Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0954398	02/14/2019
Name of Provider or Supplier	**Street Address, City, State**	
Duke Lightner Dermatology	11081 Forest Pines Drive, Suite 110, Raleigh, NC	

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
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 review of manufacturer's instructions, laboratory procedure, records review and interview with testing personnel (TP), the director, on 2/14/19, the laboratory failed to follow the manufacturer's instructions for reading the results of the ACU-DTM (Dermatophyte Test Medium). Findings: The laboratory uses ACU-DTM for for the performance of fungal cultures. Review of the manufacturer's instructions for reading cultures, it reads under, "...Results The test medium may be examined for color change from yellow to red after 24 hours. Most pathogenic dermatophyte will produce full change in 3-7 days. The medium should be observed frequently during this period to determine that the color change is concurrent with colony growth. Certain non-dermatophytes may on occasion, turn the medium red, but usually only after full colony growth. Color interpretation of test is questionable after 14 days due to the possibility of false positives...". The review of the laboratory procedure entitled Fungal Culture/Dermatophyte Test Medium (DTM), it reads under "...Test Procedure 3. Examine the culture daily during the week for the growth characteristics reported in Reading Results below. All cultures are read by two weeks...". The review of the laboratory's Test Requisition and Report Log revealed testing readings beyond the manufacturer's instructions and laboratory procedure. Findings: a. D1200195: Specimen collected and planted on 5/2/17, and read on 5/24/17. The number of days elapsed was 22. b. XT7285: Specimen collected and planted on 5/18/17, and read on 6 /12/17. The number of days elapsed was 25. c. BT9206: Specimen collected and planted on 6/26/17, and read on 7/24/17. The number of days elapsed was 28. d.

	D1221016: Specimen collected and planted on 7/11/17, and read on 8/1/17. The number of days elapsed was 31. e. G31821: Specimen collected and planted on 11/8 /18, and read on 11/28/18. The number of days elapsed was 20. The results of test read were negative. During interview with the TP, the director, at 11:30 a.m., it was revealed that the provides frequently overlook the DTM cultures, and they are placed in a secluded area of the practice, which contributes to the extended incubation period. However, even with the extended incubation period, all results were negative with no false positives.