the 3 TP records revealed no documentation of competency assessments performed by the technical consultant in 2016 and 2017. The inspector requested the competency assessments for the 3 TP. The documentation was not available for review. 3. In an interview at approximately 10:00 AM, the CLIA coordinator confirmed that the technical consultant failed to perform the competency assessments in 2016 and 2017.